“PATENT USE EXCEPTION FOR USER-GENERATED INVENTIONS.

THE MAKER MOVEMENT MEETS PATENT LAW”

Inaugural-Dissertation

zur Erlangung der Doktorwürde

einer Hohen Juristischen Fakultät

der Ludwig-Maximilians-Universität

zu München

vorgelegt von

Natalia Weronika Lukaszewicz

2015

Referent: Prof. Dr. Annette Kur
Korreferent: Univ.-Prof. Mag. Dr. Thomas Jaeger, LL.M.
Tag der mündlichen Prüfung: 20. Juni 2016

CONTENTS

Chapter 1. INTRODUCTION TO RESEARCH

1.1 Research Context

A long time ago, around the fourth millennium BC, in the area of Mesopotamia or in the North Caucasus, an individual or maybe a community made an invention that revolutionised human civilisation – a wheel. Throughout the centuries, the wheel had seen improvements to its structure, durability, and materials. We can only guess how it was invented – most likely, it was an embodiment of observations of nature performed by an intelligent mind. Certainly, no professionally trained people made it; it is probably the oldest example of *making*.

Prior to the era of mass production and fabrication, hand-production, repair of worn parts, re-making and improving were a necessity and for many – a professional occupation. Nowadays, they are a way of self-fulfilment, satisfaction, and self-identification. Irrespective of industrial, economic, or psychological implications, tinkering and inventing by individuals constitutes a normal human behaviour and partakes in human development.

Although curbed by the industrial revolution, tinkering and inventing were not completely eliminated. A certain portion of industrial invention came from users and workers, who were improving the performance of machines and devices they worked on. In *The Inquiry into the Nature and Causes of the Wealth of Nations*, Adam Smith gives the example of an improvement done by a boy who wanted to make some time for playing with his fellows. At the time of the first fire engine, many boys were employed to open and shut the communication between the boiler and the cylinder. The boy noticed that "by tying a string from the handle of the valve that opened the communication to another part of the machine, the valve would work without his assistance." In this way, this minor change allowed him to gain valuable free time. As Smith reports, this was the first important improvement to the fire engine since its invention – an example of a minor technical modification that led to greater efficiency, cost-reduction, and time-saving.[1]

Because of technological progress, devices and mechanisms became much more complicated, and hence required special preparation and knowledge to be fully comprehended. This development opened a path for popular science and technology magazines like *Popular Mechanics*, which presented complicated technical matters without resorting to a perplexing scientific jargon, and made them available and comprehensible for laymen.

[1] Adam Smith, The Inquiry Into the Nature and Causes of the Wealth of Nations, London: Penguin, 1776/1999 fromMarcel Bogers, Allan Afuah, and Bettina Bastian, "Users as Innovators: A Review, Critique, and Future Research Directions," *Journal of Management* 36, no. 4 (2010): 858-59.

For a long time, user-generated solutions were regarded as a minor issue. It was not until the 1970s when professor Eric von Hippel launched a series of surveys on the role of user engagement in technological development. In the book *The Source of Innovation* (1988), he introduced the term *user innovation* to depict the shift form manufacturer-centred to user-centred innovation. By testing more than 100 innovations and showing that around 80% of them were provided by the users (firms and individuals) themselves, he proved that users could be a major source of innovation. At the same time, another great mind, the American futurist Alvin Toffler, introduced the term *prosumer* to describe a consumer actively involved in the product development and its commercialisation.

How was the change possible? New communication technologies (means of communication) broadened the access to new ideas and communication between enthusiasts – resulting in the establishment of the open access movement. Greater access to higher education resulted in the emergence of a growing number of specialists who implement their knowledge into extra-curricular activities. Another important factor was the disillusionment with proprietary endeavours in closing software which ran counter to the communitarian and "free" spirit of sharing spread among the hackers and programmers of the 1970s. This was the first point of friction between users and rightsholders, when users had their natural right to use taken from them.

An initiative undertaken by Richard Stallman, who launched the GNU Operating System (1983), stimulated the growth of similar communities and models (like Linux or Apache); and stimulated a counter-proprietary social movement. The organisational forms and philosophy of the movement leaked into the hardware scene (e.g. sport equipment), where people collaboratively improved products neglected by producers.

Nowadays, the user innovation scene is dominated by Makers (individual innovators or prosumers), who bring great ideas into life. The notion behind the movement is new: it derives from the *MAKE* magazine (created by Dale Dougherty in 2005), the profile of which refers to the tradition of the aforementioned *Popular Mechanics*. In the globally connected world, the popularisation of the do-it-yourself approach exceeded the bravest expectations of its proponents. Open making communities are growing like mushrooms – everyone may join them and everyone may post or comment on an idea in order to stimulate its further development. The engine of the movement is the makers' self-motivation and their infectious enthusiasm.[2]

[2] A comprehensive list of research projects, studies, and articles on the maker movement: "Research on the Maker Movement,"

The expansion of the movement embraced high-tech fields such as robotics, electronics, and 3D printing, where makers become not only hobbyists, but true contributors to technological progress. Their technological advancement resulted in their growing awareness and interest in patent-related issues.

The development of do-it-yourself culture was parallel to the increasing recognition of patents and other forms of intellectual property protection, which was a manifestation of a shift in the economy toward knowledge and human resources. This shift was the cause of friction between two discrepant approaches and philosophies: open communal workings and closed proprietary operations. The possibility of patenting ideas by individual inventors always existed, but changes in IP practice and the dynamic of *making* provoked concerns about the free use of the ideas of third parties.

To that end, *making* and patents can be illustrated as two planets sharing the orbit of innovation, where they happen to collide…

1.2 Research Development

The project departed from the concept of individual *user innovators*, which was supported by the vast research done in the field of management (e.g. Eric von Hippel, Joachim Henkel, Cornelius Herstatt, Dietmar Harhoff), where users are seen as a non-exploitable source of innovation. The observations and studies perfectly characterised the main attributes of the maker movement, i.e. collectivity and openness, together with its economic inclinations; however, at the point of pre-research, the studied literature did not deliver strong indications of the technological advancement of the user-innovated solutions. Moreover, the studies indicated a strong collaboration between user communities found on the Internet and companies – a feature that did not correspond with the assumed model of individuals freely cooperating with each other and working together on common projects.

The work of Sonali Shah and Mary Tripsas on the accidental entrepreneurship of user-generated ideas[3], land-marking for this project, indicated that users could be very successful in their workings and create good marketable products without the external support of companies. Another milestone work by Christina Raasch, Cornelius Herstatt, and Kerstin Balka, *On the Open Design of*

---

https://docs.google.com/document/d/1yRyWCpd1IpTuyM7ck6xWOvAzbqNmo9B1vKRbOu_-MeE/edit#, accessed 29.09.2015.

[3] Sonali K. Shah and Mary Tripsas, "The Accidental Entrepreneur: The Emergent and Collective Process of User Entrepreneurship," *Strategic Entrepreneurship Journal* 1, no. 1-2 (2007).

Tangible Goods, described the project of the open 3D printer *RepRap* and indicated that users not only work on tangibles (beside open source software), but also engage in high-tech projects.[4] It was significant that the *RepRap* community did not rely on any company and was built by 3D-printing enthusiasts. That was the most important pull of the project.

One investigation path pertained to the ongoing transformation of the phenomenon of user-generated solutions; the other concerned the formulation of the legal question. Making *constitutes* an important element of the innovation landscape. By contesting the classical paradigm of innovation incentivised by IP protection, it questions the established principles of patent law. With the exception of the works of Kathrine Strandburg[5], the legal science has not devoted much attention to patent-related aspects of the user-generated inventions.

In this context, next to the (rightful) affirmation of the phenomenon and its spectacular growth, a great stimulus for this research was the work of Viktor Braun and Cornelius Herstatt, *User-Innovation Barriers to Democratization and IP Licensing*, which lays out legal, business, technological, and social barriers restraining users from tinkering with their goods. It was an inspiration to examine the patent system from the perspective of the balance of interests and the rights of users to freely exploit protected ideas.

1.3 Research Questions and Objectives

The project was commenced in the midst of heated debates on the misuse of the system by so-called *patent trolls*, one of the many plagues of the patent system. The expansion of patentable subject-matters, the reinforcement of patent rights, patent wars between smartphone giants, were (and continue to be) the main themes in discussions on patent reforms. It has become clear that the system has stepped off the path of its laudable objectives in incentivising technological progress.

Against this background, making represents a new trajectory of innovation based on free-sharing and communal workings. Regarded initially as a movement of low-impact developers, the speed and organisational progress of the maker movement speak to the fact that it has become a relevant

---

[4] Christina Raasch, Cornelius Herstatt, and Kerstin Balka, "On the Open Design of Tangible Goods," *R&D Management* 39, no. 4 (2009).

[5] Katherine Strandburg, "What Does the Public Get? Experimental Use and the Patent Bargain," *Wisconsin Law Review* 2004(2004); "User Innovator Comunity Norms at the Boundary Between Academic and Industry Research," *Fordham Law Review* 77(2009); "Users as Innovators: Implications for Patent Doctrine," *University of Colorado Law Review* 79(2008); "What If There Were a Business Method User Exemption to Patent Infringement?," *Mich. St. L. Rev.* 2008(2008); "Patent Fair Use 2.0," *New York University Law and Economics Working Papers*, no. 268 (2011).

market player in spite of its limited resources. Studies in the management field point to a growing interest of corporate entities in the makers' solutions (e.g. Mindstorm Lego, the purchase of Makerbot by Stratasys), which implies the high monetization potential of such projects. However, the preponderance of makers' solutions is developed without the patronage of bigger market players.

In this context, the research focused on the applicability of existing patent limitations to the effects of patents in protecting makers from infringement liability.

It was hypothesised that the communitarian profile of the movement and the uncontrollable dissemination of information, often in a form of instructions on how to introduce an improvement and replicate it, do not allow for the movement to fit under the protective umbrella of patent exceptions, an assumption which required further verification and become the aim of this project.

The primary objective of the patent system is allowing for technological development, which is, on the one hand, safeguarded by granting patent protection limited timely and territorially; and, on the other, by maintaining a balance in regard to patent rights, which should neither harm nor become a large burden on the users and subsequent developers. Therefore, the pivotal axis of the project are patent limitations – instruments that derogate patent exclusivity from certain acts, without which the scope of patent monopoly would be excessive and detrimental to research and development. They serve not only as the *openers* of patent exclusivity, but also as tools of defence against infringement claims.

In that respect, the project sets out to explore to what extent makers benefit from patent limitations in terms of the free use of patented solutions. Furthermore, it evaluates the adaptability and functionality of the patent system to a modern technological phenomenon such as making. In light of the formulated hypothesis, the project intends to advocate for the introduction of a new form of patent limitation tailored precisely to the context of making based on public and non-commercial dissemination of knowledge.

In terms of the underlying purpose, the project is driven by the strong ethical conviction in regard to the need to protect the weaker parties, here understood as individual end users and inventors, on the IP playground with its fierce rules of conduct.

1.4 Methodology

To determine the accuracy of the hypothesis, a classic form of legal investigation, namely the comparative analysis of patent limitations was adopted in order to illustrate the main trends and assumptions in this subject-matter. The comparison covers four patent systems of the following countries – Germany, the UK, the USA, and Japan – selected for their significance in the global patent market. The four aforementioned patent systems belong to the main target countries for patent applications and important IP economies. Moreover, their national regulations or judicial decisions affect the international standards of IP protection.

The analysis focuses on law application and substantive legal aspects which dominate over procedural ones. The comparison does not serve to indicate the "better" system, but the one with the greater freedom to operate. Considering the global unification of IP protection within the legal framework provided by the TRIPS Agreement, it stands to reason that questions of patent limitations would underlie similar considerations in the analysed systems.

With respect to applied terminology, legal instruments limiting the effects of a patent are termed patent exceptions, patent limitations, or patent flexibilities. Only these terms are used in the aforementioned context by the author. The terms *exemptions* or *exclusions* are not regarded as suitable in this context, because they pertain to norms regulating subject matters excluded from patentability. However, some titles and direct citations used in this work may apply this wording in the context of patent exceptions.

The legal norms and doctrines in the analysis are categorised into two groups: statutory and non-statutory. The analysis of statutory limitations follows the catalogue of patent limitations provided in the UPC Agreement in Articles 27 and 28 (prior use) because of its exhaustiveness and topicality. The study also includes compulsory licensing as a countervailing measure, understood as a forceful instrument which derogates patent exclusivity.

The UPC Agreement serves as a point of departure in the search for similar provisions in two non-European systems. In terms of non-statutory limitations, i.e. legal doctrines, the German system serves as a touchstone in the search for corresponding forms in other jurisdictions.

Another path of investigation comprised of an empirical study on the makers' experience with patents and patent law, which constitutes a measurable justification for this project. The survey was motivated to collect information on the willingness to patent solutions and on infringement claims against makers. The core part of the survey investigated the types of obstacles makers face in their activities, with the emphasis on patent-related matters.

1.5 Composition of the Work

The work proceeds as follows: *Chapter 2* introduces and explores the notion of the maker movement (*making).* It explains the inception of the phenomenon and its development into the current form. The chapter presents a complete picture of the movement and provides various examples of maker-driven products and collaborative projects.

Chapter 3 delivers an overview of patent law and the patent system: its historical evolution, theories, and controversies. Due to the high complexity of this subject matter, the chapter only highlights points from the current discussions on the shape of the system. Despite a quite critical tone, it is not the purpose of this work to underestimate the contributions of patent law to technological progress. Instead, it is the misappropriate practice of patent law which warrants reconsiderations and changes.

Chapter 4 outlines all found patent limitations, both statutory and non-statutory, and explores their application in selected jurisdictions. The chapter closes with an assessment of the compatibility of patent limitations with the making model. Likewise, *Chapter 5* investigates compulsory licensing schemes and ends with an examination of its conditions applied to *making*.

Chapter 6 demonstrates a novel patent limitation in regard to addressing the conditions of making – the green light license.

The results of the online survey are included as an appendix due to their supplementary role in the project.

Chapter 2. WHO ARE MAKERS?

2.1 Introduction

We all are Makers. Beyond any doubt, everyone has certain tinkering skills: some people make their own clothes; others know how to repair their own car or build a house; those with high-tech skills know how create e.g. robots, 3D printers, or solar cells. Owing to breakthroughs in communication technology, people left their basements and garages with the aim of sharing their ideas and developing them with others. The process took the form of a viral infection, which lead to the establishment of diverse groups – communities of like-minded enthusiasts.

This phenomenon has become the subject of the attention of scholars from diverse fields, such as sociology, management, and marketing. With a fine-tooth comb, scholars attempted to classify its features and frequencies, and, last but not least, to label it. Various depictions emerged to describe the phenomenon of innovative individuals: *User Innovation* (by Professor Eric von Hippel), *Prosumption* (by Alvin Toffler), *Do-It-Yourself* (*DIY*) (by Professor George McKay), and the *Maker Movement* (by Dale Dougerty).

This study adopts the term *maker* as the most appropriate and up-to-date term describing resourceful people who work on technological projects: initiate and lead them to their completion. The observation of communities on Google+ concentrated around *MAKE* magazine and its derivatives, as well as other *making* groups[6], clearly indicates the successful adoption of the term – the participants identify themselves as makers. Another term that often emerges is *DIYers* (also *diyers*), which is a generic term for people constructing things themselves. While the latter covers a variety of domains from knitting and crocheting to electronic gadgets and devices, *making* connotes with technology. Terms such as *User Innovators* or *Prosumers* are highly academic and circulate primarily in management and sociological literature.

This chapter is designed to present the complete picture of making. Because makers innovate, the point of departure is the notion of innovation and its characteristics, which serves to locate the contributions of makers on the map of innovations. A historical insight into the evolution of the phenomenon allows us to understand the circumstances of its development to the current form. This involves investigating political, economic, and social changes in the post-war reality, such as the redirection of the economic paradigm to intangible resources and knowledge, the shift of focus on the consumer as a value co-creator, and the advent of new technologies. Knowing this, we can

[6] E.g. *Maker Faire, Maker Hangar; Makers, Hackers, Artists & Engineers; Makers – Electronics, 3D Printing & More*.

focus on the features of making. Why do people get involved? How do they profit from innovating without patenting? These questions will be answered. Since making has various forms, a certain model had to be adopted in order to continue with subsequent stages of the project. On the backdrop of the full picture of making, recent cases of clashes with patent law are displayed as evidence justifying the standing of this research.

2.2 The concept of Innovation

$$Inn = Inv + Exp$$

This simple formula presents innovation as the sum of two variables: invention and exploitation. The former denotes the generation of a new technical idea; the latter denotes its application, i.e. the transfer to the market and/or the society, with its "broad-base utilisation, dissemination, and diffusion."[7] A technological change is the logical consequence of implementing this math in practice.[8] Despite the simplicity of the equation, the nature of innovation remains disputable.

It is certain that innovations are inevitable: no civilizational progress would be possible without technological input. Joseph Schumpeter argued that all economic stages could be clarified through the lens of technological development[9], and that every new development derived from a previous development. However, in his opinion only spontaneous and discontinuous *new-combinations* could be seen as the source of change: the implementation of a new combination (invention) could affect the form and the content of development.[10] An invention as such, in Schumpeter's view, had no greater meaning: "an invention was possible without anything; it did not necessarily induce innovation, but produced of itself (…) no economically relevant effect at all."[11] Solely the following actions constituted "the content of development" that resulted from "new combinations:"

1) the manufacturing of new consumer products or introducing new product quality,
2) the introduction of a new production method,

---

7 Edward Roberts, "What We've Learned. Managing Invention and Innovation," *Research-Technology Management* 31, no. 1 (1988): 13.

8 Vernon Ruttan, "Usher and Schumpeter on Invention, Innovation and Technological Change," *The Quarterly Journal of Economics* 73, no. 4 (1959): 596.

9 Ehud Zuscovitch, "The Economic Dynamics of Technologies Development," *Research Policy* 15, no. 4 (1986): 175-76.

10 Joseph Schumpeter, *Theorie der wirtschaftlichen Entwicklung* (Berlin: Dunker Humbolt, 1964), 98.

11 Joseph Schumpeter, Business Cycles, I, 84 from Ruttan, "Usher and Schumpeter on Invention, Innovation and Technological Change," 597.
Ruttan states that Schumpeter did not succeed in clarifying the concept of innovation. Ibid., 598.

3) the opening of a new market, i.e. a market of a relevant branch of industry that the country in question has not been introduced to,
4) the conquest of a new supply source of raw materials or half-manufactured goods, regardless of whether the source of supply existed before or had to be created,
5) the establishment of a new organisation, like the establishment or breaking up of a monopoly position.[12]

The concept of innovation has been investigated in diverse fields. For example, the anthropologist H. G. Barnett defined an innovation as "any thought, behaviour, or thing that is new because it is qualitatively different from existing forms."[13] Everett Rogers, a sociologist, defined *innovation* as "newness" perceived by an individual*:* an idea, a practice, or an object is innovative (new), if it is so perceived by *"*an individual or other unit of adoption.*"*[14] An innovation can be adopted only if it reaches its receivers (also other inventors), by dissemination through "communication channels."[15]

Coming back to the initial equation, an invention is an innovation minus exploitation: Inv = Inn – Exp. However, the simplicity of the formula is misleading because the notion of invention also bears a certain level of ambiguity:

> Is the invention the idea; or the first conception of a way of using the idea; or the actual working utilisation of the ides; or the compounding together of two existing ideas; or the effective fusion of two ideas for a useful purpose?[16]

While an invention is an artefact of human inventive activity, an innovation is the invention served to the public, in a process which imbues the invention with a practical and economic meaning. Without the transfer to the society (market), an invention remains just an idea without a broader emanation.[17]

Some scholars rejected this inconvenient distinction between invention and innovation, arguing that innovating embraces the entire process from the invention to the technological change (this being the practical application of innovation in technology and business).[18]

---

12 Schumpeter, *Theorie der wirtschaftlichen Entwicklung*, 100-01.
13 Thomas Robertson, "The Process of Innovation and the Diffusion of Innovation," *Journal of Marketing* 31, no. 1 (1967): 14.
14 Likewise by Robert Dewar and Jane Dutton, "The Adoption of Radical and Incremental Innovations: An Empirical Analysis," *Management Science* 32, no. 11 (1986): 1422.
15 Everett Rogers, *Diffusion of Innovations*, 3 ed. (New York: The Free Press, 1983), 11.
16 John Jewkes, David Sawers, and Richard Stillerman, *The Source of Invention*, 2 ed. (Edinburgh: Macmillan, 1969), 25.
17 Ruttan, "Usher and Schumpeter on Invention, Innovation and Technological Change," 599.
18 ibid., 606.

A. P. Usher formulated a cumulative synthesis approach, according to which the emergence of a new idea (an invention) is an act of insight that exceeds the standard application of one's knowledge and skills. Concisely, he outlined the following steps: 1) the perception of the problem, 2) setting the stage (compiling the elements for the solution), 3) the act of insight when the solution to a problem emerges, 4) critical revision (testing the solution). Here, the individual act of insight becomes the agent of the *new thing.* Usher's theory unified the inventive and innovative processes and was intended to apply in diverse domains (from science to arts).[19]

In practice, such comprehension of a process manifests itself only when an idea moves smoothly to the application stage and becomes available on the market – a tested prototype does not end the process. Otherwise, an idea ends up as e.g. a costly patent that does not have any greater significance for the society.

The shift from an invention into an innovation is time-demanding and requires certain conditions – *opportunities.* A success in "innovating" can be attributed to knowledge, ingenuity, focus, and purposeful work[20]:

> There are (...) innovations that spring from a flash of genius. Most innovations, however, especially the successful ones, result from a conscious purposeful search for innovation opportunities, which are found in only a few situations. Four such areas of opportunities exist within the company (...): unexpected occurrences, incongruities, process needs, industry and market changes. Three additional sources of opportunities outside a company (...): demographic changes, changes in perception, new knowledge. (...)[T]ogether they account for the great majority of all innovation opportunities.[21]

The innovation process is determined by multiple factors characterised by a high level of inconsistency and speculation. Preconditioned by an invention, the process modifies a technical idea into a solution (a piece of technology) that has a real impact on social life and economy.[22]

Patents constitute an important factor of the invention-into-innovation transition. On the dichotomy map, they are located right after the invention they are granted for and precede the workings on innovations, i.e. further developments and commercialisation, that they largely stimulate but do not guarantee.

---

19 ibid..
See also A.P. Usher, *A History of Mechanical Inventions* (Cambridge: Harvard University Press, 1954); "Historical Implications of the Theory of Economic Development," *The Review of Economics and Statistics* 33, no. 2 (1951).

20 Peter Drucker, "The Discipline of Innovation," *Harvard Business Review* 76, no. 6 (1998).

21 ibid., 4..

22 "Measuring Innovation. A new Perspective," (OECD, 2010), 12.

2.2.1 The Degree of Departure

Various typologies of innovations have evolved over time. Innovations are classified according to:

a) the type of solution – product vs. processing, or
b) the nature of the problem they solve – technical vs. organisational, or
c) the degree of changes they introduce - radical vs. incremental.[23]

The last category is of a special attention in academia and among practitioners. Radical innovations, Schumpeterian *new combinations,* signify fundamental and revolutionary changes; involve a high degree of expertise and involve complex organisational preparation. They bring new qualities and benefits to the market.[24] Incremental innovations are improvements on current technologies; the complexity and the novelty of their technological content are significantly lower than in the case of radical innovations.[25]

Discontinuous (disruptive, radical) innovations are accompanied by a high level of technological and economic uncertainty (risk) – they are rather risky departure from existing practice and technology.[26] Major changes require new skills, a profound market understanding, and expanded processing abilities. Their feasibility and potential applications can be determined through prototyping and a thorough market analysis.[27] The distinction depends on the perception of the *departure-degree* from existing technology and knowledge.[28]

Somewhere between those two types reside re-inventions, i.e. changes provided during the process of implementation and/or adaptation of the invention: "the new idea departed from the mainline version of the innovation that was initially promoted."[29]

This is possible because an invention is a bundle of components with differing intensities – during the re-invention process all or only some components might undergo alternations. In inventions with highly correlated elements, one element cannot be changed without changing the other. In

---

[23] S. Gopalakrishnan and F. Damanpour, "A Review of Innovation Research in Economics, Sociology and Technology Management,," *International Journal of Management Science* 25, no. 1 (1997): 18-19.

[24] Robert Veryzer, "Discontinuous Innovation and the New Product Development Process," *Journal of Product innovation Management* 15, no. 4 (1998): 307-08.

[25] Dewar and Dutton, "The Adoption of Radical and Incremental Innovations: An Empirical Analysis," 1422-23.

[26] John Ettlie, William Bridges, and Robert O'Keefe, "Organisation Strategy and Structural Differences for Radical Versus Incremental Innovation," *Management Science* 30, no. 6 (1984): 683.

[27] Veryzer, "Discontinuous Innovation and the New Product Development Process," 317.

[28] Dewar and Dutton, "The Adoption of Radical and Incremental Innovations: An Empirical Analysis," 1423.

[29] Rogers, *Diffusion of Innovations*, 17.

the case of a *loose bundle,* inventors can mix and adjust only necessary elements.[30] Re-inventing can be triggered e.g. by problems with converting the original idea into a practical solution, false assumptions on applications, and the unpreparedness of customers to use the invention. A re-invention constitutes "a response to a threat of political survival of the innovation."[31]

2.2.2 The Offer of Makers

Makers perform all types of innovating: a solution might be a completely new idea, drafted from scratch, or an improvement over an existing product. The defining variable of makers is their use of a solution in a beneficial manner. Professor Eric von Hippel calls this paradigm "the functional source of innovation"[32], in which the use itself constitutes the main incentive to innovate.

The distinction between an invention (a pure technical idea) and an innovation (the idea put into practice) does not occur because makers develop solutions with the purpose of using them – the transition from an inventive idea into an applied innovation is immediate and fluent.

Makers are in charge of the complete development process – they are the fundamental agents of innovation: they recognise the problem, find the solution, and build a prototype.[33] As studies documented, fabrication of the innovation and its commercialisation is handed over to manufacturers, but not in every case.[34] The open source projects best illustrate makers' self-sufficiency in product conceptualisation, creation, distribution, and management. Here, manufacturing capacity is not even required as the whole process is digitalised. The situation differs in the case of physical products, where the manufacturer's involvement can contribute to a wider dissemination of the innovation due to lower production costs.[35]

The spectrum of Makers' innovations is enormous: sport equipment, electronics, robotics, 3D printing, engineering, and software. Mountain bikes, surfboards and their derivatives, and kayaks are classical illustrations of "revolutionary" making.

---

30 Ronald Rice and Everett Rogers, "Reinvention in the Innovation Process," *Science Communication* 1, no. 4 (1980): 503.

31 ibid., 502-03.

32 Eric von Hippel, *The Sources of Innovation* (New York Oxford: Oxford University Press, 1988), 3.

33 *Democratizing Innovation* (Cambridge, Massachusetts: MIT Press, 2005), 13-15.

34 "The Dominant Role of Users in the Scientific Instrument Innovation Process," *Research Policy* 5, no. 3 (1976).

35 Dietmar Harhoff, Joachim Henkel, and Eric von Hippel, "Profiting from Voluntary Information Spillovers: How Users Benefit by Freely Revealing Their Innovations," ibid.32, no. 10 (2003).

Just a quick look through maker communities leaves the one with the impression of the great richness, diversity, and advancement of makers' capabilities. Depending on their knowledge and expertise, they can either provide complex solutions or suggest some minor improvements.[36] Proficiency is not required because *making* assumes "learning by doing (and by playing)"[37] – "Makers at their core are enthusiasts."[38] Community posts reflect the eagerness and happiness stemming from the simple act of making. As a result, the technological know-how imparted into projects has skyrocketed in recent years.

A great example of a maker project is the 3D printer project *RepRap*, developed by a community under the same name, which was founded in 2005 by Dr. Andrian Bowyer, a senior lecturer of mechanical engineering at the University of Bath. *RepRap* was the first low-cost printer that started the revolution of open-source 3D printing. The first *RepRap* printer 1.0, named "Darwin," printed its first parts in 2008. Its 2.0 version, "Mendel," was produced in 2009, and the third generation, "Huxley" – in 2010.[39]

Another example from the basket of low-cost open projects is *Arduino* – a single-board microcontroller designed around the Atmel AVR microcontroller. It was launched in 2005 by students of the Interaction Design Institute in Ivrea (Italy) in order to simplify the process of electronic prototyping. Nowadays, it enables "everyday people with little or no technical background to create interactive products." Currently Arduino can be purchased as pre-assembled or assembled, at the costs of approx. $30; with even cheaper variations available for $9 (Chinese models available for $4). As stated on its Google+ profile, Arduino exists due to three factors:

1) a small electronic board manufactured in Italy that makes it easy and affordable to learn to program a microcontroller, a type of tiny computer found inside millions of everyday objects;
2) a free software application used to program the board;

---

[36] Viktor Braun and Cornelius Herstatt, *User-Innovation. Barriers to Democratization and IP Licensing* (New York: Routledge, 2009), 4; Christoph Hienerth, "The Commercialization of User Innovations: The Development of the Rodeo Kayak Industry," *R&D Management* 36, no. 3 (2006); Christopher Lettl, Cornelius Herstatt, and Hans Georg Gemuenden, "Users' Contributions to Radical Innovation: Evidence from Four Cases in the Field of Medical Equipment Technology," ibid.; Sonali Shah, "Sources and Patterns of Innovation in a Consumer Products Field: Innovations in Sporting Equipment," in *Working Paper, WP 4105 Sloan School of Management* (Cambridge, MA: Massachusetts Institute of Technology, 2000); von Hippel, *Democratizing Innovation* 14-15.

[37] John Dewey strongly propagated this learning method. See Alex Howard, "The Maker Movement's Potential for Education, Jobs and Innovation is Growing," http://radar.oreilly.com/2011/11/dale-dougherty-make-white-house.html, accessed 09.05.2014; Christopher Voss, "The Role of Users in the Development of Applications Software," *Journal of Product Innovation Management* 2, no. 1 (1985): 117.

[38] Dale Dougherty, "The Maker Movement," *Innovations* 7, no. 3 (2012): 12.

[39] "RepRap Project," http://en.wikipedia.org/wiki/RepRap_Project, accessed 10.05.2014; "RepRap.org," https://plus.google.com/communities/108419464619607320823, accessed 09.05.2014.

3) a vibrant community with a true expression of the enthusiasm powering the project.[40]

Mr. Beam is an open source, DIY portable laser cutter and engraver kit for wood, metal, or plastic, designed by Mr. Beam Lasers located in Munich. As the authors explain, they were inspired by the *RepRap* printer kit and by other self-made laser cutters like *ct hacks Laserplotter*, Laseraur, and *Domestic Hacks*. (They also implemented the Arduino microcontroller into the kit.)[41]

Raspberry Pi is another open source project powered by individuals. It is a low-cost single board computer (a mini-computer) developed by the Raspberry Pi Foundation, founded in 2006[42], which gathers teachers, academics, and computer enthusiasts with the aim of promoting computer science among youngsters – to "make programming fun again." Raspberry Pi can be plugged into a computer monitor or a TV set; it also requires a mouse and a keyboard. Popular at schools, it supports teaching students (and adults) how a computer works and how to program in languages, such as Scratch or Python. Its schematics, together with printed circuit board, were publicly disclosed. The Raspberry Pi B model costs $35, the Model A – $25. Because of its price and a wide functionality, Raspberry Pi is used in various maker projects, e.g. music machines and weather stations.[43]

A brand new project, *Pepino*, is a comprehensive drag&drop programming tool. As stated on the webpage, "Pepino is a complete open source micro-controllers development environment (hardware and software) web based Drag & Drop solution." It was developed by Tovi Levis as his final project at the Afeka College of Enginnering (Israel). Non-programmers are also able to easily apply Pepino, since no lines of code are necessary to develop a program due to the availability of drag&drop tools. It is installed on a Raspberry Pi B that connects to an Arduino based on Atmel

[40] "Arduino," http://en.wikipedia.org/wiki/Arduino, accessed 09.05.2014; " About Arduino," https://plus.google.com/+Arduino/about, accessed 09.05.2014; "Massimo Banzi: How Arduino is Open-Sourcing Imagination," https://www.ted.com/talks/massimo_banzi_how_arduino_is_open_sourcing_imagination, accessed 09.05.2014.

[41] "Mr Beam, a Portable Laser Cutter and Engraver Kit," https://www.kickstarter.com/projects/mrbeam/mr-beam-a-portable-laser-cutter-and-engraver-kit, accessed 09.05.2014; Atmel, "Laser Cutting and Engraving with Mr. Beam," http://atmelcorporation.wordpress.com/2014/05/09/laser-cutting-and-engraving-with-mr-beam%E2%80%A8%E2%80%A8/, accessed 09.05.2014.

[42] Founded by: Eben Upton, Rob Mullins, Jack Lang and Alan Mycroft, based at the University of Cambridge's Computer Laboratory. "The Making of PI," http://www.raspberrypi.org/about/, accessed 10.05.2014.

[43] "About Raspberry Pi," https://plus.google.com/+raspberrypi/about, accessed 10.05.2014; "Raspberry Pi," http://en.wikipedia.org/wiki/Raspberry_Pi, accessed 10.05.2014.

atmega328. The source code along with installation instructions has been published online in May 2014.[44]

A “must-mention” is Limor Fried's company *Adafruit Industries*, which is based in New York. Limor, an electrical engineer by profession, founded a company distributing online electronic parts and kits for original, open source hardware electronics featured on the website *adafruit.com*. Apart from this, Limor’s other projects are documented on the website *ladyada.net*. With more than 3 million followers on google+, Adafruit, and “associated” community platforms, Fried is able to hold massive brainstorming sessions on diverse electronic projects.[45]

2.3 Making a Place for Makers

The maker movement is a phenomenon of the last decade, but its roots go back to the late 1970s, with economic and technological breakthroughs initiated at that time. Concepts such as value of use, intangibility, customer co-creation, and, last but not least punk, culture, modified the customer relation together with the profile of modern business. Most importantly, they conceived a safe niche for creative and inventive individuals.

2.3.1 Historical Insight

The classical economic view established in the advent of the Industrial Revolution focused predominantly on tangible output (a commodity), the value of which was embedded in its exchange capacity (*value of exchange*[46]). Emphasis was put on the production and its size. Fordism, a business model named after Henry Ford, based around standardised mass production (with subordinated

[44] "Project Pepino," http://pepino.tovilevis.com/, accessed 09.05.2014; "Drag & Drop Programming with Pepino," http://atmelcorporation.wordpress.com/2014/05/08/drag-drop-programming-with-pepino/, accessed 10.05.2014; "tlevis/Pepino," https://github.com/tlevis/Pepino, accessed 10.08.2014.

[45] "About Limor Fried," https://plus.google.com/+ladyada/about, accessed 09.05.2014; "Limor Fried," http://en.wikipedia.org/wiki/Adafruit, accessed 09.05.2014; "About Adafruit Industries," https://plus.google.com/+adafruit/about, accessed 09.05.2014.

[46] “The exchange value” is a theoretical concept which describes the value of an object “ when placed in a value or exchange with another commodity of a different kind”, e.g. milk and chicken.
Karl Marx, Capital: A Critique of Political Economy. Harmondsworth, Middlesex, England. 1867 (New York: Penguin Books in association with New Left Review, 2001): 88 from Ashlee Humphreys and Kent Grayson, "The Intersectiong Roles of Consumer and Producer: A Critical Perspective on Co-production, Co-creation and Prosumption," *Sociology Compass* 2/3(2008): 965.

mass consumption), remains a good example of that mind-set.[47] Activities were ranked by their productivity, which was the core wealth accumulation factor; hence, another important factor was the (implied) durability of the output. In the view of classicists like Adam Smith, services were useful as such, but did not contribute to value creation; utility (*value in use*[48]) itself did not have a direct impact on the increase of net capital and was categorised as unproductive.[49] According to Karl Marx, the value in use *"*becomes a reality only by use or consumption*"*[50], which implies subjectivity[51], and so cannot be recognised as a measurable and reliable trade asset. Those theoretical assumptions negatively affected the position of services and customers in the capitalist society of the time. Services did not generate profit[52] and customer consumption was considered as value destruction.[53] By the same token, interaction with the customer as a source of value creation was out of the question – the companies equipped with sets of tools were targeting and managing "their" customers.

The post-1945 reality was marked by the shift of economic attention from production to consumption.[54] The post-war consumerism "replenished desires of the war scarcity on consumer goods", but was also a successful tool of economic recovery. The growing demand for consumer goods ensured peacetime prosperity despite the intensive military production for the purposes of the Cold War. In the USA, consumption was promoted as a civic responsibility, as it was a crucial element of the *prosperity-producing cycle*: "the good customer devoted to more, newer and better was in fact the good citizen, responsible for making the United States a more desirable place for all

---

47 Edward Comor, "Contextualizing and Critiquing the Fantastic Prosumer: Power, Alienation and Hegemony," *Critial Sociology* 37, no. 3 (2011): 4.

48 The distinction between *value in exchange and value in use* underlies the separation between producers and consumers. According to Marx, *value in exchange* is orientated toward others, whereas *value in use* toward an object. That diversification brings two separate products: enjoyment of the purchased product versus the sale. Marx inferred that the exchange process resembles a negotiation process in which one actor persuades another.
Humphreys and Grayson, "The Intersectiong Roles of Consumer and Producer: A Critical Perspective on Co-production, Co-creation and Prosumption," 965-66, 70-74.

49 Rafael Ramirez, "Value Co-Creation: Intellectual Origins and Implications for Practice and Research," *Strategic Management Journal* 20(1999): 50-52.

50 Marx, Karl, Captial, 1867 [2001], 55 from Humphreys and Grayson, "The Intersectiong Roles of Consumer and Producer: A Critical Perspective on Co-production, Co-creation and Prosumption," 965.

51 The same object can have different usefulness for two different people.

52 Despite the prevalent stance on the low productivity of services, opposite views like those of Le Pesant de Boisguilbert considered income and consumption as wealth creation. Even Marx and Smith, firm proponents of the exchange value, considered services useful *per se*, however, without the necessary and wished impact on capital accumulation. John Stuart Mill advocated for the indirect effect on value creation. Ramirez provides an interesting overview of the historical literature on this subject-matter in Ramirez, "Value Co-Creation: Intellectual Origins and Implications for Practice and Research," 51-52.

53 ibid., 49.

54 George Ritzer and Nathan Jurgenson, "Production, Consumption, Prosumption: The Nature of Capitalism tn the Age of the Digital 'Prosumer'," *Journal of Consumer Culture* 10, no. 1 (2010): 15-16.

its people."[55] Even the oil crisis from 1973 did not stop consumption. On the contrary, consumption as the public duty proliferated and accelerated (however, due to the decline in domestic production, the quantity of imported goods increased). "Cathedrals of consumption" were springing up like mushrooms.[56]

The late 1960s and 1970s were stigmatised with socio-political disturbances, such as the Vietnam War, racial tension, immigration, threats of terrorism, and economic unease. Slower growth and higher inflation forced the review and reorganisation of the economic regime, which resulted in the erosion of Fordism and its mass production.[57] The technological changes have led to economic shifts as well. Entrepreneurs propagated the free market, free trade, and the free flow of information – ideals strongly promulgated in the era of Margaret Thatcher and Ronald Regan**.** The Left promoted the Post-Industrial Society as "a modern version of Jeffersonian democracy."[58] Additionally, postmodern philosophy destabilised the traditional paradigm of the distinction between production and consumption. The postmodernists acknowledged consumption as a productive process, in the course of which consumers produce their own identity and actively participate in value creation.[59]

At the same time, however, massive consumerism triggered its counter movement, the best expression of which was the punk culture of the 1970s. Anti-mainstream music, independent recording studios, as well as independent distribution venues pronounced a deep desire of independence and self-expression. That mixture set in motion the Do-It-Yourself culture (DIY). The *DIY culture* was "a self-proclaimed cultural movement, challenging the symbolic codes of mainstream culture."[60] In the music sector, DIY bands were in charge of the complete production chain, and because they acted outside big recording studios, they established new ways of communicating with their fans. DIY culture spread among artists and artisans who opposed consumerism, mass-production, and the prevailing industrialised forms, in favour of bringing back the natural and individual sense of aesthetics by encouraging people to participate in hands-on activities. The DIY principles were clearly noticeable in the sport sector: skateboarding, surfing,

---

[55] Lizabeth Cohen, "A Consumers' Republic: The Politics of Mass Consumption in Postwar America," *Journal of Consumer Research* 31(2004): 236-39. For an extensive historical evidence see *A A Consumers' Republic: The Politics of Mass Consumption in Postwar America* (New York: Knopf, 2003).

[56] Ritzer and Jurgenson, "Production, Consumption, Prosumption: The Nature of Capitalism tn the Age of the Digital 'Prosumer'," 15.

[57] Robert Antonio and Alessandro Bonanno, "A New Global Capitalism? From "Americanism and Fordism" to "Americanization-Globalization"," *American Studies* 41, no. 2/3 (2000): 37-38.

[58] Comor, "Contextualizing and Critiquing the Fantastic Prosumer: Power, Alienation and Hegemony," 312.

[59] Humphreys and Grayson, "The Intersectiong Roles of Consumer and Producer: A Critical Perspective on Co-production, Co-creation and Prosumption," 967.

[60] Derrick Purdue et al., "DIY Culture and Extended Milieux: Lets, Veggie Boxes and Festivals," *The Sociological Review* 45, no. 4 (1997): 647.

biking, or kayaking enthusiasts tended to repair and improve their equipment on their own. Here, the market shortage played a role: since the manufacturers did not furnish the market properly, the users took things into own hands. Politically, the DIY situated itself alongside the left movement and anarchism, but with time it evolved into a formation of various individuals, often politically neutral, dedicated to making things for their own joy.[61] As Cosmo, a DIY activist, said:

> (…) DiY culture was born when people got together and realized that the only way forward was to do things for themselves.… Ingenuity and imagination are the key ingredients.… Free parties, squat culture, the traveller movement and later Acid House parties pay testament to the energy and vision of people who decided it was now time to take their destinies into their own hands.[62]

It is indisputable that developments in electronics and communication technologies assisted that transformation and affected a wide spectrum of activities in the post-industrial society.[63] The Internet and other communication platforms facilitated the exchange and dissemination of ideas (viral distribution). Computer innovations and software applications made it possible to produce high quality works at home; eventually, home-based start-ups could compete with giant companies. Through low-cost hardware and software, individuals have become independent and self-sufficient. IT technologies have brought into life the Industrial Revolution 2.0.[64]

2.3.2 Intangible Resources – Speed instead of Size

The Industrial Revolution established the conviction that high profits could be generated only by mass-production. Capital accumulation became the main paradigm: the more capital was accumulated, the more resources for the production could be purchased. The distribution of capital in society, however, remained unequal, creating wealth disparities.[65] Karl Marx foretold the collapse of the flawed system. Society, however, was not liberated by communism, but information

---

61 "DIY Ethic," http://en.wikipedia.org/wiki/DIY_ethic, accessed 09.05.2014.

62 "George McKay: Professor, Writer, Musician. DIY protest," http://georgemckay.org/diy-protest/, accessed 15.05.2014.

63 Richard Badham, "Post-Industrial Society," *Current Sociology* 32, no. 1 (1984).
Badham presents a number of linguistic collocations to describe the new social quality: active society, service society, knowledge society, technotronic society, leisure society, post-bourgeois, post-modern, post-economic, post-scarcity, and post-historic.

64 Justin Lahart, "Tinkering Makes Comeback Amid Crisis," http://online.wsj.com/news/articles/SB125798004542744219, accessed 16.04.2014.

65 The gap has never stopped growing. An interesting talk given on TED "Chrystia Freeland: the Rise of the New Global Super-Rich," http://www.ted.com/talks/chrystia_freeland_the_rise_of_the_new_global_super_rich, accessed 18.04.2014.

technology: Marx' dream of the "capitalist worker came true in Silicon Valley."[66] Technology launched the *Knowledge Revolution*, in the course of which knowledge rose to the position of the fundamental parameter of economic growth. The source of wealth drifted to intellectual capital.[67]

The core variable of the modern system is change – those who manage change become leaders. According to Gordon Smith and Russell Parr, in the new regime there is no time to accumulate expertise in all areas and there is no room for a not-invented-here mind-set.[68]

Furthermore, the new paradigm of intangibility has shaken the classical economic doctrine: it introduced the notion of the abundance of resources. Knowledge is the asset of the modern economy – endlessly consumed and multiplied, unaffected by the number of users, it can be sold many times over, which may only increase its value.[69] Knowledge can be everything from an opinion to an observation, captured in diverse communication means, e.g. emails and reports. Likewise, intangible assets are of great value to the company.[70] Neither is declared on financial statements.[71] Human capital has evolved to the status of the most important intangible asset. It denotes the know-how extracted from employees and customers. In the knowledge economy, everything starts and ends with people who possess knowledge. This understanding results in an immense appreciation of customers: "today the customer capital counts"[72] – strong and sustainable relations with customers contribute to the company's success. The customer from the 1960s was accustomed to the *one-size-fits-all*, or the *zero-services approach*. Nowadays, customers expect to participate fully in the product or service design in order to ensure that the product matches their individual needs. Those companies succeed which shape good relations with their customer and

---

66 Gordon Smith and Russell Parr, *Valuation of Intellectual Property and Intangible Assets*, 3 ed. (New York: John Wiley & Sons, Inc, 2000), 2; Juergen Daum, *Intangible Assets and Value Creation* (England: John Wiley & Sons Ltd., 2003), 8-9.

67 Alan Burton-Jones, *Knowledge Capitalism. Business, Work, and Learning in the New Economy* (Oxford: Oxford University Press, 2004), 3.

68 Smith and Parr, *Valuation of Intellectual Property and Intangible Assets*, 4.

69 Knowledge is very time-sensitive and out-dated dramatically decreases its value. Daum, *Intangible Assets and Value Creation*, 35-39.

70 ibid., 16-17.

71 ibid., 6. E.g. Coca Cola reported only 6.6% of its market value on its balance sheet as of December 31, 1999. It means that out of 100$, 93$ had to be paid for intangible assets.
The terms *knowledge* and *intangibles* are used interchangeably. Kristandl and Bontis provide a set of diverse terms referring to intangibles: intellectual property, intangible assets, intellectual capital, intellectual assets, knowledge capital, and knowledge-based assets. See Gerhard Kristandl and Nick Bontis, "Construction of a Definition of Intangibles Using the Resource Based View of the Firm," *Management Decision* 45, no. 9 (2007): 1511.
Intangible resources classify under the term "capital" human, organisational, technological, or relational capital.
Esteban Fernandez, Jose Montes, and Camilo Vazquez, "Typology and Strategic Analysis of Intangible Resources. A Resource-Based Approach," *Technovation* 20, no. 2 (2000): 81-92.

72 Daum, *Intangible Assets and Value Creation*, 17.

possess the most knowledge about the customer.[73] The competition rests upon the paradigm of being the first, of anticipating trends ahead of others – flexibility is the remedy for entrepreneurial anxieties. Under these circumstances, Haeckel formulated "sense and respond" strategy, which transformed into a leading post-industrial managerial paradigm and replaced the rigid "make and sell" business model.[74]

2.3.3 Embedding Customer Knowledge into Business Strategies

Under the new paradigm, marketing practitioners had to answer the following question – "how to meet customer needs?" "People don't want to buy a quarter-inch drill. They want a quarter-inch hole."[75] The success relied on the proper recognition of practical, emotional, and aspirational dimensions of a potential customer, which were later associated with a specific product.[76] Customer-centricity was followed by greater openness and stronger interactions between companies and customers. The process of "opening" was aided with new communication technologies, which also helped customers communicate with one another. They liberated themselves from their dependency on companies: the exchange of ideas allowed them to learn new perspectives and share expertise on companies' services.[77]

2.3.3.1 The Concepts of Co-creation and Co-production

The concept of customer-centricity evolved into the concept of *co-creation* understood as *joint problem solving*. Co-creation assumes a personalised interaction between the customer and the company: the customer shares with the company their unique experience; the company gains access to new resources (*an infinite source of creation*) and builds its competitive advantage. [78]

Eric von Hippel coined the term *customer-active paradigm* (CAP) in contrast to the *manufacturer-active paradigm* (MAP), and refuted for good the archetype of the manufacturer as the only possible innovator. The CAP assumes that the customer provides an idea for a new industrial

---

[73] ibid., 24-26.

[74] Stephan Haeckel, *Adaptive Enterprise: Creating and Leading Sense-and Respond Organizations*, vol. 1999 (Boston: Harvard School of Business).

[75] Clayton Christensen, Scott Cook, and Taddy Hall, "Marketing Malpractice: The Cause and the Cure," *Harvard business review* 83, no. 12 (2005): 4.

[76] ibid., 6-8.

[77] C. K. Prahalad and Venkat Ramaswamy, "Co-Creation Experiences: The Next Practice in Value Creation," *Journal of Interactive Marketing* 18, no. 3 (2004): 6.

[78] ibid.

product or service to a selected manufacturer. A *chosen* manufacturer responds to the customer's request by "screening" emerging ideas for new designs, and selecting the most promising design available. In the study, Hippel remarked that the "customer request" may contain a partial or complete product solution.[79] With this concept and further studies, he opened an interesting chapter on non-manufacturer-generated innovations and propelled users (customers) to the forefront.

C.K. Prahald and Venkat Ramaswamy proposed a model of co-creation that consisted of four characteristics (blocks): dialogue, access, risk-benefits,, and transparency (DART). The DART describes a constant process of *encountering the customer*. The dialogue can be enhanced only through open access and the high transparency of the information. This allows the customer to understand the whole context of the ongoing action and to assess the risk-benefits of the offering. Each DART block is of equal importance for the proper interaction. The outcome of co-creation is the *experience*. All points of the interaction are opportunities for value creation and extraction. The DART model enables companies to *co-shape* the expectations and experiences with the customer.[80]

Another interesting concept by Stephen Vargo and Robert Lusch presents the co-creation within the *service-dominant logic* as a counterpoint to the traditional concept of *good-dominant logic*, which illustrates the shift from tangible toward intangible resources.[81] The *new dominant logic* homes in on specialised skills and know-how: services are "the application of specialised competences (knowledge and skills) through deeds, processes and performances"[82], and are integrated with goods. Co-creation as defined by Vargo and Lusch shares similarities with the distinction between *operand* and *operant* resources introduced by Constantin and Lusch. *Operand* resources, primary for good-dominant logic, were defined as "resources on which an operation or act is performed to produce an effect;" *operant* resources, substantial for service-dominant logic, "were employed to act on operand resources." The latter are invisible, intangible, dynamic, and infinite; they easily multiply and create additional *operant* resources. The embodiment of this rather abstract idea is the microprocessor, where an *operand* resource, silica, was embedded with an *operant* resource, knowledge.[83] By applying these concepts to the service dominant logic, we come to the conclusion that the customer is an *operant* resource acting and performing on *operand* resources. The new logic rejects the dichotomy of production and consumption. The market is seen

[79] See Eric von Hippel, "Successful Industrial Products from Customer Ideas," *Journal of Marketing* 42, no. 1 (1978); "The Dominant Role of Users in the Scientific Instrument Innovation Process."

[80] Prahalad and Ramaswamy, "Co-Creation Experiences: The Next Practice in Value Creation," 8.

[81] Stephen L. Vargo and Robert F. Lusch, "Evolving to a New Dominant Logic for Marketing," *Journal of Marketing* 68, no. 1 (2004): 2.

[82] ibid.

[83] ibid., 2-3.

as a platform of continuing social and economic processes: interactivity, integration, and cooperation.[84]

The concept of co-production, in which the customer rises to the role of the co-producer, goes a step further – the customer assumes certain activities, which were previously performed by the company. Co-production denotes a shared product design and shared production, e.g. assembling IKEA furniture. It occurs when the customer wants to "exercise the control over the process or the outcome of service." The customer engages in the governance of the project and provides additional quality control over its performance. The company gains competitive advantage through enhanced customer experience.[85]

In the *co*-reality, the impetus comes from the customer to the manufacturer. This approach has proven to be more efficient, as nowadays customer needs change rapidly and are much more heterogeneous, making traditional "exploration" time and cost consuming. To facilitate this process, companies provide their customers with *toolkits*[86] to obtain direct information about their product expectations. A great advantage of toolkits is the cost reduction of information transfer. Computer designs and production technologies are areas of great applicability of toolkits; in some production fields toolkits are the best option, in others they are are less effective, as they cannot substitute very refined human skills. Nonetheless, as studies showed, both users and companies take great advantage of them.[87]

2.3.3.2 DIYers and Technological Makers

Customer engagement goes even further in the concept of *prosumption*[88], which has been coined by Alvin Toffler, an American futurist, and is an amalgamation of the terms *producer* and

---

[84] ibid., 10-12.

[85] Robert F. Lusch, Stephen L. Vargo, and Matthew O'Brien, "Competing Through Service: Insights from Service-Dominant Logic," *Journal of Retailing* 83, no. 1 (2007): 11-13; Lance Bettencourt et al., "Client Co-Production in Knowledge-Intensive Business Services," *California Management Review* 44, no. 4 (2002): 113.

[86] A set of user-friendly design tools that enables its users to develop new products. Eric von Hippel and Ralph Katz, "Shifting Innovation to Users via Toolkits," *Management Science* 48, no. 7 (2002).

[87] ibid.; Frank T. Piller and Dominik Walcher, "Toolkits for Idea Competitions: A Novel Method to Integrate Users in New Product Development," *R&D Management* 36, no. 3 (2006); Nikolaus Franke, Martin Schreier, and Ulrike Kaiser, "The "I Designed It Myself" Effect in Mass Customization," *Management Science* 56, no. 1 (2010); Nikolaus Franke and Frank Piller, "Value Creation by Toolkits for User Innovation and Design: The Case of the Watch Market," *Journal of Product Innovation Management* 21, no. 6 (2004).

[88] Alvin Toffler, *The Third Wave* (New York: William Morrow and Company, Inc, 1980).

consumer.[89] In Toffler's view, the producer-consumer hybrid is much more than just a figure: "a prosumer is the liberator of humankind," who generates "the first truly humane civilization in recorded history."[90] A prosumer derives great satisfaction from creating, making, producing, and obtaining new skills.[91] Economic necessity is not the main drive; it is a lifestyle option - a way to express own personality, own ethos.[92] Toffler's presumption reflects well in the DIY culture. DIY projects involve raw and semi-raw materials and components to produce, transform, or reconstruct. Compared with *co*-concepts, DIY implies higher material costs, and requires higher skills, knowledge, as well as more time. Studies show that DIY behaviour results from a mixture of factors, varying from economic to personal that is:

1) the expected economic benefits (saving money[93]),

---

[89] Toffler contemplates human history from the perspective of societal life and its transformations at the turn of the centuries. He assumes that the agent of change, metaphorically depicted as waves, is the management of commodities. For him, prosumption is a natural state of human activity that can be dated back to the beginning of the Agrarian Revolution, after which it was destroyed by the unnatural condition of the Industrial Revolution.

[90] Toffler, *The Third Wave*, 11; see also Philip Kotler, "The Prosumer Movement: A New Challenge for Marketers," *Advances in Consumer Research* 13, no. 1 (1986); Comor, "Contextualizing and Critiquing the Fantastic Prosumer: Power, Alienation and Hegemony."
Some authors argue that prosumption is not a revolutionary institution but just the next form of capitalism. Prosumer freedom and empowerment are an illusion. Other scholars see prosumption as a constant element of capitalism, which for some time stayed in a shadow.
See ibid., 311-13; Humphreys and Grayson, "The Intersectiong Roles of Consumer and Producer: A Critical Perspective on Co-production, Co-creation and Prosumption."; Ritzer and Jurgenson, "Production, Consumption, Prosumption: The Nature of Capitalism tn the Age of the Digital 'Prosumer'."

[91] Studies on motivational mechanisms underlying prosumption engaged multidisciplinary research approaches: marketing, management, behaviourism, psychology, and ethnography. The application of non-economic methods proved that prosumption is more than an economic activity.
See C. Page Moreau and Darren W. Dahl, "Designing the Solution: The Impact of Constraints on Consumers' Creativity," *Journal of Consumer Research* 32, no. 1 (2005); Hope Jensen Schau and Mary C. Gilly, "We Are What We Post? Self-Presentation in Personal Web Space," ibid.30, no. 3 (2003); John Deighton, "The Consumption of Performance," ibid.19(1992).
In 1990, Bagozzi and Warshaw designed a theory of trying, refined by Xie, Bagozzi, and Troye in 2008, which accounts for the most of prosumer characteristics. Scholars assumed that past attempts have a considerable influence over future ones. As prosumption involves some , prosumers in their undertaking are not sure if to anticipate a success or a failure. The theory model bases on determinants such as frequency and recency that provide predictability of prosumptive attitudes, and behaviours. The study was modified by introduction of self-efficacy. The empirical evidence suggests that self-efficacy, past behaviour, and attitude have significant effects on prosumption attempts.
See Richard Bagozzi and Paul Warshaw, "Trying to Consume," ibid.17, no. 2 (1990); Chunyan Xie, Richard Bagozzi, and Sigurd Troye, "Trying to Prosume: Toward a Theory of Consumers as Co-Creators of Value," *Journal of the Academy of Marketing Science* 36, no. 1 (2008).

[92] Colin C. Williams, "A Lifestyle Choice? Evaluating The Motives of Do-It-Yourself (DIY) Consumers," *International Journal of Retail & Distribution Management* 32, no. 5 (2004).

[93] Studies on relations between the income and DIY activities documented a positive and negative correlation. This perplexing conclusion indicates that economic aspects do not suffice to explain DIY engagement.
Marco Wolf and Shaun McQuitty, "Understanding the Do-It-Yourself Consumer: DIY Motivations and Outcomes," *AMS Review* 1, no. 3-4 (2011): 159.

2) the insufficient quality of the market offering (DIYers can perform simply better than professionals do),
3) the lack of product availability on the market,
4) the need for customisation (DIYers create products tailored to their own particular needs[94]),
5) discretionary time to complete DIY project,
6) identity enhancement (self-satisfaction, feeling of empowerment),
7) community sharing (the feeling of connectedness with others),
8) enjoyment and happiness.[95]

Whereas DIY can be regarded as a generic term for all *self-made* activities, e.g. cooking, and manual and creative works, the Maker movement represents its technology-centred extension, with *MAKE* magazine and the blog *Boing Boing* as its social representatives.[96]

MAKE is a 21st century equivalent of *Popular Mechanics* that inspired individuals to play with engineering, learn new skills, and find *like-minded* makers.[97] However, *MAKE* did something more – it catalysed the worldwide growth of the movement. As stated on its homepage, "this is a magazine that celebrates your right to tweak, hack, and bend any technology to your own will."[98] The growth of makers is correlated with the establishment of (bio)hackerspaces, makerspaces, and FabLabs all around the world. These are *physical places* for people to share tools and ideas, or to fabricate their prototypes.[99]

> "We've had this merging of DIY with technology," says Bre Pettis, co-founder of NYC Resistor, one of the first hackerspaces, in Brooklyn. "I'm calling it Industrial Revolution 2."[100]

The Maker Movement has enormous momentum: it fuels social well-being and the economy, and for that reason could not remain unnoticed, even in the White House. The democratisation of technology was appreciated by proclaiming June 18 the National Day of Making in the USA.[101]

---

94 Companies deliver only a selected number of customization tools that suit their profile and capacities. Ibid., 160.

95 ibid., 158-64.

96 The *MAKE* magazine was founded by Dale Dougherty in 2005. *BoingBoing* is a 25-year-old independent blog "devoted to the weird, wonderful and wicked things to be found in technology and culture." See "MAKE:," http://makezine.com/, accessed 16.05.2014; "BoingBoing," http://boingboing.net/, accessed 16.05.2014.

97 Dougherty, "The Maker Movement," 11.

98 "MAKE: FAQs," http://makezine.com/faq/, accessed 15.05.2014.

99 Lahart, "Tinkering Makes Comeback Amid Crisis."; "FabLab," http://en.wikipedia.org/wiki/Fablab, accessed 15.05.2014; "Hackerspaces," http://hackerspaces.org/wiki/, accessed 15.05.2014.

100 "Tinkering Makes Comeback Amid Crisis."

2.4 An Escape from Labelling – Characteristics of the Movement

Two aspects of DIY and making are crucial to the legal questions this study explores and intends to answer. Making is a collective activity that is possible only thanks to the free dissemination of information.

2.4.1 Communities

Innovating communities are "nodes consisting of individuals interconnected by information transfer links, which may involve face-to-face, electronic, or other communication."[102] They vary in size, organizational structures, and subject matters. A community might be a group of friends and family members or a well-organised community with a paid membership. Coordinated by leading users[103] and forum moderators, communities can introduce very competitive products to the market. The membership is not restricted to one community; maker communities are open to everyone and people join different groups, which intensifies the exchange of knowledge.[104]

Observations of collective innovation lead to the conclusion that the assistance of community members improves the overall quality of innovation and its dissemination.[105] The synergy effect explains the success of communities in accomplishing their goals: the greater the number of entrants, the higher the quality and the frequency of assistance, the stronger the cooperation and the greater the number of problems identified and solved.[106] A classic example of a com unity is the

---

[101] Atmel, "President Obama proclaims National Day of Making," http://atmelcorporation.wordpress.com/2014/06/17/president-obama-proclaims-national-day-of-making%E2%80%A8%E2%80%A8/, accessed 19.06.2014.

[102] von Hippel, *Democratizing Innovation* 96.

[103] Lead users can be distinguished by two characteristics: 1) they come with an idea months (or even years) ahead of the majority, and 2) they have a higher expectation of profits gained from the solution. Morrison et al. elaborated on Hippel's binary characteristic and added following variables: access to more sources and better technical equipment, lower administrative barriers, and greater intellectual capability to modify complicated products. See *The Sources of Innovation* 107; Pamela Morrison, John Roberts, and Eric von Hippel, "Determinants of User Innovation and Innovation Sharing in a Local Market," *Management Science* 46, no. 12 (2000).

[104] Nikolaus Franke and Sonali Shah, "How Communities Support Innovative Activities: An Exploration of Assistance and Sharing among End-Users," *Research Policy* 32, no. 1 (2003); Stacey Kuznetsov and Eric Paulos, "Rise of the Expert Amateur: DIY Projects, Communities, and Cultures," in *Proceedings of the 6th Nordic Conference on Human-Computer Interaction: Extending Boundaries* (Reykjavik, Iceland: ACM, 2010).

[105] Robert C. Allen, "Collective Invention," *Journal of Economic Behavior & Organization* 4, no. 1 (1983): 21.

[106] Franke and Shah, "How Communities Support Innovative Activities: An Exploration of Assistance and Sharing among End-Users," 166-67.

Apache software community. Its designer, Rob McCool, revealed the source code of NCSA HTTPd web server in the 1990s, so that others could download it and modify. The community members carefully documented all modifications and bugfixes, and continued developing the code in the form of "a consolidated patch."[107] The same occurs the in *RepRap* or Raspberry Pi communities. The Raspberrians are additionally involved in educational activities, as the Raspberry mission is the popularisation of computer science among children. Despite the prevalence of online communities, the maker scene also has a great offer of offline communities such as Dorkbot, whose members meet in person to discuss new electronic gadgets.[108] Another example is TechShop, organised via membership-based workshops that offer tools, equipment, sophisticated 2D and 3D design software, instructions, and the support of community members in "building your dreams."[109] *MAKE* magazine has a great offer of offline community meetings. The most important with a great publicity is Make Faire: "Maker Faire is the Greatest Show (and Tell) on Earth—a family-friendly festival of invention, creativity, and resourcefulness, and a celebration of the Maker movement."[110] It started in 2006 (a year after the first issue of *MAKE*) in the Bay Area and grew rapidly, reaching in 2013 a record attendance of 195,000 makers during MAKE Faire in NYC and the Bay Area. With time, MAKE Faires expanded throughout the world and are now organized in Rome, Tokyo, Santiago, Oslo, and Hannover. Such meetings offer the chance of showcasing projects which are being developed privately in basements and garages.[111] Last but not least, makers spin off their *spaces* into various derivatives: next to makerspaces, there are hackerspace and biohackerspace communities, both online and offline, which make feel people connected and happy. The positive attitude of participants, who want to share and build, strengthens the movement. That leads to another feature of Makers and DIYers – the sharing of information.

2.4.2 Open Sharing

Open sharing[112] *(free revealing)* contradicts the classical proprietary approach, where the return on investment is assured by keeping knowledge *locked*[113] – any involuntary information leakage impairs the awaited compensation of the investment.

---

[107] von Hippel, *Democratizing Innovation* 101.

[108] "Dorkbot. People Doing Strange Things With Electricity," http://dorkbot.org/ accessed 09.05.2014.

[109] "TechShop - About," https://plus.google.com/+TechShop/about, accessed 09.05.2014; "TechShop. Build Your Dreams Here," http://techshop.ws/index.html, accessed 09.05.2014.

[110] "Maker Faire a Bit of History," http://makerfaire.com/makerfairehistory/, accessed 15.05.2014.

[111] ibid.

[112] Kuznetsov and Paulos, "Rise of the Expert Amateur: DIY Projects, Communities, and Cultures."

[113] Knowledge locking means keeping knowledge closed via legal protection or through trade secrecy.

> When we say that an innovator "freely reveals proprietary information", we mean that all existing and potential intellectual property rights to that information are voluntarily given up by that innovator and all interested parties are given access to it.[114]

As studies have shown, neither legal protection nor trade secrecy are an effective and appealing instrument for Makers[115] - sharing is a fundamental part of the Maker conduct.[116]

Why do Makers disclose information? Sharing connects like-minded people. It offers a great learning opportunity and an opportunity for teaching its members. It is a cycle: you share a bit of your wisdom to teach others, and you immediately get a question back when you have to reflect on your information. Personal ambition, satisfaction, and enjoyment are among many driving factors. In addition, it is easy: it suffices to post a photo or a comment.[117]

From a wider perspective, free revealing fosters the dissemination of and development of ideas: all entrants permanently update and monitor the process. Collaboration enhances the process efficiency; the increase of knowledge positively affects the improvement of practice.[118] Being first to reveal a given piece of information also facilitates establishing an informal standard.[119] Free revealing provides significant advantages to the information-holder and, in the larger perspective, to the society. Just a brief look through some classical cases like Apache or sport equipment shows that driving innovating forces were generated when the information was made open. Sharing diminishes the risk of resource overuse for the same innovation. It even occurs between

---

[114] Harhoff, Henkel, and von Hippel, "Profiting from Voluntary Information Spillovers."

[115] The study on innovators of sport equipment showed that individual innovators who obtained the patent rarely gain a return on their investment. See ibid.; Shah, "Sources and patterns of innovation."
Edwin Mansfield, "How Rapidly Does New Industrial Technology Leak Out?," *The Journal of Industrial Economics* 34, no. 2 (1985). The scholar carried an interesting empirical study on the speed of unintentional release of invention-related information. He questioned CEOs of 100 American firms from 13 major manufacturing industries on the "leakage" of information on a development decision and information on a new product or process. The information was in hands of rivals after 12-18 months and up to one year, respectively.

[116] Mark Hatch, The Maker Movement Manifesto. Rules for Innvoation in the New World of Crafters, Hackers, and Tinkerers, (McGrew-Hill Education eBooks, 2014).

[117] Kuznetsov and Paulos, "Rise of the Expert Amateur: DIY Projects, Communities, and Cultures."; Allen, "Collective Invention," 17; Josh Lerner and Jean Tirole, "Some Simple Economics of Open Source," *The Journal of Industrial Economics* 50, no. 2 (2002): 198.

[118] Allen, "Collective Invention," 15.
A manufacturer acquainted with the revealed information also contributes to the innovation by either improving it or offering a significant decrease in production costs. See Harhoff, Henkel, and von Hippel, "Profiting from Voluntary Information Spillovers," 301; Eric Von Hippel and Georg Von Krogh, "Free Revealing and the Private-Collective Model for Innovation Incentives," *R&D Management* 36, no. 3 (2006).

[119] Allen, "Collective Invention," 21; Von Hippel and Von Krogh, "Free Revealing and the Private-Collective Model for Innovation Incentives," 301.

companies: a low rivalry condition, when no direct competition exists, it may appear as the only profitable solution.[120]

Two sharing websites are worth naming at this point: Instructubles and Kickstarter.[121] The first one is a place where people post and document their DIY creations (from cooking, crafting, and building toys to 3D printing) with (visual) instructions and detailed descriptions. Other participants comment on them or suggest improvements. Launched in 2005, it currently features more than 100,000 projects.

Kickstarter is a crowdfunding platform where people donate to projects to bring them to life –with many makers' projects among them.[122] Creators and DIYers must set a deadline and minimum funding goal. The crowdsourcing platform was launched in 2009 and since has collected $1 billion from 6.2 million people for 61,000 projects. 44% of the projects have met the criteria and received money – Kickstarter operates on an all-or-nothing premise.[123]

> There's just something magical about Kickstarter... You immediately feel like you're part of a larger club of art-supporting fanatics.[124]

---

[120] von Hippel, *Democratizing Innovation* 78-80.
Allen and Nuvolari found out that the practice of free revealing was an intentional practice among profit-seeking companies in the 19th century in the iron and mining industries, respectively.
See Allen, "Collective Invention."; Alessandro Nuvolari, "Collective Invention during the British Industrial Revolution: the Case of the Cornish Pumping Engine," *Cambridge Journal of Economics* 28, no. 3 (2004).
There are similar examples from modern times, for instance: IBM revealed proprietary information on copper semiconductors, Technicon Corporation in automated clinical chemistry analyser.
See Kwanghui Lim, "The Many Faces of Absorptive Capacity: Spillovers of Copper Interconnect Technology for Semiconductor Chips," *Industrial and Corporate Change* (2009); Eric von Hippel and Stan N. Finkelstein, "Analysis of Innovation in Automated Clinical Chemistry Analyzers," *Science and Public Policy* 6, no. 1 (1979).
Henkel documented the free-revealing practice among competing software manufacturers that was based on software developed for the Linux system to run the hardware of their clients. Despite sharing the same market, direct competition was not a factor, as the software was designed for a particular client and the revealed equipment-specific code with its improvements served as a base upon which one could build proprietary products.
See Joachim Henkel, "Software Development in Embedded Linux — Informal Collaboration of Competing Firms," in *Wirtschaftsinformatik 2003/Band II*, ed. Wolfgang Uhr, Werner Esswein, and Eric Schoop (Physica-Verlag HD, 2003).

[121] Others: "thingiverse.com" is the largest sharing platform of 3D printing designs.

[122] "Kickstarter Project by MURIS: Maker - A Documentary on the Maker Movement," https://www.kickstarter.com/projects/379201360/maker-a-documentary-on-the-maker-movement, accessed 16.06.2014.

[123] "Seven Things to Know about Kickstarter," https://www.kickstarter.com/hello?ref=footer, accessed 15.05.2014.

[124] Amanda Palmer, ibid.

2.5 The Adopted Model of Making

The specific model of how people pursue their making activities forms the background for further legal considerations and analysis of patent limitations. The study focuses on innovating initiated and carried out by Makers who work individually or within communities, share their ideas with other makers (online or offline), present how to achieve a given solution (an improvement or a derivative) – and all this on a non-commercial basis.

As mentioned in the previous section, people *make* for self-amusement, in-house use, or create own solutions when the market does not meet their needs. That *market gap* creates a new "design space"[125], where innovation takes place. When working on their projects, makers apply their own "local" knowledge available at low-cost – *tacit* knowledge.[126] This, however, does not undermine the quality of the embedded know-how. On the contrary, makers are often world-class specialists, ranging from aerospace engineers and software programmers to medical doctors.[127]

At some point, an idea elaborated privately (in the adverbial basement) sees the light of day via *free sharing*, e.g. by publishing it on the Web (an online forum) or by presenting it in a makerspace. From this moment on, further developments of the solution, i.e. experimentation, adaptation, and prototyping, form part of a collective process. Here, any scale of community cooperation is more beneficial than working in isolation; efficiency increases even more when diverse communities fuse into the project.[128]

In terms of project financing, the majority of makers and DIYers invest in their projects rather than obtain any return from them. High-tech creations can be expensive, requiring even a few hundred dollars of investment.[129] Therefore, an additional advantage of community exposure is feedback on commercialisation opportunities (and the recoup of investment). Makers, by principle, do not anticipate financial profits and do not evaluate marektisation opportunities for their solutions (with

---

[125] Carliss Baldwin, Christoph Hienerth, and Eric von Hippel, "How User Innovations Become Commercial Products: A Theoretical Investigation and Case Study," *Research Policy* 35, no. 9 (2006).

[126] Christian Lüthje, Cornelius Herstatt, and Eric von Hippel, "User-Innovators and "Local" Information: The Case of Mountain Biking," ibid.34, no. 6 (2005).

[127] ibid., 963.

[128] Carliss Baldwin, Christoph Hienerth, and Eric von Hippel, "How User Innovations Become Commercial Products: A Theoretical Investigation and Case Study," ibid.35, no. 9 (2006): 1307; Dietmar Harhoff, Joachim Henkel, and Eric von Hippel, "Profiting from Voluntary Information Spillovers: How Users Benefit by Freely Revealing Their Innovations," ibid.32, no. 10 (2003); Shah and Tripsas, "The accidental entrepreneur."

[129] Kuznetsov and Paulos, "Rise of the Expert Amateur: DIY Projects, Communities, and Cultures."

the exception of leading creators[130]). Within a community, members or observers express their "purchasing" interest in the solution and provide a helpful feedback on the market value of a given solution. As studies show, Makers are often "accidental entrepreneurs", i.e. the complete product development occurs much before the idea on the formation of a company sparks in one's mind.[131]

Makers, however, are not people without any business awareness – various makers' start-ups were initiated on crowdfunding platforms (like Kickstarter or Indiegogo). A good example is PiMaker (a 3D printer) by William Steel, who even applied for patent protection to license his idea to commercial companies, but keeps design files opensourced (published on Thingiverse under a non-commercial license).[132] Another is Formlab, grounded by researchers at MIT Media Lab, who aimed to launch the production of an affordable 3D printer for professionals – Form 1.[133] Their successful project initially collected $100,000 in pledges, to eventually reach almost $3 million.[134]

In terms of the use of patented solutions, makers either work *on* products embedding patents, by improving on them and by creating them; or work *with* such products by applying them into their own projects. The maker community is much concerned with patent-related issues, such as whether to seek patent protection, and how to liberate making from patents – a crucial issue. With regard to the latter, makers face certain obstacles: it is unfeasible to identify all existing patented solutions in a certain field due to the high saturation of patents (1) and to control and limit the proliferation of an idea once it is shared (2). Last but not least, certain misconceptions on the permissible use of patented solutions misguide makers on the ambit and types of lawful uses. Many believe that working on patents as individuals, i.e. privately, with no business affiliations, secures them from infringement allegations. They underestimate the fact of public sharing, even in a form of one "innocent" Internet post, e.g. suggesting (instructing) certain patent improvements, for which they can be sued for indirect patent infringement or for inducement to infringe.

---

[130] Christian Lüthje and Cornelius Herstatt, "The Lead User Method: An Outline of Empirical Findings and Issues for Future Research," *R&D Management* 34, no. 5 (2004).

[131] Shah and Tripsas, "The accidental entrepreneur," 128-29; Marcel A. Buth, *3D Printer: Patents and Innovations*, 1. English ed. (Usingen: adrenalinemedia, 2013), 23-24.

[132] "Ultra-Bot 3D Printer by William Steele," https://www.kickstarter.com/projects/wjsteele/ultra-bot-3d-printer/posts/362886, accessed 16.04.2014.

[133] Form 1 complete package costs 2799 EUR.
"Form 1+ High-Resolution 3D Printing," http://formlabs.com/products/form-1-plus/, accessed 09.04.2014; Rob Giseburt, "3D Systems Suing Formlabs and Kickstarter for Patent Infringement," http://makezine.com/2012/11/21/3d-systems-suing-formlabs-and-kickstarter-for-patent-infringement/, accessed 09.04.2014.

[134] "FORM 1: An Affordable, Professional 3D Printer by Formlabs," https://www.kickstarter.com/projects/formlabs/form-1-an-affordable-professional-3d-printer, accessed 09.04.2014.

Of course, as long as makers remain unnoticeable with their projects, they stay in a low-risk zone. However, crowdfunded projects of the scale of Formlab can hardly be ignored on the market: a successful maker project denotes a new player (a competitor) who mobilises a broad group of "customers." When we combine the following features – the successful marketization of a maker project and performance in a patent-active field (e.g., 3D printing, robotics, electronics, and solar cells) – the peril of a patent lawsuit becomes very realistic.

2.6 The Maker Movement Meets Patent Law

Patents safeguard market exclusivity upon the recoup of the investment by the patent holder. Thus, when the solution of a maker competes with a patented counterpart and attracts many purchasers, a company loses their clients and can claim financial demages – a no-go situation for any enterprise. Below are two recent cases that made the maker scene tremble.

2.6.1 3D Systems Inc. v Formlabs and Kickstarter

In 2012, 3D Systems Inc. sued Formlabs and Kickstarter for the infringement of a patent titled *Simultaneous multiple layer curing in stereolithography* (claims No. 1 and 23). The Form 1 printer works with DPL technology and inserts an object in slices onto a bath of UV light curing resin.[135] This technology creates 3D prints of much higher resolution than plastic extrusion technology (like the *RepRa*p 3D printer). Additionally, the quality of the Form 1 is comparable with 3D Systems printers and is much cheaper. The 3D Systems patent expired on January 28 2014 and due to this fact the case was voluntarily dismissed on November 8 2013; but 3D Systems did not give up and filed another suit for the infringement of eight other patents.[136]

Apart from the fact that the field of 3D printing itself becomes one of the most prominent battlegrounds of the patent wars[137], more worrying is the fact that Kickstarter itself was claimed liable for the infringement as well. 3D Systems alleged that both companies were willingly blind to

[135] Buth, *3D Printer: Patents and Innovations*, 18.

[136] John Hornick and Dan Roland, "Many 3D Printing Patents Are Expiring Soon: Here's A Round Up & Overview of Them," http://3dprintingindustry.com/2013/12/29/many-3d-printing-patents-expiring-soon-heres-round-overview/, accessed 17.05.2014.

[137] See Pramath Malik and Manikandan Balasubramanian, "The Search of the Next Patent War," *IAM Magazine* 72(July/August 2015).

the existence of their patents.[138] Another Kickstarter project is applying stereolithography technology and it seems unclear whether it will be targeted by 3D Systems as well.[139]

2.6.2 Stratasys v Afinia

In November 2013, Stratasys, one of the world-leading producers of 3D printers, sued Afinia, a division of Microboards Technology LLC, for the infringement of four of its patents.[140] Afinia produces a popular H series of 3D printers for the consumer market and is regarded as a mid-size company. It implements FDM technology[141] adopted in a great number of 3D printers.

Commentators indicate that due to a broad reading of the patents, Stratasys' claim refers to any 3D printer producer who implements a similar method, and does not address Afinia products specifically. For example, Stratasys claims the infringement of the infill concept, but does not provide specifics on how this process is infringed by Afinia. Hence, any other manufacturer or open source project that applies a similar infill infringes the Stratasys patent; as indicated, Afinia does so as well (!).[142]

The company took a big shot back and filed a declaratory judgement of non-infringement, as well as petitioned the court for jury trial. First, it intends to narrow down the broadly read Stratasys patents by confronting them with prior art and proving their invalidity. Afinia also claims that Stratasys did not disclose a patent that would undermine the novelty of the allegedly infringed patent – if that were the case, it would be an inequitable conduct in result of which Stratasys would not be able to enforce the patent. Unexpectedly, Afinia has become the defender of all players in the field of 3D printing.[143]

---

[138] "3d Systems Gets 6-Month Stay for Settlement Talks over Patent Lawsuit," http://www.sparpointgroup.com/News/Vol11No233dsuit/, accessed 15.05.2014.

[139] Giseburt, "3D Systems Suing Formlabs and Kickstarter for Patent Infringement."

[140] They concern: 1) the process of infill in a 3D printed object (US 5653925), 2) the heated build platform (US 5866058), 3) the extruder (US 6004124), 4) a seam layer concealment method (US 8349239).
Michael Weinberg, "Afinia Responds to Stratasys: Your Patents Are Invalid and Your Threats are Anti-Competitive," http://makezine.com/2014/01/03/afinia-responds-to-stratasys-your-patents-are-invalid-and-your-threats-are-anti-competitive/, accessed 14.05.2014; Buth, *3D Printer: Patents and Innovations*, 20-22.

[141] Fused Deposition Modeling.

[142] Michael Weinberg, "Stratasys Sues Afinia: Ramifications for the Desktop 3D Printing Industry," http://makezine.com/2013/11/27/stratasys-sues-afinia-ramifications-for-the-desktop-3d-printing-industry/, accessed 10.05.2014; Weinberg, "Afinia Responds to Stratasys: Your Patents Are Invalid and Your Threats are Anti-Competitive."

[143] "Afinia Responds to Stratasys: Your Patents Are Invalid and Your Threats are Anti-Competitive."; Michael Molitch-Hou, "Afinia Puts Up Its Dukes to Defend Against Stratasys Lawsuit,"

Apart from challenging infringement claims, Afinia alleges that the lawsuit was motivated by the desire to monopolize the market – an anticompetitive conduct and a patent misuse. In December 2012, Stratasys merged with Objet, a manufacturer of 3D printers, and gained 50% of the market and control over the input materials, e.g. ABS plastic (commonly used in 3D printers due to its differential melting points). In June 2013, Stratasys purchased MakerBot Industries, a producer of desktop-sized 3D printers. Apart from the corporate growth, Stratasys' licensing practice (Terms of Service) gives it the right to all developments and improvements over devices by their customers. Considering the 50% of the market share, it is a tempting offer.[144]

Many ask why Stratasys launched the infringement campaign at this precise point in time. They indicate the acquisition of MakerBot as the departure point. Before, Stratasys focused on the industrial market, but through the named purchase it opened its operations on the consumer market, where Afinia has been active and recorded a growth curve. Moreover, a desktop market is exploding now. It is worth mentioning that MakerBot grew out of the *RepRap* Project and its purchase reverberated throughout the community. Thus, the fear is that building a *RepRap* is as risky as building a proprietary printer that might infringe on Stratasys' patents.[145]

Another issue is the threat of low-cost Chinese printers that are flooding the US market through China's partnership with US companies. This motif also emerges in the case of Afinia, which licensed hardware for the printer from Delta Micro Factory Corporation, which is owned by Tiertime, a Chinese low-cost 3D printer manufacturer. Chinese companies implement technologies of established players on various market segments. The partnership with US companies facilitates the accommodation of the printers on the US market without the risk of a lawsuit. Despite Afinia's determination in the court proceedings, a settlement remains an option. The whole industry and communities await with bated breath for the outcome of the lawsuit.[146]

By September 2014, court dismissed the infringement claims for the patent on controlling infill (US5653925). Afinia counterclaimed not only to have found prior art that challenged the novelty of the said patent, but also to have found evidence that Stratasys knew about that prior art to begin

---

http://3dprintingindustry.com/2014/01/03/afinia-puts-dukes-defend-stratasys-lawsuit/, accessed 20.05.2014.

144 Rakesh Sharma, "Afinia Refuses to Buckle Down Against Stratasys; Claims Patent Misuse," http://www.forbes.com/sites/rakeshsharma/2014/01/03/afinia-refuses-to-buckle-down-against-stratasys-claims-patent-misuse/, accessed 20.05.2014; Michael Weinberg, "Afinia Responds to Stratasys II: You Failed To Disclose Old Patents, Printers," http://makezine.com/2014/01/31/afinia-responds-to-stratasys-ii-you-failed-to-disclose-old-patents-printers/, accessed 14.05.2014.

145 Rakesh Sharma, "Why Stratasys Sued Afinia," http://www.forbes.com/sites/rakeshsharma/2013/12/03/why-stratasys-sued-afinia/, accessed 14.05.2014.

146 ibid.; Weinberg, "Afinia Responds to Stratasys II: You Failed To Disclose Old Patents, Printers."

with, and, what's more, had a patent that included the invention in question. Under such circumstances, Stratasys was obliged to inform the patent office about this example of (own) prior art; otherwise, it would have committed a patent misuse. In the aftermath of Afinia's counterclaims, Stratasys offered to voluntarily dismiss the claim for a reciprocal withdrawal of Afinia arguments. This did not happen. In fact, the court upheld the counterclaims and enjoined Stratsys to voluntarily dismiss its claims. It appears that Afinia furnished strong legal evidence against the validity of the said patent; however, the court has the final word – the ruling on the counterclaims is just about to come. As reported, the full trial is set for December 1 2015, and separate rulings will come before that date. We know a bit more, but all of the old questions remain.[147]

Many indicate that patents constrain the DIY 3D printer market because companies hold patents for obvious printing methods or hardware parts: they are enforceable and thus must be obeyed unless worked around. The Electronic Frontier Foundation launched the project "Joint efforts to keep 3D printing open" in order to identify patents that might be detrimental to the industry. The so-called "creative" patent drafting might hinder the advancement of new technologies after the expiration of the current core patents.[148]

2.7 Concluding Thoughts

The maker movement has evolved into a powerful mass phenomenon that largely challenged the classic innovation paradigms. As a disruptive business model, it introduces a new value and quality: self-sufficiency and, based on crowdfunding, independence from big companies.

The movement dominates in various fields, e.g. 3D printing, robotics, software engineering, and biotechnology. Its credo is sharing and allowing others to improve (play with) the makers' ideas. As makers have reached an advanced technological level, they are confronted with patent-related questions. The rebellious and blatant character of the maker movement challenges the underlying principles of the patent system and questions its implementation.

[147] "Stratasys Drops One Patent from Its Lawsuit Against Afinia," http://makezine.com/2014/08/05/stratasys-drops-one-patent-from-its-lawsuit-against-afinia/, accessed 01.09.2014.

[148] Giseburt, "3D Systems Suing Formlabs and Kickstarter for Patent Infringement."; EFF Electronic Frontier Foundation, "Join EFF's Efforts to Keep 3D Printing Open," https://www.eff.org/deeplinks/2012/10/join-effs-efforts-keep-3d-printing-open, accessed 02.04.2014.

It is not about juxtaposing two different forms for the mere explanation of differences; it is about the actual friction between them. The 3D printing field illustrates this clash very well. A community of technology enthusiasts, who admittedly have great ideas, but nonetheless have a limited infrastructure, unintentionally infringes on multiple patents on a daily basis.

One aspect of this issue is the sheer number of infringement indications, and another – the validity of the patented solutions itself. In patent litigations, the latter determines the former: if a patent is claimed invalid, there is not ground for asserting infringement. This is what Afinia is attempting to do – it intends to prove that Stratasys lack legal grounds for claiming infringement of rights. An invalidity counter-claim is a common litigation practice and an effective instrument in cleaning the patent space from “usurped” patent rights that hinder third parties in their R&D operations, including makers. However, such a practice induces many questions and doubts on the overall patent environment.

Chapter 3. QUESTIONS ABOUT THE PATENT SYSTEM

3.1 Introduction

The patent system can either be a partner or an obstacle to *making* – with the prevalence, unfortunately, of the latter. Nonetheless, some makers decide to search for patent protection with the aim of expanding their business activities in cooperation with commercial companies. Here, worth mentioning is William Steele, the creator of the aforementioned PiMaker (a desktop 3D printer which was funded on Kickstarter), who filed a patent application for PiMaker, explaining his decision as follows:

> The patent is to protect our IP and to prevent other commercial companies from utilizing our designs in their own printers. There is a clear separation between commercial interests and hobbyists here. Hobbyists will be able to hack, modify, understand, improve... whatever they want too with their printer or derivative, including making their own from our published design files. Commercial companies that produce 3D printers will need to license our technology in order to utilize our designs.[149]

Steele's words pronounce the main purpose underlying each patent application, i.e. investment recoup and profit generation. Nowadays, patents comprise a crucial part of companies' assets, which are not necessarily involved in R&D activities; IP portfolios become more *opulent* and profoundly affect corporate strategies. Is there still a place for *romantic* ideas underlying the constitution of patent law? Has there ever been such a place?

From its inception, the idea of rewarding inventors with patents stirred debates (and disagreements) upon their objective and rationale. Despite the overall merit of the discussions, patents (or rather patent industry) provoke very emotional discourses that divide the field into strong supporters and fierce opponents of the system. In the author's view, there is ample space for neutral pragmatists, who understand both the drawbacks and the advantages of the system for the society and the economy.

Patent wars, pro-patent marketing, and patent trolls negatively influence the common perception of the system – even its most faithful proponents cannot neglect such facts. Perhaps the following words of Fritz Machlup best illustrate the situation at hand:

> If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one.

[149] "Ultra-Bot 3D Printer by William Steele. Questions about Open Source and our Patent Application," https://www.kickstarter.com/projects/wjsteele/ultra-bot-3d-printer/posts/362886, accessed 03.04.2014.

> But since we have had a patent system for a long time, it would be irresponsible, on the basis of our present knowledge, to recommend abolishing it.[150]

Proposals of complete patent abolition[151] are rare and, if they occur, receive moderate applause[152] – the patent system is too deeply anchored in economic structures. We have reached the point when not the cancellation, but the reform of the patent system can improve its effectiveness and fairness – to quote Fritz Machlup again, we have to "muddle through it."[153]

This chapter provides an outline of the fundamental theories which justify the patent system and highlights various points upheld in discussions on the current form of the system. It endeavours to paint a general picture of the system and thus it only indicates certain concerns. The analysis of economic models remains beyond the scope of this chapter and work.

3.2 The Brief History of Patents

The first recorded reference to patent-related considerations appeared in Aristotle's *Politics* in the 4th century BC. Aristotle described a proposal of Hippodamus of Miletos, who advocated a reward system for those "who contribute usefully by discovering useful things for the state." Hippodamus assumed that thanks to rewards, inventors would make more contributions to society. However, Aristotle himself criticised this idea, arguing that *rewards* could adversely affect the obedience of the law and social structures. He believed that citizens should contribute to society simply because it is good to do so, and not in anticipation of any compensation. In this manner, Aristotle foretold the intrinsic friction between the patent system and society. The proposal of Hippodamus of Miletos remains the only record of the proposal for inventor protection from the ancient times.[154]

The Middle Ages, with their rigid hierarchism and theocentricism, did not show much appreciation to inventive minds. However, the period was familiar with patent-like documents (dating back to the 14th century), then better known as open letters (*litterae patentes*[155]), which conferred exclusive rights to the inventor. However, open letters were not reserved exclusively for inventions;

---

[150] Fritz Machlup, *An Economic Review of the Patent System* (Washington: US Government Printing Office, 1958), 80.

[151] Michele Boldrin and David Levine, *Against Intellectual Monopoly* (Cambridge, Mass.: Cambridge University Press, 2010).

[152] Charles McManis, "A Rhetorical Response to Boldrin & Levine: Against Intellectual (Property) Extremism," *Review of Law & Economics* 5, no. 3 (2010).

[153] Machlup, *An Economic Review of the Patent System*, 80.

[154] Robert P. Merges and John F. Duffy, *Patent Law and Policy*, 5 ed. (Newark, NJ: LexisNexis, 2011), 1-2.

[155] The word "patent" derives from a Latin verb "patere," which means "to open," i.e. to inform the society about the invention. See John Gladstone Mills III, Donald Cress Reiley III, and Robert Clare Highley, *Patent Law Basics* (MA: Thomson Reuters/West, 2012), §1:1.

they conferred various privileges and rights within trade and craft guilds, like the conferral of officer nominations or nobility.[156]

By contrast, the Renaissance revitalised ancient philosophy and returned to the anthropocentrism that allowed individual genius to flourish.[157] The first acknowledged patent was granted in 1421 to the Florentine architect Filippo Brunelleschi for the invention of a ship construction for lifting heavy goods.[158] In 1474, Venice was the first to pass written rules on issuing patent privileges, which conceived the requirement of novelty, disclosure, and the use of invention, as well as set the time of limitation over the granted monopoly to 10 years. (However, the privileges were misappropriated and conferred against their purpose and objectives.)[159] Owing to the intensification of trade exchange between 15th and 17th centuries, Western countries began to adopt statutory regulations on "patents" in order to lure foreign inventors to bring their know-how and skills into the mainland. The privileges included the right to exclude third parties from the use of the protected idea without the permission of the inventor. Subsequent absolutism and mercantilism deformed the idea of invention privilege into a source of royal income of low incentive impact and quality. The issuance of privileges did not obey the proper patent standards: the principles of novelty and priority were abandoned for the sake of utility construed according to the current economic interests.[160]

The situation was strongly opposed by inventors and lawyers. In England, the outcry against misused privileges led to enacting the Statute of Monopolies in 1623, the *Magna Carta* of the inventor rights and the oldest recognised patent statue, which shifted the power of granting privileges from the Crown to the Parliament. The Statue declared invalid all types of granted monopolies and exclusive rights. The only exception was for privileges for the use and production of "any manner of new manufacture," which were conferred to "the first and true inventor" for the period of 14 years.[161] The jurisprudence established further principles of patent practice, such as the industrial use of the invention, disclosure, and the dissemination of the technical teaching in the society.[162]

---

156 Michal Du Vall, *Prawo Patentowe* (Warszawa: Wolters Kluwer, 2008), 25.
157 Rudolf Kraßer, *Patentrecht*, 6 ed. (München: C.H. Beck, 2009), §4.
158 Du Vall, *Prawo Patentowe*, 26.
159 ibid., 28.
160 Georg Benkard and Editors, *Patentgesetz*, 10 ed. (München: C.H. Beck, 2006), Einleitung, Rn.3; Kraßer, *Patentrecht*, §4; Merges and Duffy, *Patent Law and Policy*, 3-5.
161 Fritz Machlup and Edith Penrose, "The Patent Controversy in the Nineteenth Century," *The Journal of Economic History* 10, no. 1 (1950): 2; Kraßer, *Patentrecht*, §4.
162 Du Vall, *Prawo Patentowe*, 31.

The end of 18th century was marked by the adoption of modern statutory patent laws in the USA (1787)[163] and France (1791). They granted the right to exclude others from the exploitation of an invention, which remained the core function of patents to date.[164]

Already at the onset of patent law formation, certain troublesome issues emerged. The main objections against patent law referred to the procedural matters: the application procedure was "clumsy, expensive, and uncertain."[165] In England, special parliamentarian committees on patents suggested the reduction of the exclusivity time span to 7 years, as well as much stricter examination. Trade associations and chambers of commerce went even further and demanded abolishing patent law entirely.[166] The second half of the 19th century was hallmarked by governmental disapprobation of the patent system. In Switzerland, the government refused to adopt a patent system following a statement issued by members of the Zurich Institute of Technology.[167] Even chancellor Bismarck himself announced his objection to the principle of patent protection.[168] In the Netherlands, free-trade supporters were concerned with the low feasibility of patent law and difficulties with its re-formability to a level which was satisfactory to all of the involved parties.[169] The anti-patent movement ended rather abruptly due to the strong campaign of patent proponents, who were strengthened by external conditions such as the economic crisis and the rise of protectionism.[170] Machlup and Penrose point out that patent law proponents were extremely well organised and hence capable of enforcing their interests more effectively: "the technique propaganda was remarkable: new societies, press, pamphlets, leaflets, public competition for the best paper for the patent protection" bore expected fruits.[171] Under such circumstances, the modern concept of patents settled down in the legal structures of Western countries.[172]

---

[163] In the USA, protection of intellectual creation became part of the constitutional order.
Article 1 Section 8 of the US Constitution: Powers of Congress:
"To promote the progress of science and useful arts by securing, for limited times, to authors and inventors the exclusive right to their respective writings and discoveries."

[164] Benkard and Editors, *Patentgesetz*, Einleitung at 3; Kraßer, *Patentrecht*, §4; Boldrin and Levine, *Against Intellectual Monopoly*, 45.

[165] Machlup and Penrose, "The Patent Controversy in the Nineteenth Century," 3.

[166] ibid., 3-4.

[167] ibid., 4-5.

[168] ibid., 4.

[169] Holland was the most resistant country in introducing the patent system: with the patent act having come into force in 1912. See Fritz Machlup, *Die wirtschaftlichen Grundlagen des Patentrechts* (Weinheim/Bergstrasse: Verlag Chemie, 1962), 16.

[170] *An Economic Review of the Patent System, 5.*

[171] Machlup and Penrose, "The Patent Controversy in the Nineteenth Century," 2-6.

[172] For instance: Germany – 1877, Japan – 1885, Switzerland – 1885. See Machlup, *Die wirtschaftlichen Grundlagen des Patentrechts*, 16; Machlup and Penrose, "The Patent Controversy in the Nineteenth Century," 29.

3.3 Chosen Patent Theories

Patent theories fuse legal and economic sciences with ethical insights. They differ among each other by setting "different weights on different places of the patent system."[173] With diverse points of departure and a number of overlaps, they all arrive at the conclusion that the patent system guarantees the fairest rewarding system for inventors, and stimulates R&D activities. Notably, the words of the Supreme Court in *Brenner v. Manson* should remain a balance point in all theoretical discourses:

> [A] patent system must be related to the world of commercial rather than to the realm of philosophy (…).[174]

3.3.1 Patent as a Natural Property Right

The concept sees intellectual property as "more sacred" than property over material things – a natural property that cannot be waived. John Locke voiced that everyone obtains the right to the fruits of their own efforts – "labour provides a foundation for property" (introduced to the preamble of French and US constitutions).[175] The society must recognise this fact and provide an adequate protection of the property.[176] Categorisation of patents under the concept of natural property was too absolute for many as it resulted in a broad privatisation of subjects of intellectual property.

Nowadays, some scholars point to the existence of a phenomenon known as *the tragedy of the commons*[177] as the rationale behind the concept of private intellectual property: to counteract the depletion of common resources, they must be assigned the status of private property in the form of

---

[173] Pauline Newman, "Luncheon Speech to ABA-IPL Section," in *Cases and Materials on Patent Law*, ed. William H. Francis, et al. (St.Paul, Minn: Thomson/West, 2007), 77.

[174] *Brenner, Commissioner of Patents v. Manson, 383 U.S 519, *536 (1966).*

[175] Wendy J. Gordon, "A Property Right in Self-Expression: Equality and Individualism in the Natural Law of Intellectual Property," *The Yale Law Journal* 102, no. 7 (1993): 1540; Sigrid Stercks, "The Ethics of Patenting - Uneasy Justification," in *Death of Patents*, ed. Peter Drahos (London: Lawtext Publishing Limited, 2005).

[176] Machlup, *An Economic Review of the Patent System*, 21; Machlup and Penrose, "The Patent Controversy in the Nineteenth Century," 11; Wolfgang Bernhardt, *Die Bedeutung des Patentschutzes in der Industriegesellschaft* (Köln: Heymann, 1974), 8.

[177] Garrett Herdin, "The Tragedy of Commons," *Science* 162, no. 13 (1968): 1243-48.

patents or copyrights to the persons they originate from.[178] Above that, the ownership over intellectual creation forms part of the modern credo and remains consistent with the essence of the modern democratic order.[179]

3.3.2 Patent as an Incentive to Invest

In this understanding, patents attract indispensable investment into the research sector. In light of the utilitarian doctrine after John Bentham: patents are instruments, owing to which inventors are willing to pursue research activities.[180]

The theory rests on the conviction that inventors could not compensate for the outlay without patent protection. The exclusivity conferred by a patent allows for the extraction of better prices. By the exclusion of competition – *an automatic delay* – patents provide time for further developments and market conquest.[181]

Patents in the hands of small or new companies are treated as trump cards to attract investors: they decrease the risks involved in commercialization by constraining the competition.[182] In practice, this conviction underlay the Bayh-Dole Act, enacted in 1980, which was designed to stimulate technological entrepreneurship at universities, investment in their R&D departments, and encourage the stronger integration of universities with the industry.[183]

---

[178] Michael A. Heller and Rebecca S. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research," *Science* 280, no. 5364 (1998): 698-701; Dan L. Burk and Mark M. Lemley, *The Patent Crisis and How the Courts Can Solve It* (Chicago: University of Chicago Press, 2009), 69.

[179] Gerd Dahmann, *Patentwesen, technischer Fortschritt und Wettbewerb. Formulierung einer empirisch prüfbaren Patenttheorie und Bewährungstest am Beispiel der Rasiergeräteindustrie* (Frankfurt a. M., Bern: Peter D. Lang, 1981), 74.

[180] Du Vall, *Prawo Patentowe*, 132.

[181] Machlup, *An Economic Review of the Patent System*, 39; Rebecca S. Eisenberg, "Patents and the Progress of Science: Exclusive Rights and Experimental Use," in *Cases and Materials on Patent Law*, ed. William H. Francis, et al. (St.Paul, Minn.: Thomas/West, 2007), 85-86.

[182] Roberto Mazzoleni and Richard R. Nelson, "The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate," *Research Policy* 27, no. 3 (1998): 277.

[183] ibid.
In the late 1970s, the competitiveness of the US market decreased and the country felt a growing pressure exerted by growth of their Japanese competitors; the US needed the newest technologies. Impressed by the success of Silicon Valley and Route 128, policy makers resorted to research entities and universities, and granted them the right to own patents resulting from federal-found research.
See Rosa Grimaldi et al., "30 Years after Bayh–Dole: Reassessing Academic Entrepreneurship," ibid.40, no. 8 (2011): 1046. See also David C. Mowery et al., "The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh–Dole Act Of 1980," ibid.30, no. 1 (2001); David C Mowery, *Ivory Tower and Industrial Innovation: University-Industry Technology Transfer before and after the Bayh-Dole Act in the United States* (Stanford: Stanford University Press, 2004); Jerry G.Thursby Thursby, Marie C., "University Licensing and the Bayh-Dole Act," *Science* 301, no. 5636 (2003); Richard

3.3.3 Patent as an Incentive to Disclose

The point of departure for this theory is the firm belief that trade secrecy deprives society of the opportunity to grow. Industrial progress could not happen if inventions were to be kept secret. For this reason, technologies must be made public and available – the aforementioned goals are satisfied through disclosure, which enables a person skilled in the art to make and use the embodiments as described in a patent specification.[184] In the time of patent privileges, the beneficiaries were obliged to present their solutions and disseminate the novel teaching throughout the society.

The disclosure theory corresponds with the theory of the social contract: a patentee and the society sign a contract in which disclosure is exchanged for protection.[185] Unlike the concept of trade secrecy, patents ensure that exclusivity "survives the disclosure."[186] Notably, trade secrecy accompanies many patents, as it covers the know-how necessary to implement the disclosed patent information; it is licensed either together with a given patent or in a separate agreement.[187]

In spite of multiple claims against patents, their informative function can be hardly challenged: thanks to the disclosure, new technical teaching becomes available to everyone and enriches the state of the art.

3.3.4 Reward (Compensation) Theory

This theory derives from the economic conception of a reward for the work performed (for the risk and expenses involved). In the context of patents, the inventor receives a reward (compensation) for his or her efforts in delivering a useful invention to society. That reward takes the form of market exclusivity, which enables the patent holder to benefit from the exploitation of the

---

Atkinson, "Public Sector Collaboration for Agricultural IP Management," *Science* 301, no. 5630 (2003); Rebecca S. Eisenberg, "Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research," *Virginia Law Review* 82, no. 8 (1996).

184 Robert P. Merges and Richard R. Nelson, "On the Complex Economics of Patent Scope," *Columbia Law Review* 90, no. 4 (1990): 845.

185 Vincenzo Denicolò and Luigi Alberto Franzoni, "The Contract Theory of Patents," *International Review of Law and Economics* 23, no. 4 (2003): 366.

186 Eisenberg, "Patents and the Progress of Science: Exclusive Rights and Experimental Use," 84-85.

187 Jack Ellis, "Keeping Secret," *IAM Magazine*, no. 62 (November/December 2013): 45; Wesley M. Cohen, Richard R. Nelson, and John P. Walsh, "Protecting Their Intellectual Assets: Appropriability Conditions and Why Us Manufacturing Firms Patent (or not)," (National Bureau of Economic Research 2000), 7-8.

invention. Further rewards, i.e. income from patent commercialisation, depend on the merits and social contributions of the invention (its utility).[188] The concept of a reward constitutes the core motivator behind various patent theories: the reward is both an incentive and an award.

A reward might also be seen as a rent. Grady and Alexander proposed the concept of *invention renting* where the reward is the rent paid by society to the inventor. The focus of this concept rests on the social benefit being dissipated by redundant technological development due to secrecy or improvements.[189]

3.3.5 The Prospect Theory

The prospect theory is an interesting and complex theoretical conceptualization that goes beyond the scope of the reward theory. It demonstrates an *ex post* perspective on the effective management of IP ownership.

In 1977, Edmund Kitch introduced the term *prospect*[190] – the opportunity to introduce technological improvements following the disclosure of an invention: a patent displays a prospect that the patentee, a coordinator, utilises to increase its value. The opportunity (the prospect) is feasible because:

a) patent claims have an abstract and general character and as such do not embrace all possible products;
b) a patent is granted in the very early stage of development, which implies further research.[191]

Kitch argued that each invention "generates a shift in the matrix of technological possibilities" that overwhelms the original inventive idea alone.[192] He also assumed that the *prospect* improves the

[188] Newman, "Luncheon Speech to ABA-IPL Section," 81; Bernhardt, *Die Bedeutung des Patentschutzes in der Industriegesellschaft*, 9.
Other proposals included prizes and bonuses to honour excellent inventions; however, administrative issues stirred reservations on the side-effects, such as corruption and partiality. See Machlup and Penrose, "The Patent Controversy in the Nineteenth Century," 20.

[189] Mark F. Grady and Jay I. Alexander, "Patent Law and Rent Dissipation," *Virginia Law Review* 78(1992).

[190] Kitch derived his theory from the mineral claim system developed in the American West at the end of the 19th century. The mineral claim allowed private companies to work on government-owned land in order to search and extract minerals. The companies did not have to show any commercial interest in the excavation. With the advent of the oil industry, the mineral claim underwent some modifications. Government granted "mineral leases" for the first-to -discover oil resource before drilling. The claims had to delineate the area of drilling and the scope of activities separate from the public domain. See Edmund W. Kitch, "The Nature and Function of the Patent System," *Journal of Law and Economics* 20, no. 2 (1977): 271-75.

[191] ibid., 268.

management of innovations. Patent monopoly can be more efficient than competition itself, and the patent system effectively contributes to the exchange of information and the management of resources. A patent disclosure signalises (and warns) not to duplicate the invention and hence, not to waste resources; it also alarms other market entrants who deliver substitute technologies. This scenario may involve a patentee-producer tandem to minimise resource dissipation and maximise technological achievements. Kitch indicated that the implementation of an invention could succeed when its social costs were lower than those of existing technologies. Like the reward theory, the prospect theory assumed the existence of a return based on the economic value of the technology.[193]

3.3.6 Theory versus Practice. Concluding Thoughts

Patent theories underscore the social and public functions of patents: honouring inventors for their research efforts and their enrichment of the society with useful and valuable inventions. Recognised as an important R&D stimulus, together with an inherent link to commerce, one can make the argument that patents perform the function of the proverbial carrot: they encourage innovating, offering in the end a limited exclusivity with the aim of extracting value out of the technology and recouping the investment from the market. The system tends to create an inventor-friendly environment in order to stimulate technological progress, with its ultimate goal being welfare growth via the creation of new industries and workplaces, increasing trade, and making life better and easier.[194]

The justification of patents leaves place for scepticism and questions: if the existence of patent law was so evident and unequivocal, why would there exist so many different theories speaking in favour of patents? In terms of scientific evidence, no clear proof of the virtual contribution of patents to technological progress has been delivered so far apart from sectorial studies[195], and available statistics can be interpreted in different fashions according to intended statements and

---

[192] ibid., 271; Eisenberg, "Patents and the Progress of Science: Exclusive Rights and Experimental Use," 87.

[193] Kitch, "The Nature and Function of the Patent System," 275-80; Burk and Lemley, *The Patent Crisis and How the Courts Can Solve It*, 69; Rudolph J.R. Peritz, "Patents and Progress: The Economics of Patent Monopoly and Free Access: Where Do We Go from Here?," in *The Structure of Intellectual Property Law: Can One Size Fit All?*, ed. Annette Kur and Vyatuatas Mizaras (Cheltenham: Elgar, 2001), 44.

[194] Burk and Lemley, *The Patent Crisis and How the Courts Can Solve It*, 66.

[195] Du Vall, *Prawo Patentowe*, 144-45; Ruth Towse and Rudi Holzhauer, *The Econmics of Intelectual Property: Patents*, 8 ed. (Aldershot: Elgar, 2002).

interest.[196] Solely the informative function of patents in regard to novel technical teaching remains unchallenged even on the side of patent contesters.

The modern IP reality proves that the initial philosophical (and somehow romantic) premises of patent law are, in the least, outdated – nowadays, not only are patents legal protection instruments, but also (and foremost) business assets. The IP market has grown immensely and developed various models with the intention of monetizing the "protected investments."[197] Regardless of their size, innovating companies that possess IP portfolios, with patents being the most prestigious component, resort to various methods of recouping their R&D investments: via classical licenses, enforcement of rights, or sale of patents. The latter accentuates the tradability of patents and opens the secondary IP market, where profits from IP rights are captured either via the direct reassignment of patents to competitors, or via their reassignment to intermediary firms that assist in IP transfer between companies. But while this practice expands the utilisation potential of patents, it does is not equal to consumption of patents as "legal embodiments of commoditised assets."[198] If patents are not eventually licensed to a producing company, they function as liquid assets booked on a balance sheet and await further resale on the stock market or to an investment vehicle. The patent utilisation practice has reached a point where even "Wall Street has discovered patents," where patent transactions require rigorous quasi-litigation preparations.[199] The presented facts provoke the question of how such practices remain in touch with the overall objectives of the patent system.

3.4 Makers in the field of patents

3.4.1 Natural Property

The notion of *natural property* met with much criticism. Machlup and Penrose pointed out that the introduction of the term *property* in the 19th century was a deliberate manipulation to disassociate patents with the detested privileges[200]: "the spirit of that time was so much for liberty and equality,

[196] Du Vall, *Prawo Patentowe*, 145.

[197] Raymond Millien, "Landscape 2013: Who are the Players in the IP Marketplace?," http://www.ipwatchdog.com/2013/01/23/ip-landscape/id=33356/, accessed 04.05.2014.

[198] Ian McClure, "The Value of IP as a Commodity," *IAM Magazine*, no. 46 (May/June 2011): 31.

[199] Terry Ludlow, "Sign of the Times: Trends in Technology IP Licensing," ibid., no. 66 (July/August 2014): 33.

[200] Likewise with term "monopoly": before 1873, pro-patent economists avoided using this term, but after the triumph of the pro-patent movement monopoly was purified from the association with devilish market control and became exclusivity granted *pro publico bono.* See Machlup, *An Economic Review of the Patent System*, 26.

and against privileges and monopolies of any sort." Thus, patents read as *property* had better chances of being respected and obeyed.[201]

The opponents of the concept argue that an idea once communicated to the public stops being the property of its creator – it becomes a publicly circulated good. Moreover, a single invention cannot be disentangled from the environment: every new solution originates from previous ones – an invention is "a new combination of already existing data"[202] and part of continuous development.[203] The prior art present in every patent application demonstrates the origins of the solution: how a new solution improves on the drawbacks of former ideas. From this perspective, the view that each invention is *common* deprives the inventor of the right to claim property and monopoly. Polanyi formulated the concept as follows:

> I believe that paten law is essentially deficient, because it aims at a purpose, which cannot be rationally achieved. It tries to parcel up a stream of creative thought into a series of distinct claims, each of which is to constitute the basis of a separately owned monopoly. (…) Ideas usually develop gradually by shades of emphasis, and even when, from time to time, sparks of discovery flare up and suddenly reveal a new understanding; it usually appears on closer scrutiny that the new idea had been at least partly foreshadowed in previous speculations.[204]

The interpretation of patents as natural rights is all the more complicated by the fact that an inventor must first apply for a patent, which is granted only when the idea (and the application) complies with the requirements for patentability. Furthermore, the granted right is hedged territorially and limited in time – it can be withdrawn either due to invalidation or unsuccessful utilisation. To accentuate the incoherence of the arguments supporting the natural-property view on patents, the practice demonstrates that (1) in the majority of cases patents are assigned to corporate entities (i.e. employers), (2) in the first-to-file regime filing a patent application resembles a chase in which possibly a person other than the inventor manages to be the first to patent the solution.[205]

---

[201] Machlup and Penrose, "The Patent Controversy in the Nineteenth Century," 16.

[202] Alfred E. Kahn, "Fundamental Deficiencies of the American Patent Law," *The American Economic Review* 30, no. 3 (1940): 484.

[203] Machlup and Penrose, "The Patent Controversy in the Nineteenth Century," 12-13.

[204] Michael Polanyi, "Patent reform," Review of Economic Studies XI (1944), 70-71 from Machlup, *An Economic Review of the Patent System*, 29.

[205] Du Vall, *Prawo Patentowe*, 130-31.

3.4.2 Monopoly & Prospect

Market **monopoly** (*the winner takes all*) is criticised as an adverse consequence of patents and as their false justification. It is a strictly economic question and represents a complex issue that is only sketched in the following paragraph.

Opponents of patent exclusivity affirm that monopoly works to the detriment of the competition, which is regarded as the best inducement to innovate – competitive rivalry is far more profitable than coordinated planning.[206] They also argue that a low-rivalry context harms product advancement. For example, the prospect theory magnifies the advantages of monopoly and underestimates the benefits which stem from competitiveness. Due to the patent monopoly, competitors choose to innovate on the secondary market of compatible products, and abandon the primary market with an *unrivalled* product. An early patent application, like in the prospect theory, often leads to a sub-optimal product development (underdevelopment), which in the condition of restricted competition negatively affects consumer welfare: the first-mover advantage lures inventors to accelerate commercialisation before product completion. In effect, premature and broad patents may decrease the incentive for incremental developments (improvements) and lead to a waste of resources in order to work around a patent to develop substitutable solutions.[207]

3.4.3 Disclosure

Although even patent sceptics underscore the informative function of patents in a positive manner, the practice of patent disclosure opens another discussion field: the revealed patent information may not present complete technical data. In the idealistic scenario, patent information should be sufficient to enable the reader (a person skilled in the art) to comprehend the technical solution, and to make it.[208] Patent information consists of two elements: the written description and patent

---

[206] Merges and Nelson, "On the Complex Economics of Patent Scope."

[207] Seth A. Cohen, "To Innovate or not to Innovate, That is the Question: The Functions, Failures, and Foibles af the Reward Function Theory of Patent Law in Relation To Computer Software Platforms," *Mich. Telecomm. & Tech. L. Rev.* 5(1998): 12-18; Eisenberg, "Patents and the Progress of Science: Exclusive Rights and Experimental Use," 83; Bogers, Afuah, and Bastian, "Users as Innovators: A Review, Critique, and Future Research Directions," 868.
A similar situation occurs on a market dominated by one standard. Cohen indicates that such a situation might badly affect innovativeness by reducing the incentives to introduce competitive technologies. See William E. Cohen, "Competition and Foreclosure in the Context of Installed Base and Compatibility Effects," Antitrust Law Journal 64, no. 3 (1996): 550.

[208] Article 83 EPC; 35 U.S.C. §112.

claims, where the former is intended to support the latter.[209] Apart from the presentation and explanation of the new idea, the disclosure serves various purposes, e.g. the avoidance of duplicating the research efforts, the estimation of the value of the invention, and the determination of the protection scope. However, a patent may not reveal *sufficient* information. The patentee can protect (and thus disclose) certain elements of the solution, while keeping other elements secret. Such a practice enhances the bargain power of the patentee who, apart from licensing a patent, delivers the know-how.[210]

On the other hand, disclosure appears to be a good strategy to create prior art with the aim of blocking competitors' operations – companies extensively disclose patent information in applications without the intention of pursuing the patents (the application is published 18 months from the date of filing and then abandoned).[211] Apart from its questionable effect on the quality and quantity of the patent information, such a practice also puts into question the instrumentalisation of patents, as well as overall business standards.

The language of patents is another issue. The formulations (particularly in patent claims) are very convoluted and include special *phrases*, such as *comprising, consisting of*, and nuances, such as *more preferably* and *most preferably* that cannot be ignored. What seems normal in conventional language, in the context of patent language has a concrete and specified meaning. Moreover, patent language allows for the uncommon use of words, i.e. an unusual combination of words or their use as a different part of speech (e.g. verbs as adjectives).[212] This peculiarity of patent language complicates the comprehension of solutions presented in patent documents – even for the technicians who possess the required knowledge to embrace the technical teaching. In that regard, a certain level of competence in reading patents as legal documents is a precondition to correctly understand the scope of sought protection.

Reading a patent is challenging, but writing one is even harder – patents are regarded as the most complex legal instruments in existence[213]. In terms of patent drafting, the application cannot be too broad, too narrow, or too ambiguous, and must leave a certain space for stretching the scope on possible equivalents. It is even more challenging to provide an accurate translation of complex

[209] Article 84 EPC. On disclosure requirement, e.g. Mark Janis, "On Courts Herding Cats: Contending with the Written Description Requirement (And Other Unruly Patent Disclosure Doctrines)," *Wash. UJL & Pol'y* 2(2000).

[210] Ashish Arora, "Patents, Licensing, and Market Structure in the Chemical Industry," *Research Policy* 26, no. 4-5 (1997).

[211] Scott Baker and Claudio Mezzetti, "Disclosure as a Strategy in the Patent Race," *Journal of Law and Economics* 48, no. 1 (2005).

[212] Kristen Osenga, "Linguistic and Patent Claim Construction," *Rutgers Law Journal* 38(2006): 97-101.

[213] *Topliff v. Topliff*, 145 U.S. 156 (1892).

technical material to secure the same scope of protection as specified in the original version of the patent application. Proper translation has a tremendous impact on the overall management of an IP portfolio: the scope of protection, enforceability, licensing negotiations, and litigations (e.g. in discovery procedure). Translation mistakes are expensive, hence experienced patent translators are at a premium (and rare).[214]

3.4.5 Patent Scope

The matter of patent scope does not seem to ever disappear from the agenda of uneasy and unanswered patent questions. The breath of a given patent bears two implications: one in the post-invention phase (commercialisation), and another – in regard to follow-up inventions.

The success of marketization cannot be guaranteed – it depends on various factors, including good timing and luck in finding interested partners. In this context, a broader patent (a *prospect* patent) covers a broader scope of sectors and offers greater chances of monetizing the investment.[215] On the other hand, broad patents take away a greater portion of the technology market and block competitors in their R&D undertakings. When the competitors use a patented solution as a research tool or need to perform certain tests[216], they have to either obtain a license or establish a R&D project to continue their operations. For that reason, narrow (well-tailored) patents would be more welcomed:

> (…) some people jump from that to the conclusion that the broader the patents rights are, the better it is for innovation, and that isn't always correct, because we have an innovation system in which one innovation builds on another. If you get monopoly rights down at the bottom, you may stifle competition that uses those patents later on, and so the breadth of utilization, maybe I should say, in a broader sense, the breadth and utilization of patent rights can be used not only to stifle competition, but also have adverse effects in the long run on innovation. We have to strike a balance.[217]

---

[214] Amanda Montecinos, "Demystifying Patent Translation. Just as Patents Require Specialised Writing Skills, They also Require Specialised Translation Skills," *Communicator. The Institute of Scientific and Technical Communicators*(Autumn 2009), http://www.multiling.com/Portals/0/NewsFiles/Communicator.pdf; Matt Sekac, "For Patent Practinioners, Translation is Everywhere," *IAM Magazine*, no. 67 (September/October 2014); Theo Gruenewald and Alexander Wurzer, "Translation of Patent Applications: A Challenge in Globalised IP Management," ibid., no. 62 (November/December 2013).

[215] Ted M. Sichelman, "Markets for Patent Scope," *IP Theory* 1, no. 2 (2010); Merges and Nelson, "On the Complex Economics of Patent Scope."

[216] E.g., research mice (oncomice).

[217] Joseph Stiglitz at the FTC Hearings on Global and Innovation-Based Competition on October 12, 1995 in Carl Shapiro, "Patent Reform: Aligning Reward and Contribution," in *Innovation Policy and the Economy*, ed. Adam B. Jaffe, Josh Lerner, and Scott Stern (Chicago: University of Chicago Press, 2008), 148.

Questions arise as to how to achieve such balance and where the virtual boundaries of patent protection reside. The latter are determined through the construction of patent claims, which should neither rely on a literal meaning of the wording, nor treat it as a guideline.[218] This position, though fair and reasonable at first glance, is fraught with uncertainty and obstacles, as there is no single yardstick to ascertain the distance between the literal and non-literal meaning of patent claims. The notion of equivalency or the consideration of the intentions of the inventor (like in Catnic principle[219]) introduces even more legal insecurity. Certain doctrines and principles may guide the course of interpretation but they themselves do not contain any measurable features. Ultimately, the virtual scope of protection for a given patent is specified by a court in the course of patent litigation, but even then, the boundaries are set in reference to an allegedly infringing subject-matter (i.e. whether it falls within the ambit of protection). Nonetheless, a court decision is the most firm signpost; until then, attempts to recognise the correct scope of protection are assumptive and resemble floundering the in the dark.[220]

3.4.6 Patent Term

The patent term amounts to 20 years, with the option for an extension in certain sectors, such as the pharmaceutical sector. Considering that patent prosecution time spans from 4 to 5 years, patent holders theoretically have 15-16 years to monetise their solutions, which is a fair period, if not too fair. Unarguably, pharmaceutical and biotechnology sectors are affected adversely with the fixed patent term due to long development process and arduous approval procedures. However, to compensate the loss due to regulatory delays, legislators introduced supplementary protection certificates for medicinal products extending the protection term up to five years.[221]

---

[218] Article 1 of the Protocol on the Interpretation of Article 69 EPC. http://www.epo.org/law-practice/legal-texts/html/epc/2013/e/ma2a.html (accessed 24.03.2015).

[219] *Catnic Components Ltd. v. Hill & Smith Ltd.*, [1981] R.P.C. 183.

[220] Margaret Llewelyn, "Schrodinger's Cat: An Observation on Modern Patent Law," in *Death of Patents*, ed. Peter Drahos (London: Lawtext Publishing Limited, 2005), 54-56.

[221] "REGULATIONS REGULATION (EC) No 469/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 May 2009 concerning the supplementary protection certificate for medicinal products," Official Journal of the European Union L 152/1, 16.6.2009; "REGULATION (EC) No 1901/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 001/83/EC and Regulation (EC) No 726/2004," Official Journal of the European Union L 378/1, 27.12.2006; "REGULATION (EC) No 1902/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 20 December 2006 amending Regulation 1901/2006 on medicinal products for paediatric use," Official Journal of the European Union L 378/20, 27.12.2006.

In that regard, it is questionable whether the one-size model of patent protection is beneficial to all industry sectors. Industries, such as information technology and life sciences, have different needs and innovation cycles. Accordingly, patents from the different fields are written in a different way and with different business purposes in mind. Therefore, it would be reasonable to form doctrines and models which are applicable separately depending on the sector.[222] Such proposals appear all the more reasonable when we take into account that out of all the granted patents, only a low percentage of patents reaches the threshold of 20 years – mainly blockbusters and the aforementioned pharmaceuticals.[223] Patent holders close their patents for various reasons, e.g. misfortune in commercialisation, or a shift in technologies. The current patent term manifests generosity for business sectors affected with quickly changing market trends, like electronics or IT, where companies themselves may not even last 20 years, whereas their patents might do so by landing in the hands of either bigger market players or patent assertion entities. The patent term is questionable with regard to the patent quality. As estimated, up to 50% of litigated patents are claimed invalid (!).[224] However, until the invalidity of a given patent is proved, a patentee enjoys all benefits of doubt and may extract benefits from the granted right, and successfully enforce it.

3.4.7 Patent Quality

The name of the game is the patent quality – the issue has never been as significant as nowadays, when low patent quality has been blamed for the major sins of the system.

The notion of patent quality is liquid and can be defined in at least three complementary manners, i.e. with regard to drafting quality, validity standards, and economic value.[225]

In order to differentiate between a good and a bad patent, it is more reasonable to first describe a good patent. A high-quality patent contains technical details pronounced in a well-formed, i.e., clear and definite, patent claims, and includes alternative embodiments which support the general

[222] Richard Lloyd, "Lemley: The Case for Congressial Patent Reform is Far Weaker Than It Was a Year Ago," http://www.iam-media.com/Blog?Detail.aspx?g=28572386-7cf9-4003-8513-12f3edb914a0, accessed 02.06.2015.

[223] Based on the author's professional experience. See also Erik Sherman, "Patent Life Spans Shorter than Law Allows," http://www.cbsnews.com/news/patent-life-spans-shorter-than-law-allows/, accessed 19.03.2014.

[224] Marshall Phelps and David Kline, "Building a White-Hat Brand in the Patent Industry," *IAM Magazine*, no. 67 (September/October 2014): 41.

[225] See Christi Guerinni, "Defining Patent Quality," *Fordham Law Review* 82, no. 6 (2014); Bruce Berman, "Towards a Working Definition of Patent Quality," *Intellectual Asset Management* (May/June 2015).

claim, but are also grounded in the patent description and the main claim.[226] A bad patent is everything opposite.

From another perspective, patent quality pertains to the validity of a patent in legal terms, its technical contribution, and its inventiveness. A good patent stands firmly on three criteria of patentability, i.e. novelty, non-obviousness (an inventive step), and industrial application. In a nutshell, the criterion of novelty indicates that a claimed invention has not been available prior to the date of the application. The patent authority approves documented evidence on the claimed form and described uses. The requirement of industrial application pertains to the finished form of an invention that can be industrially implemented, and does not require further research and development. In the author's opinion, the most crucial criterion that addresses true inventive efforts, which are embedded and socially awaited in every patent-rewarded solution, is inventiveness (non-obviousness). Inventiveness is a factor which describes the level of inventive contribution (rewarded with a patent) that exceeds the threshold of obviousness, i.e. the availability of a solution for a person skilled in that art without inventive efforts. Non-obviousness is connected with prior art and existing knowledge, against which it is scrutinised. However, a claimed idea not only cannot be mentioned in the prior art, nor can it be inferred directly therefrom. Instead, it must deviate from what is known and obvious – it must be beyond and above it. Nowadays, when dissemination of information is advanced and knowledge has become available to many, the threshold of patentability (non-obviousness) should be permanently elevated in order to maintain the said distance between easily deductive and truly inventive ideas. Critical voices assert that patent practice stray from this presumption: patents are granted for solutions that “have not been produced yet” and are hence regarded as “non-obvious.”[227] This alarming practice undermines the constituting objectives of the system.

The responsibility for patent quality rests mainly in the hands of patent authorities, which are expected to secure the issuing of qualitative patents. They should detect elusive and broad claims for solutions of no contribution to the state of the art.

As estimated, the examination of a single patent takes approximately 30 hours[228], during which a patent examiner assesses the prior art and manages formalities. In other words, the patent office

[226] Jack Ellis, "Change in Practice," *IAM Magazine* 65(May/June 2014): 11.

[227] Llewelyn, "Schrodinger's Cat: An Observation on Modern Patent Law," 27.

[228] John Barton, "Reforming the Patent System," *Science* 287, no. 5460 (2000): 4.
“According to the USPTO Performance and Accountability Report for the fiscal year 2012, last year the office had a payroll of nearly US$ 1.6 billion and employed 7,935 patent examiners addressing some 565,566 applications (going by these figures, a typical examiner reviews about 71 patents a year).”

evaluates and grants a patent in less than one labour week. Such speedy patent assessment might result in awarding patents for premature, trivial, and obvious solutions.[229] A patent expert commenting on the Amazon "Studio Arrangement" patent (photos taken on the white background) holds the following opinion:

> As a patent attorney, I saw plenty of applications rejected, saw examiners finding remarkable prior art, and still saw plenty of patents issued on the most obvious ideas.
> The problem is not with the examiners, but with the law that governs that examination. That law makes it possible to get patents on ideas that any ordinary person would find old, well-known, and obvious. (…)
>
> Examiners are far from the rubber stamps they are sometimes caricatured to be. Even the examiner of the Studio Arrangement patent found precisely the right reference to cite. But examiners work within a regime of law that constrains them to allow patents that we would not expect or desire. That systemic constraint needs to be corrected if we are to stop the tide of obvious patents being issued.[230]

Some experts, however, point to the insufficient training of patent examiners, who oversee certain flaws and oversights of patent applications, such as overly broad claims (insufficient disclosure), or fail to find the proper prior art.[231] Such mistakes may cause costly troubles for patent owners who first invest, and then lose as much as millions of dollars before the patent is eventually invalidated. A good illustration of the malpractice in prior art detection is the case of NTP patents: Research in Motion paid $612 million to NTP to settle a patent infringement case in 2006, only to find their NTP's patents invalidated three years later after a research paper was discovered in a university library in Norway (!).[232]

Another critical point upheld in discussions on patent quality is the questionable significance of patented solutions, i.e. patents are granted for unimportant (unworthy) solutions, or, to put it in other words, mere gadgets, such as a "contactlessly-chargeable light-up shoe" (a recharging

---

See Mike Pellegrino, "Apple, Samsung and the Battle for Patent Supremacy," *IAM Magazine*, no. 58 (May/June 2013): 65.

229 E.g., U.S. Patent No. 8,762,173, titled "Method and Apparatus for Indirect Medical Consultation" or U.S. Patent No. 8,676,045 titled "Studio arrangement."
See "Introducing EFF's Stupid Patent of the Month," https://www.eff.org/deeplinks/2014/07/inaugural-stupid-patent-month?utm_content=bufferff516&utm_medium=social&utm_source=plus.google.com&utm_campaign=buffer, accessed 31.07.2014; Charles Duan, "How Amazon Got a Patent on White-Background Photography. A Drama in Five Acts: Bad Laws, Not Bad Examiners, Create Obvious Patents," http://arstechnica.com/tech-policy/2014/06/how-amazon-got-a-patent-on-white-background-photography/, accessed 11.06.2014.

230 "How Amazon Got a Patent on White-Background Photography. A Drama in Five Acts: Bad Laws, Not Bad Examiners, Create Obvious Patents."

231 Cheryl Milone, "The Real Problem is Patent Quality, not NPEs," *IAM Magazine*, no. 61 (September/October 2013): 13.

232 ibid., 15.

process for colourful lights in children shoes).[233] Trivial industrial application of patents, which alone defines other qualities of such a solution, makes a lot of shake their heads in disbelief. In the common perception, patents should be granted for inventions that can truly change and facilitate life, like Edison's light bulb. However, patent practice goes against this common belief and demonstrates that the patent system can award socially meaningless inventions.

From the economic perspective, good quality patents ensure licensing prospects, sales, and the acquisition of R&D projects. They ensure greater economic recoup of investment and they are more reliable in the pursuit of various business models. However, to a certain extent, the economic system (the market economy) supports the imbalance between the recoup of investment and the actual contribution to welfare and technological progress. Excessive rewards for trivial solutions lead to disadvantages in short and long terms: the increased pricing of goods and services, and economic inefficiency by discouraging investment.[234] However, the rules are set by the market itself. If a certain market sector is not mature enough to welcome and appreciate an invention, e.g. the manufacturing capacities are insufficient or customers cannot comprehend and apply the solution, no commercial success can be expected. It should be stressed that victorious patent prosecution does not necessarily translate into successful commercialisation.

Low patent quality works against the system by increasing mistrust and disbelief in the system as a whole. Bad patents block others in their research undertakings and may land in the hands of so-called patent trolls, i.e. companies that extort nuisance settlements and deepen the negative perception of the system.[235] Opponents of the patent system assert that the system does not serve its purpose: once an inventor obtains a patent, he or she enters a patent-litigation-driven industry. The costs of patent lawsuits, particularly in the US, "escalate very fast and challenge the business reason behind it."[236] Eventually only big market players can afford enforcing their rights in a court proceeding; however, like smaller market entrants, they also tend to lean toward settlements that represent more *reasonable* business solutions. The economic report of the American Intellectual Property Law Association shows that legal costs (including expensive discovery proceedings) can amount to as much as 60% of the total sum at risk, e.g. $600 000 in the case of $1 million at risk

[233] US 7,510,293 B2.

[234] Shapiro, "Patent Reform: Aligning Reward and Contribution," 112-13; Machlup and Penrose, "The Patent Controversy in the Nineteenth Century," 23-24.

[235] Milone, "The Real Problem is Patent Quality, not NPEs," 13; Marshall Phelps and David Kline, "Building a White-Hat Brand in the Patent Industry," ibid., no. 67 (September/October 2014): 42; Jack Ellis, "Change in Practice," ibid.65(May/June 2014): 11.

[236] John DuPre and John Hamann, "Controlling Costs in Patent Litigation," *IAM Magazine - 2013 IP Value. Building and enforcing intellectual property value* (2013): 54.

(*only* $5 million in a litigation for more than $25 million).[237] The likelihood of a settlement increases when the exorbitant legal costs make at least one party amenable to such offer. Settlements are a common practice as the US system conceived a general rule that each party covers own legal expenses (the American rule[238]). This, however, has been changed with the fee-shifting that the losing party covers a certain amount of attorney fees of the winner, which had an impact on decrease litigations number, with the focus on the "frivolous" ones.[239] Cory Doctorow, a science fiction author and co-editor of *Boing Boing*, sums up the pitfalls of the patent system as follows:

> (…) I'm very suspicious of them [patents] because of a bunch of systemic issues with patent law, the USPTO, and the way that most patent lawyers game the first two. In particular, the fact that the USPTO routinely grants "overlapping" patents that cover the same inventions; and that patent attorneys routinely set out a very broad set of claims ("a method for doing anything with stuff") that narrow down to a specific claim, in the hopes that an overworked patent examiner will grant them a patent over very broad things that their clients did not in any way invent; and that the patent courts don't allow people who've been sued for patent infringement to claim their expenses if they're victorious, combine into a vicious, especially pointy triangle that means that big, well-heeled companies can patent everything under the sun and can sue everyone else into oblivion using those patents, whether or not anything was actually invented and whether or not that invention is ever infringed upon.[240]

3.4.8 Patentable Subject Matters

Rightly said, almost anything can be patented. The ambit of patentable subject-matters expands in a natural manner. As technology develops and new forms emerge, we observe a shift from physical structures towards "conceptual" patentable solutions. Initially, patents were granted for tangible and visible objects that could be intuitively understood: mechanical devices, their components, or physical processes. Due to its abstract character, the intangible remained outside the realm of

---

[237] Jim Kerstetter, "How much is that patent lawsuit going to cost you?," http://www.cnet.com/news/how-much-is-that-patent-lawsuit-going-to-cost-you/, accessed 21.02.2015.

[238] The U.S.C. envisages an exception to this principle in Section 285 that applies to "exceptional cases" like misconduct in the patent litigation, inequitable conduct during patent prosecution. *Brooks Furniture Mfg., Inc. v. Dutailier Int'l, Inc.*, 393 F.3d. 1380, 1381-82 (2005).

[239] *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 134 S.Ct. 1749(2014); *Highmark, Inc. v. Allcare Health Management Systems, Inc.*, 134 S.Ct. 1744(2014); EFF Electronic Frontier Foundation, "Find the Best Fee-Shifting Decisions," https://www.eff.org/files/2014/06/03/findthebest_fee-shifting_decisions.pdf, accessed 21.02.2015.

[240] Cory Doctorow, "What's The Story with the Makerbot Patent?," http://boingboing.net/2014/05/30/whats-the-story-with-the-mak.html?utm_content=buffer50111&utm_medium=social&utm_source=plus.google.com&utm_campaign=buffer, accessed 31.05.2014.

protection.[241] Even certain types of products, such as pharmaceuticals, chemical substances, and food products, were excluded from patentability due to moral and economic reservations on their monopolization, which could block progress and access to solutions in sectors satisfying important social needs.[242] Nowadays, however, patent authorities award patents for computer-implemented inventions[243], business methods[244], and biotechnological inventions[245].

Notwithstanding the expanding scope of eligible solutions, no legal definition of an invention has been formulated thus far. Legal provisions stipulate the requirements that a patentable solution (an invention) should meet in order to be conferred with protection. The TRIPS Agreement states in Article 27 (1) that patents shall be available for any inventions, whether products or processes, in all fields of technology given they are new, involve an inventive step, and are capable of industrial application (which echoes the Article 52(1) EPC). This provision means that (1) patents are granted in all fields of technology and (2) patentable solutions must have a technical character. To that end, before an application falls under the scrutiny on the legal requirements of patentability, it should be first recognised as an invention in terms of its technicality, which, again, has not been unitarily specified within the TRIPS, EPC, and national regimes.[246] It is therefore safe to assume that an invention is a technical mean of altering a substance, "a mean of controlling natural forces to achieve predictable results in the physical world"[247]; human intervention is an inevitable construction element. Products of nature, i.e. discoveries of minerals or plants, mathematical

---

241 Richard S. Gruner, "Intangible Inventions: Patentable Subject Matter for an Information Age," *Loy. L. A. L. Rev.* 35(2001-2002).

242 Ryszard Skubisz, *Prawo Własności Przemysłowej*, vol. 14A (Warszawa: C.H. Beck, Instytut Nauk Prawnych PAN, 2012), 519.

243 Earlier "software-related inventions."
The EPO accepts computer-implemented inventions if they serve the solving technical problems. See *Programs for Computers*, The Enlarged Board of Appeal of the European Patent Office, G 0003/08.

244 Predominantly in the US. See *State Street Bank and Trust Company v. Signature Financial Group, Inc.*, 149 F.3d 1368(1998); *In re Bilski*, 545 F.3d 943(2008).
According to Article 52(2)(c) EPC, methods of doing business are not regarded as inventions.

245 *In vitro* processes, i.e. isolation of biological materials from their natural environment or production by means of a technical process, e.g. purification and isolation of natural materials, or production of forms that do not occur in nature; genetic modification of pre-existing animal or plant materials, are eligible to patent protection. See
"DIRECTIVE 98/44/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 July 1998 on the legal protection of biotechnological inventions," Official Journal of the European Communities L 213/13, 30.7.1998.
See Article 53(a) of the EPC: "inventions the commercial exploitation of which would be contrary to 'ordre public' or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States."

246 Aurelia Nowicka, "Programy Komputerowe w Systemach Prawa Patentowego," *Ochrona Własności Przemysłowej*, no. 45 (2014): 12.

247 ibid., 29.

formulas, or laws of physics are not patentable, because they exist independently of a human factor.[248]

As mentioned before, no legal definition of an invention exists, but law determines subject-matters eligible for patent protection. The EPC specifies this issue in a *negative* manner, i.e. it states what is not patentable (is not regarded as an invention) or cannot be patented. Articles 52(2) enlists exclusions from patentability, such as a discovery, a scientific theory, a mathematical method, an artistic work, an aesthetic creation, doing business, a program for a computer, or the presentation of information. Article 52(3) clarifies further that the application of the former provision refers only to the named forms "as such," as they have no technical implications in their pure form. However, no legal definition has followed the determinative "as such," neither on the European nor the national level.[249] Article 53 demarcates those subject matters which are not patentable, such as inventions contrary to *ordre public* or morality, inventions on plant or animal varieties (other than microbiological processes or products), on methods of human and animal treatment (but not products for the use thereof). Notably, there is no practical difference between the two types of exclusions – in both cases, patent protection is not conferred.[250]

In turn, US law (35 U.S.C. §101) provides positive guidelines and enlists four eligible categories, such as processes, machines, manufacture, composition of matters, and any improvements thereof that must comply with the requirements of novelty, non-obviousness, and utility. The catalogue, however, remains open , since the invention may be "anything under the sun that's made by man."[251] The US system does not provide any provisions on exclusions from patentability similar to those included in the EPC. Nonetheless, judicial decisions and the USPTO practice established a framework for non-patentable solutions that *per se* does not drift much from the European catalogue. The framework concerns the aspects of morality and *ordre public*; forms that remain outside the scope of patent protection are scientific discoveries, mathematical methods, aesthetic creations, mental acts, and the presentation of information.[252]

---

[248] Janice M. Mueller, *Patent Law*, 4 ed. (New York: Wolters Kluwer Law & Business, 2013), 388-89; Du Vall, *Prawo Patentowe*, 160-61.

[249] Aurelia Nowicka, "Programy Komputerowe a Wynalazki Mające Zdolność Patentową – Praktyczne Aspekty Badania Zdolności Patentowej," *Ochrona Wlasnosci Przemyslowej*, no. 46 (2014): 6.

[250] Du Vall, *Prawo Patentowe*, 174.

[251] The Committee Reports S Rep. No 1979, 82d Cong., 2d Sess., 5 (1952); H.R.Rep. No. 1979, 82d Cong., 2d Sess., 6 (1952),quoted in *Diamond v. Chakrabarty* 447 U.S. 303(1980).

[252] See *Gottschalk v. Benson*, 409 U.S. 63(1972); *Parker v. Flook*, 437 U.S. 584(1978); *Diamond v. Diehr*, 450 U.S. 175 (1981); *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200(1991); see also Gruner, "Intangible Inventions: Patentable Subject Matter for an Information Age."

Legal exclusions from patentability do not slow down the expansion of the patentisation of new forms. The general way of formulating the rules enable their flexible construction and demand further specification and clear definitions that undergo certain alternations with time. Commentators point out that the emphasis rests not on the *exclusion*, but on the *inclusion* of subject-matters: materials are excluded only in extreme circumstances. Illustratively, the inclusion of biotechnological inventions stirs broad debates, because in this field in particular, a discovery and an invention may occur within one research operation. The answer to the puzzle on how to set the demarcation line has purely commercial implications as basic-research patents opens up broad (*inappropriate* in the opinion of some) market opportunities.[253] Similar objections arise in discussions on the patentability of computer-implemented inventions (previously defined as software-related inventions[254]). Objections concern the questionable technical character of the mentioned types of solutions, such as whether human factor contributes to the claimed solution, whether it exists (causes specified reactions) without human intervention altogether, and whether the achieved solution goes beyond the normal interaction between software and hardware, i.e. has further technical effect. The demarcation lines are blurred, as both biotechnology and software involve technical considerations; however, the mere fact of using technical infrastructure is insufficient to assert technical character in the patent definition.[255] As commentators point out, observations of EPO practice in terms of granting patents on computer-implemented inventions allow for the conclusion that the interpretation of Articles 52 and 53 has undergone an excessive curtailment, as if the exclusion rule for computer programs has literally been removed from the list.[256] The *inclusion* practice adds fuel to the fire: it supports the "over-patentisation" of technology and science and negates the validity of exclusion rules that (should) secure "the balance of interests" of all participants. Given the current patent practice, it appears that the patent system serves the private interest of patent holders and not the public welfare.[257]

---

[253] William Cornish, David Llewelyn, and Tanya Alpin, *Intellectual Property: Patents, Copyright, Trade Marks And Allied Rights*, 7 ed. (London: Sweet & Maxwell, 2010), 230-32, 924-25; Llewelyn, "Schrodinger's Cat: An Observation on Modern Patent Law," 45-49.

[254] Professor Nowicka argues that the term *software-related invention* is more accurate because it is software that is claimed as the subject of a patent application and not hardware as it is suggested (in a misguided manner) by the current terminology in use. The European Parliament proposed the term *computer-aided solutions*.
Nowicka, "Programy Komputerowe a Wynalazki Mające Zdolność Patentową – Praktyczne Aspekty Badania Zdolności Patentowej," 4-5.

[255] In the EPC practice, the technical character is assessed in light of Article 56 on the inventive step, and not in light of the Article 52 on patentability requirements.
ibid., 20.

[256] "Programy Komputerowe w Systemach Prawa Patentowego," 16.

[257] Llewelyn, "Schrodinger's Cat: An Observation on Modern Patent Law," 38-39.

3.4.9 The Patent Landscape

In spite of various objectives, the system is constantly fuelled with thousands of patent applications a year. It is estimated that only in the USA (the most important patent market) there were 2,239,231 million patents in-force in 2012 (549,521 in Germany).[258] The EPO granted 64,613 patents in 2014[259]; Samsung Electronics field 21,659 applications (on utility, design, and plant patents) to the USPTO in the same year.[260] IP portfolios are bursting at the seams – they have to achieve critical mass in order to defend themselves from attacks. During the famous (or notorious) *Apple v Samsung* litigation, Samsung's lawyers estimated that 250,000 patents apply to a single smartphone (!).[261] Media report on big IP transactions without ever mentioning the idea of technical progress, e.g. IBM transferring 750 patents to Twitter as part of licensing deal and litigation settlement[262], Google buying 17,000 patents from the Motorola handset business for $12.5 billion (in the form of a company acquisition).[263]

How is the system capable of *processing* this amount of IPs? The market developed various instruments and business models with the aim of supporting companies dealing (more) with the quantity of patents embedded in their IP portfolios and overlooking valuable solutions.[264]

As statistics present, companies are doing more than well with patent monetisation. Microsoft and Ericsson report royalty revenues of over $2 billion a year, Qualcomm – $6.1 billion.[265] How do they do it? They collaborate with patent brokers[266], patent assertion entities[267] (PAEs, also labelled as *patent trolls*), and more.[268] PAEs gain particular attention as they generate bad publicity for the patent system, destroying the faith held in it. The term *PAEs* refers to market players who

[258] The volume of patents that are granted by the USPTO is three times higher than in 1970s. Pellegrino, "Apple, Samsung and the Battle for Patent Supremacy," 64; Terry Ludlow, "Sign of the Times: Trends in Technology IP Licensing," ibid., no. 66 (July/August 2014): 32.

[259] "Annual Report 2014. Granted patents.," http://www.epo.org/about-us/amial-reports-statistics/annual-report/2014/statistics/granted-patents.html, accessed 11.06.2015.

[260] Michael Chernoff, "Patent Kings- the Dominat Players in the US Patent Landscape," *IAM Magazine* (May/June 2015).

[261] Terry Ludlow, "Sign of the Times: Trends in Technology IP Licensing," ibid., no. 66 (July/August 2014): 33, 36.

[262] Ibid., 32.

[263] Steve Lee, "A Tale of Two Patent Battles: Key Lessons on IP and Business Strategy," ibid., no. 64 (March/April 2014): 37.

[264] Terry Ludlow, "Sign of the Times: Trends in Technology IP Licensing," ibid., no. 66 (July/August 2014): 33; Millien, "Landscape 2013: Who are the Players in the IP Marketplace?" The author describes 19 forms on the IP market.

[265] Ludlow, "Sign of the Times: Trends in Technology IP Licensing," 34.

[266] Kent Richardson and Erik Oliver, "The Brokered Patent Market in 2013," ibid., no. 63 (January/February 2014).

[267] Also known as "non-practising entities" (NPEs), in contrast to "operating companies." However, the term *NPE* also pertains to universities and technology development companies.

[268] Millien, "Landscape 2013: Who are the Players in the IP Marketplace?"

aggregate IP portfolios with the aim of only asserting them for financial gain – with no manufacturing intentions whatsoever. They approach (often small and medium-sized) producing companies via demand letters, alleging patent infringement without merit with the aim of extorting nuisance settlements.[269] Since patent litigations can be extremely expensive, most addressees choose to pay rather than to start a court battle. Such practice, common in the USA (but not exclusively[270]) is regarded as an evident system abuse. The lawmakers attempt to constrict such a business model; commentators remain sceptic about their efforts. The America Invents Act[271] conceived a new procedure of *inter partes* review and covered the business method patent review, both post-grant examination procedures at the Patent and Trial Appeal Board of the USPTO. As faster and cheaper alternatives to patent revocation lawsuits, they were intended to affect PAEs practise. However, as recent studies present, they are predominantly used by operating companies in cases where there is no litigation.[272] The US Congress has prepared a number of legislative proposals to combat the plague of non-serious lawsuits[273], but they also face criticism for the possible adverse impact of their proposals on other non-practising entities, such as universities.[274] The USPTO and Conversant opened platforms furnishing Q&A to identify demand letters and educating entities how to further proceed in case of such notifications.[275] Additionally, Conversant has launched a campaign to increase ethical standards in licensing and to dissociate serious patent licensing businesses from patent trolls, e.g. "never threaten litigation against a start-up company, a local retailer, or an end-user customer, unless it is your direct competitor."[276]

---

[269] However, there are always one or more patents, for which PAEs could prepare a well-grounded infringement claim for. Phelps and Kline, "Building a White-Hat Brand in the Patent Industry," 42.

[270] The German system appeals PEAs with its interlocutory injunction procedure, highly educated judges, and fast first instance. Benedikt Fuest, "Die "Patenttrolle" blasen zum Sturm auf Deutschland," Die Welt Newspaper, http://www.welt.de/wirtschaft/webwelt/article124702746/Die-Patenttrolle-blasen-zum-Sturm-auf-Deutschland.html, accessed 24.06.2014.

[271] *Leahy–Smith America Invents Act*, Public Law 112–29—Sept. 16, 2011.

[272] Gregory Gonsalves, TC Beckett, and Barry Leff, "Trends in Inter Partes Review and Covered Business Method Review," *IAM Magazine*, no. 64 (March/April 2014).

[273] E.g. Innovation Act (H.R. 3309), Patent Transparency and Improvements Act (S. 1720), Patent Abuse Reduction Act (S. 1013), Transparency in Assertion of Patents Act (S. 2049), Demand Letter Transparency Act (H.R. 3540) from "Patent Progress's Guide to Federal Patent Reform Legislation," http://www.patentprogress.org/patent-progress-legislation-guides/patent-progresss-guide-federal-patent-reform-legislation/, accessed 01.10.2014.

[274] Steven Musil, "Patent Reform Bill Targeting Patent Trolls Shelved in Senate," http://www.cnet.com/news/patent-reform-bill-targeting-patent-trolls-shelved-in-senate/, accessed 14.06.2014; "Patent Progress's Guide to Federal Patent Reform Legislation." "Patent Progress's Guide to Federal Patent Reform Legislation."

[275] "Stand up to the Demand Brought to You by Conversant," http://www.standuptodemand.com, accessed 06.10.2014; USPTO, "Answers to Common Questions about Abusive Patent Ligitation," http://www.uspto.gov/patents/litigation/index.jpg, accessed 17.10.2014.

[276] Richard Lloyd, "Conversant Launches New Anti-Patent Troll Campaign," http://www.iam-magazine.com/Blog?Detail.aspx?g=18d8fcc6-5ab0-43c4-82b-db50581b4e3c, accessed 06.10.2014.

Besides patent trolls, the IP field is plagued with *patent battles*, e.g. *Apple v Samsung*[277], *Yahoo! v Facebook, Qualcomm v Broadcom, Stratasys v Afinia*. They are neither beneficial for the patent system (by deteriorating its image), nor for the participants themselves, who could instead invest in R&D operations. However, the party that loses the most are the end-users who have to "pay back" enormous litigation costs that are recouped in the ultimate product price.

An example of fierce patent practice is the cease of operations by IPXI, a Chicago-based company, which offered a new model of IP licensing aimed at safeguarding transparency and fairness of patent transactions. IPXI proposed a complex, albeit well-thought business solution in a form of an exchange platform for patent licenses covering consumable products (e.g. five square meters of OLED), named the Unity License Right (ULR). Transparency concerned the determination of the price, which was based on profound market analysis and a standard license on publicly disclosed terms. Another distinguishing element of this business model was an obligation to deliver consumption data reports by purchasers of URLs, who were given the right to re-sell unconsumed ULRs that were offered in the second (and subsequent) offering tranches.[278] On March 25 2015, IPXI announced:

> IPXI's business model offered fairness and transparency and relied upon patented technology users to be good corporate citizens. In the end, potential licensees made it clear that the only way IPXI would really get their attention was through litigation, and that's exactly what our business model tried to overcome.[279]

The IPXI case revealed probably the main reason behind the disillusionment with the patent system, namely widespread low and fierce business ethics. As announced, if IPXI attempted to pursue its model and objectives, it would be involved in multiple legal proceedings against its potential customers, who would be using the product without a license. IPXI would then almost automatically face suits challenging the validity of the infringed patents, despite a careful examination of patents before launching an offering. Not only would this development generate exorbitant costs, but also completely block the operations of the platform. In light of the above, business termination was the sole reasonable decision.[280]

Against this background, initiatives like that of Elon Musk (Tesla Motors) are very surprising and encouraging, though seen by many as anecdotal rather than as a form of setting a new patent practice.

---

[277] Pellegrino, "Apple, Samsung and the Battle for Patent Supremacy."
[278] Ian McClure, "The Value of IP as a Commodity," ibid., no. 46 (May/June 2011).
[279] "IPXI Trading Innovation," https://www.ipxi.com/, accessed 24.03.2015.
[280] See "Insight: Broken by a system that encourages bad behaviours, IPXI closes down," *IAM Magazine* 72(July/August 2015).

On 12 June 2014, Tesla Motors announced that it would not initiate lawsuits against anyone who applies its technology in good faith (the term stayed undefined). It was an unusual step – a public declaration on allowing "patent infringements," or a promise not to sue for using Tesla's patents.[281] Why? Elon Musk indicated opening Tesla's technologies for their further development as the main reason for his move. As Tesla's business does not deal with a lot of competition, it would benefit more by establishing a partnership with companies willing to work on its patents within a single innovation platform. Commentators indicate that this situation is similar to to cross licensing: Tesla blocks those who use Tesla's patents (in *good faith*) in filling lawsuits against Tesla itself for using its patents. In this way, Tesla secured access to external R&D. The competitors and users must remember that Tesla did not abandon its patents so any use deemed as a bad-faith would still be prosecuted.[282] An overall positive impact on Tesla's image is an added value to this move. Regardless of the business motivation, the decision was much welcomed in the open maker community. Some commentators recognised it as marking a new spirit of cooperation and openness. After all, working in good faith is one of the main characteristics of making. Were other patent holders to adapt a similar attitude as Tesla, the change would be a huge step forward in the pursuit of free *making.* Mark Lamley interpreted this as "a Silicon Valley mindset of creating a network effect to further boost the adoption of disruptive products and grow the ecosystem of company in the space."[283] Likewise, *Android* became the prevalent operating system on smartphones after Google made it open.[284]

Time will tell whether this development will remain a single episode, or whether it will become a common practice. Nonetheless, this example shows that closing down access to inventive solutions is not the sole option for technology and business making.

As studies of R&D labs demonstrate, patent protection situates itself in the third place after lead-time and trade secrecy in various industries as an effective appropriation mechanism, with patents prevailing in the chemical and pharmaceutical sectors.[285]

---

[281] Elon Musk, "All Our Patent Are Belong to You," http://www.teslamotors.com/blog/all-our-patent-are-belong-you, accessed 13.06.2014.

[282] "Insight: Going In with Eyes Wide Open," *IAM Magazine*, no. 67 (September/October 2014): 4.

[283] Dana Hull, "Tesla Motors Making Patents Public," http://www.mercurynews.com/business/ci_25949696/tesla-ceo-elon-musk-all-our-patented-tech, accessed 13.06.2014.

[284] ibid.

[285] Studies provide evidence that the significance of patents differs among industry sectors. For instance, pharmaceutical sector relies on patents. In the semiconductor and aerospace industries, secrecy and lead-time are the top mechanisms applied. See Cohen, Nelson, and Walsh, "Protecting Their Intellectual Assets: Appropriability Conditions and Why Us Manufacturing Firms Patent (or not)."; Richard C. Levin et al., "Appropriating the Returns From Industrial Research and Development," *Brookings Papers on Economic Activity - Special Issue on Microeconomics* 1987, no. 3 (1987); Najib Harabi, "Appropriability of Technical

Trade secrecy is an appealing instrument for many companies, large companies included. For example, reports claim that in the EU, DuPont spends two billion US dollars on R&D, a great portion of which is not patented. Trade secrets may pertain to very valuable technologies that are difficult to re-engineer (e.g. production of Kevlar by DuPont), but also to small and incremental improvements that, when assembled together, can be used to run a whole factory and are crucial in maintaining a competitive edge. A short technological lifespan (2-3 years), the failure to meet the threshold of patentability, or tight budgets may determine the fact that the information is kept confidential. However, not only does trade secrecy represent an alternative to patenting, it also complements it by situating patents within an implementable and marketable framework. Due to its importance, national legal regimes protect trade secrecy (obligation under Article 39 of the TRIPS Agreement) through regulations, such as the Uniform Trade Secret Act in the USA and respective national regulations in the EU.[286] Moreover, trade secrecy theft is a legal crime (in the USA – a federal crime). For example, Kolon Industries had to pay $920 million in restitution and cease manufacturing and selling products for stealing DuPont's trade secrets on the production of Kevlar.[287]

Another alternative to patents is the system of utility models, designed to protect *small (petty)* inventions, i.e. inventions of lesser importance, with a shorter term of protection (e.g. 10 years in Germany) and lower protection requirements (only novelty and industrial applications). Although utility models belong to the catalogue of intellectual property stipulated in the Paris Convention, not every system makes use of this form of protection. Owing to lower protection threshold in countries such as Germany, prior art pertains to written descriptions of the solution published within the country, utility models are granted in the course of faster and cheaper procedures. In Germany, applications are evaluated in light of compliance with formal requirements. The material aspects of the claimed solution are excluded from the examination and hence minor validity level of protected solution. In various places, the utility model law refers to patent law; however, it does not cover all types of inventions the patent protection applies to (e.g. methods), and envisages a

---

Innovations an Empirical Analysis," *Research Policy* 24, no. 6 (1995); Jorg Thoma and Bizer Kilian, "To Protect or not to Protect? Modes of Appropriability in the Small Enterprise Sector," *Research Policy* 42(2013).

[286] The EU lacks harmonised protection of trade secrets. Practitioners and scholars indicate legal complexity as the main hurdle – trade secrecy pertains to various legal fields such as IP law, competition law, criminal law, contract law, and labour law (e.g. NDAs with employees).
Annette Kur, "Two Tiered Protection - Designs and Databases as Legislative Models?," in *Common Principles of European Intellectual Property Law*, ed. Ansgar Ohly (Tuebingen: Morh Siebeck, 2012), 110-11; Ellis, "Keeping Secret."

[287] Cohen, Nelson, and Walsh, "Protecting Their Intellectual Assets: Appropriability Conditions and Why Us Manufacturing Firms Patent (or not)," 8; Ellis, "Keeping Secret," 45-49; Bruce Story, "America Invents Act Shines the Spotlight on Trade Secrets," ibid., no. 58 (May/June 2013).

grace period of 6 months for own disclosures and use. Utility models are considered useful for incremental innovation or for solutions (products) with a short commercial lifespan. Due to their lower costs, they represent a good option for SMEs or in the case of unsuccessful patent application – some countries allow the conversion of a patent application to a utility model.[288] (However, patents in a company portfolio render more prestige than utility models.)

Finally, yet importantly, why do inventors seek patent protection? As studies suggest, pure business motives dominate, such as preventing copying, blocking competitors (compelled to cross licensing), preventing infringement suits, building patent fences (e.g. patenting substitutes around own core invention), enhancing reputation, or using patents in negotiations.[289]

3.5 Concluding Thoughts

In the knowledge economy, patenting constitutes a lucrative business strategy that puts under fire the romantic concept of technological progress supported by (and possible only because of) patent protection.

Perhaps, if patents were openly portrayed as legal and financial instruments, the current criticism of and disappointment in the system would not be that strong.

The fact that the system requires modifications is clear to everyone. However it cannot be reformed *ad hoc*. Long-term changes first demand the restructuring of underlying mindsets and a new vision, which should be mirrored on the legislative level by inducing higher patent quality, stricter examination, and greater transparency in patent litigation. Higher ethical standards among practising companies should certainly lead such reforms.

Reforms that have already been initiated, such as the *inter partes* review within the AIA, bore their fruits and assisted in sorting out invalid patents. Notably, the majority of patents (64.3% in the USPTO fiscal year 2015) concerned electrical and computer sectors, with another 7.5% coming from the biotech and pharma fields. This does not require further comment. The rulings of the US Supreme Court also steer the changes: in *Alice Corporation v CLS Bank International,* the Court

[288] Manfred Buhring, *Gerbrauchsmustergesetz*, 8 ed. (Koln: Cark Heymanns Verlag, 2011), §1 at 109-12; Kur, "Two Tiered Protection - Designs and Databases as Legislative Models?," 110-11; Krasser Rudolf, "Developments in Utility Model Law," *IIC* (1995).

[289] Cohen, Nelson, and Walsh, "Protecting Their Intellectual Assets: Appropriability Conditions and Why Us Manufacturing Firms Patent (or not)."; Harabi, "Appropriability of Technical Innovations an Empirical Analysis."

invalidated business-method patents at suits. However, the court's decision caused mixed feelings: the revocation of patents in itself did not surprise as much as the explanation on the abstract character of eligible subject matters, which provoked discussions; but most importantly, the case called for the clear, definite, and tighter drafting of patent claims.[290]

The proliferation of low-quality patents remains a substantial problem to solve, which would subsequently solve other related issues. Certainly, this would support making by removing invalid and weak patents that only block and deter the makers' performance. The concerns upon the friction between makers and patent law might be expressed in another way: maybe it is the maker movement that has become too technological and too advanced, having reached the level of sophistication where patents are involved. The pendulum swings in both directions.

Setting aside the genuine cause of friction, we need to face the facts as they are. Before taking any further steps, it should be established whether the instruments provided by patent law allow makers and other users to legitimize unauthorised uses of patented solutions. Perhaps the critical opinions on the fake balance of interests that the patent regime provides are erroneous with regard to limitations on patent effects. The following comparative analysis of patent flexibilities attempts to solve this puzzle and presents just how much free space has been carved out in the system for end users.

Only with this knowledge in mind can we determine if there is a need for a toll designed for makers, or whether the existing patent exceptions sufficiently support makers in their routine operations.

[290] Cohen, Nelson, and Walsh, "Protecting Their Intellectual Assets: Appropriability Conditions and Why Us Manufacturing Firms Patent (or not)."; Harabi, "Appropriability of Technical Innovations an Empirical Analysis."

Chapter 4. COMPARATIVE ANALYSIS OF PATENT EXCEPTIONS

4.1 Introduction

From a legal standpoint, a patent is a complex document that bestows exclusivity upon the use of a patented solution that translates into market monopoly. All permissible uses can be conducted only with the permission of the patent holder, who steers the utilisation and commercialisation processes in regard to the said patented solutions. Each jurisdiction regulates this matter in details but the core of protected rights remains the same: law protects the economic exploitation of rights, pursuant to Article 28 of the TRIPS Agreement:

> A patent shall confer on its owner the following exclusive rights:
> (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing (6) for these purposes that product; (…).

A patent does not entitle the patentee to use the invention – such a possibility exists without a patent – but constitutes a legal condition of an exclusive use of a patent in a commercial manner (*ius positivum;* a subjective exclusive right). In the practical dimension, this translates into the right to exclude others from the use (*ius negativum, ius prohibendi*), which remains the core functionality of patents – the exclusion of unauthorised use and a legitimate enforcement of the infringed rights from a patent.

The right to exclude finds it expression in patent licensing, where the patentee chooses a party to which he or she secedes the exploitation rights to a patent. In a license agreement, a patentee not only allows others to use the invention in the negotiated manner, but also voluntarily refrains from enforcing their rights against such uses (in a specified territory and for a specified time), i.e. a license is a contractual promise *not to sue*.

An unauthorised use of an invention constitutes a legal ground to enforce the rights from a patent. Infringement occurs when an unentitled party conducts one or more of activities stipulated in the norm, such as manufacturing, using, putting into circulation, offering to sell or selling. A patented subject matter might be either imitated (reproduced or applied into working) or worked around (which diminishes the value of such a patent). Infringement means that the infringing party has encroached on the area protected with a patent – the substance of an infringement demands a detailed examination in light of the conferred patent protection.

However, certain unauthorised uses are sanctioned by law and therefore they do not establish any legal ground for claiming an infringement of patent rights. Patent exclusivity is limited by norms and doctrines that set boundaries on the exploitation and the enforcement of patent rights, and that limit the effects of a patent.

Patent law seeks to achieve balance between the commercial interest of the inventor and access to the invention to support important public interests and *ordre public*. The latter is safeguarded with patent limitations (patent exceptions) that derive from legal and ethical considerations upon the permissible uses of a patented subject-matter. They either do not violate the exploitation rights of the patent holder or support crucial public interests. It is therefore legitimate, to e.g. use a patented solution in a private sphere and for a non-commercial purpose, or to conduct experiments on patented subject matters with the aim of discovering new applications and new information. In principle, patent limitations deal with very specific situations. Without them patent law could not achieve its objectives and would represent a burden to trade relations (e.g. without the exhaustion principle) and established social practices (e.g. farmer's privilege).

The proper application of a patent limitation can secure the use of a patented solution without the peril of a patent lawsuit. From this perspective, patent flexibilities constitute limitations *ex ante* – they create a space free from the effects of a patent. However, the rightfulness of such application is often determined in the course of legal proceedings on an infringement allegation, when limitations are applied *ex post* as defence tools.

This chapter presents the profiles of a number of patent limitations adopted and exercised in the analysed jurisdictions. It begins with a sketch of the international background specified in the TRIPS Agreement, which stipulates the allowed "unauthorised freedom to operate." The analysis ends with a summary of general trends transposed directly onto the *making* model. The objective of the study is to determine which limitations and to what extent facilitate the activities of makers.

The comparison follows the catalogue of patent limitations provided in the UPC Agreement, categorised as statutory limitations. It investigates further judicial doctrines, i.e. non-statutory limitations, which complete the palette of patent flexibilities.

4.2 The TRIPS Agreement as the International Foundation for Patent Exceptions

Once patent protection ingrained itself in national legal orders, its development entered the stage of internationalisation[291]. In the second half of the 19th century, the issue which raised much concern was the protection of foreign inventions. International trade contacts expanded and stirred debates over the protection of foreign (imported) goods. At that time, to benefit from patent protection in third countries, an inventor had to file applications simultaneously in various patent offices. Countries regulated protection-related matters in bilateral agreements; however, those efforts were insufficient[292]. At the same time, international exhibitions organised in European capital cities demonstrated an urgent need for the unification of patent norms. Although a complete unification of patent laws was unfeasible due to discrepant national interests of contracting countries, a compromise on certain common principles of patent protection was attainable. In 1883, the first international convention, the Paris Convention on the Protection of Industrial Property (the Paris Convention, PC), was signed.[293] It conceived of two core principles of international patent law: the recognition of foreign patents at a national level (equal treatment) and a patent priority (union priority) of twelve months. However, the convention did not impose any obligation on the contracting countries to harmonize their substantive laws among each other, unless the national provisions went to an extreme (national protectionism) and e.g. nullified patent protection for imported goods. Other provisions of the PC that affected further law developments concerned the failure to function or the insufficient working of patents (and established the standard of compulsory licensing) in Article 5A, the principles of unimpeded transport (transport privilege) in Article 5 ter.[294]

The internationalisation of IP protection has progressed since the Paris Convention[295]. However, the next milestone in standardisation was enacted only 100 years later, launching the era of "IP globalisation."[296]

---

[291] Du Vall, *Prawo Patentowe*, 24.

[292] Until 1883, 70 bilateral agreements were signed but only two of them concerned patents: 1) Lichtenstein and Austria-Hungary from 1876, 2) Germany and Austria-Hungary from 1881. Ibid., 48.

[293] Revised in: Rome 1886, Madrid 1891, Brussels 1900, Washington 1911, London 1934, Lisbon 1958, and Stockholm 1967.

[294] Du Vall, *Prawo Patentowe*, 48-49; Kraßer, *Patentrecht*, 80-81.

[295] E.g. Berne Convention for the Protection of Literary and Artistic Works (1886), Patent Cooperation Treaty (1970) establishing international patent registration regime; European Patent Convention (1973) on granting European patents, Madrid Agreement Concerning the International Registration of Marks (1891) and the Protocol Relating to that Agreement (1989).

[296] Du Vall, *Prawo Patentowe*, 24.

The Agreement on Trade-Related aspects of Intellectual Property (TRIPS) was enacted at the end of the GATT Uruguay Round (1986-1994) and converged on establishing the World Trade Organization (WTO), which assumed the administration of the Agreement. (The fact of enforcing IP outside of the WIPO forum – proposed and exercised by developed countries, mainly the US – was strongly criticised[297]; however, as commentators indicate otherwise the legislation would never have happened.[298])

The TRIPS revolutionized the IP field in two ways:

1) it recognized IP protection as an economic tool in international trade, and
2) comprehensively regulated the IP field , determining a framework for national IP regulations.[299]

It attempted to eliminate impediments to and differences in the protection of intellectual property between countries to a much greater extent than any other treaty.[300] In that regard, the TRIPS Agreement went much further than its predecessors: the Paris Convention, the Berne Convention, the Rome Convention, the Treaty on Intellectual Property in Respect of Integrated Circuits, and the Patent Cooperation Treaty (Article 2); the regulations of which remain in force.[301]

In terms of patent-related issues, the TRIPS Agreement broadly covers:

1) patentable subject matter (Article 27) – requirements and exclusions from patentability,
2) effects of conferred rights (Article 28) – the scope of patent exclusivity,
3) conditions on patent applications (Article 29) – sufficient patent disclosure,
4) patent exceptions (Articles 30 and 31),
5) judicial review by patent revocation or forfeiture (Article 32),
6) term of patent protection (Article 33) – 20 years,
7) the burden of proof in patent infringement cases (Article 34).

As stipulated in Article 1, the Agreement conceives “the minimal standards of protection”; hence, it justifies the authority of the Member States to introduce more restrictive regulations. Paradoxically, already in the first provision it implies a limited power of a country when defining the framework of IP protection according to domestic interests and conditions because the minimum

---

297 Mainly by India and Brazil. See Anitha Ramanna, "Shifts an India's Policy on Intellectual Property: The Role of Ideas, Coercion and Changing Interests," in *Death of Patents*, ed. Peter Drahos (London: Lawtext Publishing Limited, 2005), 156.

298 Du Vall, *Prawo Patentowe*, 103; Kraßer, *Patentrecht*, 86.

299 Joseph Straus, "Bedeutung des TRIPS für das Patentrecht," *GRUR Int.* (1996): 187.

300 Cornish, Llewelyn, and Alpin, *Intellectual property*, 134-35.

301 The Article 2 of the TRIPS Agreement. Straus, "Bedeutung des TRIPS für das Patentrecht," 183-85; Kraßer, *Patentrecht*, 87.

standards must be met. The initial concept behind the TRIPS Agreement, which was forced by developed countries, was to harmonize the threshold of patent protection as established there, eventually leading to the elevation of standards in the global scale. In that regard, it is rightly claimed that for many countries (mainly, developing and less-developed countries[302]), the minimal standards were (and still are) too high to be implemented without harm for their domestic economies.[303] In addition, next to the proclamation on the minimal standards, the Agreement introduces instruments which support the uplifting of standards. For example, it appended the principle of national treatment from the Paris Convention with the principle of the most favoured nation (Article 4), i.e. privileges and favour granted to one Member States shall apply to all others. To that end, non-formalised reciprocity and pressure, predominantly economic, oblige countries to mirror the standards adapted in the country of higher norms, which apply to both national and foreign inventors.[304]

The Agreement introduces certain exceptions to IP protection, which traditionally constitute a part of all IP regimes, in Articles 13 (copyright), 17 (trademarks), 26 (industrial designs), and 30 (patents), with the aim of securing a fair trade-off between the interests of the rightsholders and users. Another "safety valve" was inserted in Article 8, which gives the Members the discretion to adapt measures necessary in sectors of vital importance to their socio-economic and technological development, provided that they are consistent with the Agreement.[305] It pertains to the wording of Article 7, which states that IP protection should contribute to the promotion, transfer, and dissemination of technology to the mutual advantage of producers and users, social and economic welfare, and to a balance of rights and obligations.

Critics nonetheless point to the strong pro-IP mechanisms incorporated in the Agreement, which impede the sensitive balance between producers and users.[306] Commentators reproach the industrialized countries for shaping the Agreement according to their interests, bent on enhancing and stimulating greater IP protection, although they themselves enjoyed much greater freedom at

[302] Egypt, Argentina, Brazil, Chile, China, Columbia, Cuba, Nigeria, Peru, Tanzania, Uruguay. Straus, "Bedeutung des TRIPS für das Patentrecht," reference No. 82.

[303] Rochelle Cooper Dreyfuss, "TRIPS-Round II: Should Users Strike Back?," *The University of Chicago Law Review* 71, no. 1 (2004); Carlos M. Correa, "The Role of Intellectual Property Rights in Global Economic Governance " in *Initiative for Policy Dialogue Working Paper Series* (New York Initiative for Policy Dialogue, 2011).

[304] Du Vall, *Prawo Patentowe*, 106; Hans Ullrich, "Technologieschutz nach TRIPS: Prinzipien und Probleme," *GRUR Int* (1995): 631-33.

[305] This provision opened the way to the Doha Declaration ("Declaration on the TRIPS Agreement and Public Health. Adopted on 14 November 2001," Doha WTO Ministerial 2001, WT/MIN(01)/DEC/2, (2001).

[306] Dreyfuss, "TRIPS-Round II: Should Users Strike Back?," 21.

earlier stages of development.[307] As commented by an Indian representative: "This piece of document is going to do maximum good to maximum countries (…)"[308] The practice shows that compliance with the TRIPS is extorted via economic means: industrialised countries impose pressure on developing countries by blocking technology transfer or applying other sanctions affecting the local economy (e.g. higher customs, import embargoes). The United States, for instance, lists the suspect countries on a "watch list" based on Section 301 of the Omnibus Trade and Competitiveness Act. It also pursues higher IP norms via bilateral free trade agreements introducing TRIPS Plus IP regimes, much tighter than in the US itself.[309] Considering the objective of the Agreement, i.e. the dissemination of technology and the promotion of innovations within the framework of an international trade system, and with the public and global welfare in mind, the execution of the Agreement remains controversial. In this context, the assessment of the implications of TRIPS, reinforced by negotiation history that was shaped mainly by industrialised countries, leads to the conclusion that IP protection is instrumentalized for the benefit of "the maximum countries" that steer international trade according to own interests.[310]

4.2.1 Limited Exceptions to the Effect of a Patent – Article 30 TRIPS

During the TRIPS negotiations, diverse proposals emerged on how to regulate the matter of exceptions included in Article 30. The European Commission proposed the exclusion of private and non-commercial use, along with experimental uses; later appended with the preparation of medicines, governmental uses, and prior use. The proposal concerned an exhaustive and closed catalogue of exceptions. The contracting states eventually rejected this concept in favour of an abstract formulation that was intended to serve greater flexibility in shaping patent limitations, and which should offer the Member States the widest possible discretion in determining the types and scopes of limitations according to their policies.[311]

---

307 Correa, "The Role of Intellectual Property Rights in Global Economic Governance " 4.

308 Straus, "Bedeutung des TRIPS für das Patentrecht," 182.

309 Cornish, Llewelyn, and Alpin, *Intellectual property*, 133; Du Vall, *Prawo Patentowe*, 103-04.

310 See Ullrich, "Technologieschutz nach TRIPS: Prinzipien und Probleme," 623-41.

311 Andreas Sasdi, *Innovationsschutz im Trips-Übereinkommen. Unter besondere Berücksichtigung der Arzneimittelbezogenen Aspekte der Rechte des Geistigen Eigentums* (Berlin: Duncker & Humboldt, 2004), 32; Martin Senftleben, "Towards a Horizontal Standard for Limiting Intellectual Property Rights? WTO Panel Reports Shed Light on the Three-Step Test in Copyright Law and Related Tests in Patent and Trademark Law," *International Review of Intellectual Property and Competition Law* 37, no. 4 (2006): 411; WTO, "Canada – Patent Protection of Pharmaceutical Products. Complaint by the European Communities and Their Member States," WT/DS114/R, (2000): 7.70-7.72.

Article 30 adopts the three-step test from the Article 9(2) of the Berne Convention[312] (intended for copyright law) and accommodates it to the prerequisites of patents. Its abstract character does not denote unrestricted flexibility in defining possible exceptions; a number of *limitations* (*steps*) are hidden in the provision that every exception introduced into a national system has to comply with.[313] The three criteria that qualify a given exception as lawful and acceptable, stipulate that an exception must be limited (1) and must not "unreasonably conflict with normal exploitation of the patent" (2), as well as must not "unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties" (3). Each condition constitutes a separate and independent requirement; however, all three conditions must apply cumulatively – failure to comply with one of them prohibits the application of the exception at question.[314] Article 30 was indispensable, as TRIPS vastly regulated the substantive law on patents. Like other provisions, the purpose and objective of the Article stay in accordance with Article 7 and 8.1 of the Agreement. However, like no other provision on patents in TRIPS, Article 30 serves the balance of rights and obligations and the mutual advantage of producers and users, as pronounced in Article 7. Considering the fact that it functions as "a yardstick" that all limitations adapted in domestic laws of countries, signatories of the Agreement, must comply with, it serves the named objectives globally.[315]

Notably, Article 30 broadens the scope of the three-step test from the Berne Convention by acknowledging the interests of third parties, but only in the third step, and simultaneously, already in the first step, it specifies the term of exception as a limited one. In other words, it sets an *ab initio* limitation to a limitation; this manoeuvre is all the more remarkable in light of the fact that exceptions *per se* are construed in a narrow manner.[316] Thereby, the initial formulation of the provision suggests that negotiating countries addressed the matter of exceptions with a great precaution, as if intentionally framing the minimum ambit possible for norms circumscribing the effects of a patent.

---

[312] "It shall be a matter for legislation in the countries of the Union to permit the reproduction of such works in certain special cases, provided that such reproduction does not conflict with a normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author."

[313] Senftleben, "Towards a Horizontal Standard," 411-12.

[314] WTO, "Canada – Patent Protection of Pharmaceutical Products. Complaint by the European Communities and Their Member States": 7.20-7.21; Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis*, 4th ed. (London: Thomson Reuters, 2012), 472; Viviana Munoz Tellez, "Dispute Settlement under the TRIPS Agreement: the United States-Brazil (2000) and United States-Argentina (2002) Patent Disputes," in *Research Handbook an othe Interpretation and Enforcement of Intellectual Property under WTO Rules*, ed. Carlos M. Correa (Cheltenham, UK: Edward Elgar, 2010), 243.

[315] Annette Kur, "Of Oceans, Islands, and Inland Water - How Much Room for Exceptions and Limitations under the Three-Step Test," *Richmond Journal of Global Law & Business* 8, no. 287 (2008-2009): 305.

[316] Gervais, *The TRIPS Agreement (2012)*, 472; Kur, "Of Oceans, Islands, and Inland Water," 311.

The practice, however, has revealed an imbalance and a double-standard policy in regard to forming legal tools: support for the expansion of IP protection (i.e. a stronger protection) and contempt for any attempt at reducing the scope of protection by introducing new derogations.[317] Despite the abstract formulation of the Article, the scope of TRIPS-conforming limitations appears to be exhausted. Limitations that comply with the Agreement existed in national systems long before the TRIPS and were determined by a legal tradition and practice[318], e.g. private and non-commercial use, prior use, experimental use, traditional exceptions for pharmacists, acts done on vessels (as in the Paris Convention in Article 5ter), and permissible agricultural uses. The cautious academic analyses of the three-step test for patents as construed by WTO[319] prove a narrow comprehension of the permissible and lawful ambit of exceptions, and emphasise the political considerations that significantly determine law construction under the auspices of an international organisation.

4.2.2 The Three-step Test for Patents

The interpretation of the patent three-step test was the subject of the WTO Dispute Settlement Panel report[320] in the case *Canada – Patent Protection of Pharmaceutical Products* (2000).

In this widely commented case, the European Communities (EC) challenged the provisions of the Canadian Patents Act: Section 55.2 (1) on *regulatory review exception* (allowing making samples for market permission) and 55.2(2), a *stockpiling exception* (allowing making and storing larger quantities of protected pharmaceuticals until the lapse of a patent). The EC argued that the named provisions of Canadian law contravened Articles 27.1, 28, 30, and 33 of the TRIPS Agreement.[321]

---

[317] Dreyfuss, "TRIPS-Round II: Should Users Strike Back?," 21.

[318] WTO, "Canada – Patent Protection of Pharmaceutical Products. Complaint by the European Communities and Their Member States": 7.70.

[319] Likewise for copyrights and trademarks, see Kur, "Of Oceans, Islands, and Inland Water."; Senftleben, "Towards a Horizontal Standard."

[320] The dispute settlement system of the WTO secures and clarifies the provision of the WTO agreements. Members direct their question mainly to the Dispute Settlement Body, the Appellate Body, panels and arbitration, which adopts reports in the questioned subjects. Decision taken have an informative character and are not binding.
See DSU Understanding on Rules and Procedures Governing the Settlement of Disputes or Dispute Settlement Understanding (DSU): Articles 2, 3, 3.2, 19.2

[321] WTO, "Canada – Patent Protection of Pharmaceutical Products. Complaint by the European Communities and Their Member States"; Pedro Roffe and Christoph Spennemann, "Canada- Patent Protection of Pharmacutical Products," in *Research Handbook on the Interpretation and Enforcement of Intellectual Property under WTO Rules*, ed. Carlos M. Correa (Chentelham, UK: Edward Elgar, 2010), 239-41; Kur, "Of Oceans, Islands, and Inland Water," 312.

The reasoning of the panel is extremely lengthy and repetitive. As commentators indicate, the issues addressed in the report were of high political concern, which was manifested in excessive character of the wording and "little substance" to extract.[322] They also point out that the Panel literally "measured" the exceptions and did not examine the motivation and policies underlying the limitations in light of the TRIPS objectives. Some shadows of policy re-thinking emerged in respect to the second and third criteria. However, that only concerned the limitations that passed through the sieve of the first requirement, as a result excluding provisions that could otherwise also bear significant social implications. In the end, quantitative features prevailed over their qualitative aspects, as if the Panel applied mathematical formulas. [323]

The following summary of the Panel's interpretation of the three steps highlights the core statements on each step and serves as a reference point in the further analysis of a proposal for a maker-related exception.

4.2.2.1 The First Step – Limited Exception

The phrase *limited exception* was split and each term was rendered a separate meaning.

In regard to the word *limited,* the Panel consented to the argumentation of the EC that the word connotes with words like "narrow, small, minor, insignificant, or restricted."[324] Canada opted for "a broader" understanding[325], which was unacceptable in light of its juxtaposition with the word *exception.* The Panel also agreed that *limited* must be measured by "the scope of curtailment of the patent rights." However, it does not suffice to enumerate the curtailed rights. As the first factor does not evaluate the economic impact, the extent of rights a given exception curtails must be determined, i.e. "to which extent the patent owner's rights to exclude 'making' and 'using' the patented product have been curtailed."[326]

---

[322] "Of Oceans, Islands, and Inland Water," 313.

[323] ibid., 316; Senftleben, "Towards a Horizontal Standard."

[324] Canada asserted that the word *limited* should be interpreted according to its conventional meaning, such as "confined within definite limits." In regard to the *stockpiling exception*, Canada argued that the provision did not affect the owner's exclusive right to commercial sale during the patent term, i.e. sale to the ultimate customer. Moreover, it had a time limit of six months and could be invoked only by the person that made, construed, or used the invention under Section 55.2(1).The EC argued that the exception took away three of the five rights provided in Article 28(1), i.e. the right to exclude *making, using,* and *importing,* and *c*hallenged the six-month period.
WTO, "Canada – Patent Protection of Pharmaceutical Products. Complaint by the European Communities and Their Member States": 7.27 -7.28.

[325] ibid., 7.27.

[326] ibid., 7.31.

Canada proposed the concept of a hierarchy of the exclusive patent rights; it suggested that the right to sell is the one that matters, indicating that *manufacturing* and *using* were of secondary significance.[327] The Panel rejected these arguments. It found the stockpiling exception to be a substantial curtailment to the exclusive rights of the patentee, as it did not impose any limits upon the quantity of production during the last six months of the patent term.[328]

The regulatory review exception was recognised as *limited* for its *narrow* curtailment of Article 28.1.[329] The Panel acknowledged the exception as narrow and limited because it confined the patent rights solely within the borders of the regulatory approval process. The production of the patented product for approval purposes did not prevent the patent holder from reaping commercial profits, because the production did not result in the merchandise of the products outside the claimed approval process.[330]

Although the first condition is considered as not bearing economic implications, the Panel already at this point admitted that the regulatory review exception could have a considerable economic impact. Without the regulatory review exception, the patent owner could extend the patent term by an additional period (even up to 6 years required to develop and obtain regulatory approval for a generic company), gaining an additional market exclusivity term. In that respect, the exception had a limited impact on patent rights.[331]

To summarize, the Panel delivered a double qualification of the term *limited exception*: the word *exception* indicates a narrow derogation of the granted right; the phrase *limited* additionally reduces its scope, resulting in a small diminution of patent rights. The extent to which an exception in question narrows the rights is a determinative factor. It cannot hinder the patent holder in pursuing business activities.[332]

---

[327] ibid., 7.33.
[328] ibid., 7.34, 7.36.
[329] At this point, Canada argued the exception to be found in other legislations, known as the *Bolar* exception. It was well-known during the negotiation of Article 30 and the States were aware that the given wording of the Article would permit the *Bolar* exception. Ibid., 7.42.
[330] ibid., 7.45.
[330] ibid., 7.48-49.
[331] ibid.
[332] Kur, "Of Oceans, Islands, and Inland Water," 314; WTO, "Canada – Patent Protection of Pharmaceutical Products. Complaint by the European Communities and Their Member States": 7.31.

4.2.2.2 The Second Step – Normal Exploitation

Since the stockpiling exception did not comply with the first exception, the panel examined the second criterion only with regard to the regulatory review exception.[333]

Again, the Panel first focused on the definitions of the terms. It stated that the term *normal* describes something that is "regular, usual, typical, ordinary, and conventional*".* It added that it could be depicted as: "empirical conclusion about what is common within a relevant community, and the normative standard of entitlement." The term *exploitation* was understood as a "commercial activity by which patent owners employ their exclusive rights to extract economic value from their patent."*[334]*

The Panel introduced even more ambiguity in regard to the interpretation of the term *normal* by accepting as a *normal practice* certain (extreme) acts that exclude "all forms of competition that could detract the economic returns anticipated from the patent exclusivity" – which warrants further explanations. The Panel admitted that no specific form of patent exploitation exists – exploitation results from technological developments and marketing practices that constantly change and evolve.[335]

The Panel returned to the argument of the prolonged exclusivity obtained by forbidding competitors to prepare for regulatory approvals. It admitted that post-patent exclusivity might be the natural consequence of a patent. However, it should not apply in fields where regulatory approvals are required to enter the market, like in the pharmaceutical sector. The time required would extend patent exclusivity far beyond the normal patent term (3-6 years). Meanwhile, fields in which products enter the market without specific certifications are not affected by the extension of patent exclusivity.

Here, the Panel found no conflict with normal patent exploitation, and justified the regulatory review exception in light of the patent policy.[336] Nonetheless, legal uncertainty remains, because no

---

[333] Canada argued that review exception did not conflict with the normal exploitation. It also took the view that exploitation concerns "extracting the commercial value from the patent" by selling the product, licensing it or selling the patent rights. The EC reasoned that the Canadian provision focused solely on one type of working the patent, namely the sale, exempting *making* and *using* from the patent protection. That was not correct, since patent rights encompass more types of behaviour: not only the right to exclude third parties from sales, but also the right to exclude them from making and using a patented product.
"Canada – Patent Protection of Pharmaceutical Products. Complaint by the European Communities and Their Member States": 7.51-53.

[334] ibid., 7.54.

[335] ibid., 7.55.

[336] ibid., 7.57.

clear boundaries of the term of normal exploitation were given, as a result of which it is explained and justified in various manners due to differences in legal traditions, practice, and national interest. However, the proposed interpretation of the term does not provide clarity, but instead raises further questions.

The term *reasonable* was not scrutinised, as the Panel found the compliance of the regulatory review provision with the second step. It underlaid only a theoretical discussion that, by reversing the term "reasonable limitation of a normal exploitation," should stay in accordance with important domestic policies, such as healthcare.[337] By the same token, the Panel left a lot of place for legal puzzles.

4.2.2.3 The Third Step – Legitimate Interest

The third condition is the most challenging, since it requires negative evidence, i.e. "an act must not unreasonably prejudice the legitimate interest of patent owner." There are two elements to be determined in this regard: 1) the legitimate interests of the patent owner and 2) unreasonable prejudice of these interests in light of the legitimate interest of third parties (in other words, a reasonable limitation considering the interests of third parties).[338]

This step involves similar considerations as the second criterion. The question was whether the production and use of a patented product for regulatory approval and the rejection of "prolonged" exclusivity from the patent owner that he or she could have enjoyed if making and using were not constricted, rest within the legitimate interest of the patent holder.[339]

The Panel defined the term *legitimate interest* as used in legal discourse: "a normative claim calling for justifiable protection of interest, which supports relevant social and public policies." An example of an exception that complies with this (convoluted) requirement is an experimental exception that supports key public policies: technical development and knowledge transfer.[340]

Canada claimed that the patentee had no right to extend the period of protection beyond the prescribed period: "the interest of a patentee of pharmaceutical invention can be no different from those of patentees in other fields of technology." It argued that societal interest and health policy

[337] Kur, "Of Oceans, Islands, and Inland Water," 318-19.
[338] WTO, "Canada – Patent Protection of Pharmaceutical Products. Complaint by the European Communities and Their Member States": 7.60.
[339] ibid., 7.61.
[340] ibid., 7.69.

were within the ambit of third parties' legitimate interest.[341] The Panel accepted Canada's argumentation.

The Panel also highlighted the practice of granting a prolonged (additional) protection period with the aim of compensating the pharmaceutical companies for the delay and shortening of patent exclusivity that was adopted only in some countries. However, the Panel did not elaborate further on this politically sensitive subject matter and remained by the point that the reduced patent term was not to the detriment of the legitimate interest of the patent holder.[342]

4.2.2.4 Concluding Thoughts

The Panel pronounced a restrictive interpretation of the three-step test, accepting exceptions that provide a small diminution of the patent rights and concern specific uses. If the curtailment is substantial, i.e. embraces various forms of patent exploitation, it falls out of the lawful scope already in the first step. A normal exploitation of a patent pertains to activities that concern commercial uses with the aim of extracting economic value from the patent.[343] Therefore, one could think that uses of patented solutions that do not affect the commercial uses are lawful – it is so, for instance, in the exception for private and non-commercial uses. However, such uses are only permissible if they represent a small diminution of the rights (as stipulated in the first step, and as in the named limitation). The interests of third parties which concern motivation and public policies underlying a given exception are unfortunately considered at the very end of the process, if they are considered at all.

4.3 The European Catalogue of Exceptions

The catalogue of exceptions proposed during the TRIPS negotiations, was based on the catalogue of limitations stipulated in the Community Patent Convention (CPC) in Article 31 (the 1975 version), which had been adapted in the national systems of the Member States within the harmonisation measures to establish a single patent regime in Europe.

The patent unification efforts constitute a significant chapter of the EU history, as the desire to establish a unitary patent system for the entire European Union has been as old as the Union

[341] ibid., 7.66-67.
[342] ibid., 7.82-83.
[343] ibid., 7.76.

itself.[344] Exertions to give this wish a genuine form have taken more than half of the century (and will still take a fair bit of time until completion). The legislative activities succeeded in a sinusoidal manner, with frequent tides of intense political disputes, followed by silent works on further proposals, amendments, and regulations.[345] The necessity of a single patent and court system was clear: the European market is not as competitive and alluring as the US or Japanese markets, with one reason behind this fact being a fragmented patent system.[346] The creation of a single patent for the entire territory of the European Community (i.e. an equal protection scope, single enforcement, licensing schemes for all participants, and an autonomous legal system) was intended to assist the principle of the free movement of goods (protected by patents) – one the four basic freedoms of the European Community.

The process evolved in two directions: 1) the creation of a Community patent available only for the Member States of the European Communities, and 2) establishing a European Patent that non-Community Members could also apply for. To implement these goals, in the 1970s interested countries singed special conventions: the Convention for the European Patent for the common market signed in Luxembourg on December 15 1975 (the CPC), and the European Patent Convention singed in Munich on October 5 1973 (the EPC) that established the European Patent Organization.[347] (The CPC was to remain within the EPC system that governed patent prosecution). The ratification process ended successfully only for the EPC (1977), with the establishment of a system of unified patent registration and examination, which nonetheless preserved the regime of separate national patents (a bundle of national patents). The ratification of the CPC did not go that swimmingly as one would wish: the Convention had to be ratified by all nine Community Members, but Denmark and Ireland objected to it, leaving the CPC out of force.[348] Despite that misfortune, further attempts to calibrate the framework for the Community patent were undertaken: in 1985

---

[344] In 1949 the French senator Henri Longchambon proposed the introduction of a single Europe-wide patent system. See Henri Longchambon, "Creation of a European Patent Office," in *Report of the Committee on Economic Affairs and Development of the Council of Europe* (6 Septemeber 1949); from Pieter Callens and Sam Granata, *Introduction to the Unitary Patent and the Unified Patent Court. The (Draft) Rules of Procedure of the Unified Patent Court* (The Netherlands: Kluwer Law International, 2013), 7.

[345] A tabular presentation of major steps in Reto Hilty et al., "The Unitary Patent Package: Twelve Reasons for Concern," *Max Planck Institute for Intellectual Property & Competition Law Research Paper*, no. 12-12 (2012); see also Stefan Luginbühl, "Das europäische Patent mit einheitlicher Wirkung (Einheitspatent)," *GRUR Int.* (2013); Matthias Brandi-Dohrn, "Some Critical Observations on Competence and Procedure of the Unified Patent Court," *IIC* (2012).

[346] Alan Johnson and Philip Westmacott, "Europe Has Spoken: Now It's Up to the Judges," *Intellectual Asset Management*, no. 57 (March/April 2013): 11.

[347] 1) The Convention for the European Patent for the common market (or Community Patent Convention, herein: CPC) signed in Luxemburg on December 15, 1975, 2) the European Patent Convention singed in Munich on October 5, 1973.

[348] Callens and Granata, *Introduction to the Unitary Patent and the Unified Patent Court. The (Draft) Rules of Procedure of the Unified Patent Court*, 8.

and 1989[349]. However, again with a little ratification success – language requirements and the (controversial) patent litigation system remained outstanding issues.[350]

Yet although the CPC has never entered into force, it had an immense impact on substantive patent laws in the Member States of the European Communities. With a view to ratifying the CPC, the countries-signatories adopted provisions implementing the CPC (rights, limitations, and obligations) within their domestic systems.[351] The CPC comprehensively regulated patent matters pertaining to exclusivity (Articles 29-32), property aspects (Articles 39-43), and compulsory licensing (Articles 46-48) (CPC 1975). The catalogue of limitations in Article 31 included private and non-commercial use, experimental use, the preparation of medicines, and permissible uses of patented subject matters on vessels, aircrafts, and vehicles to safely continue their operations (after the Paris Convention Article 5ter and Article 27 of the Convention on international civil aviation of 7 December 1944).

The process of unifying the patent system in Europe did not stop. After many pitfalls, the Council decided to apply the instrument of enhanced cooperation in order to give the process a desired momentum.[352] The new cooperation framework resulted in the adoption of two regulations:

---

[349] The Agreement relating to Community Patents and to Jurisdiction. See Brandi-Dohrn, "Some Critical Observations on Competence and Procedure of the Unified Patent Court."

[350] National courts were to decide on the validity of a Community patent, with the possible outcome of a judgement in one country nullifying a Community patent for the entire territory of the Community. Additionally, it was contested that lengthy procedures in some national systems could impede patent procedures.
Thomas Terrell and Editors, *Terrell on the Law of Patents*, 17 ed. (London: Sweet & Maxwell, 2011), 19-20; Luginbühl, "Das europäische Patent mit einheitlicher Wirkung (Einheitspatent)," 305.

[351] E.g., Section 11 of the German Patent Act, Section 60 (5) of the UK Patents Act 1977, Article 53 (3) of the Dutch Patent Act 1995. See Henrik Holzapfel, "Die patentrechtliche Zulässigkeit der Benutzung von Forschungswerkzeugen," *GRUR Int* 10(2006): Fn. 5.

[352] The principles of enhanced cooperation are laid down in Article 20 TFEU. The Commission submitted a proposal on enhanced cooperation in December 2010, which was later approved by the Council. See "Proposal for a Council Decision Authorizing Enhanced Cooperation in the Area of the Creation of Unitary Patent Protection ", European Commission, COM (2010) 790, 2010/0384, 14 December 2010; "COUNCIL DECISION of 10 March 2011 authorizing enhanced cooperation in the area of the creation of unitary patent protection (2011/167/EU)," Official Journal of the European Union, L 76/53, 22.3.2011.
Spain and Italy contested this move on the ground of the misapplication of the procedure requirements in light of Article 118 TFFU. The matter was much more nuanced and delicate. Apart from strictly legal reservations, the two countries did not accept the language regime, since they recognized their languages as being of the same importance as French and German. (No reservations were made against English, recognized as the language of science and technology). National economic interests were involved here as well. The CJEU dismissed the applications.
See *Kingdom of Spain v. Council of the European Union* Case C-274/11; *Italian Republic v. Council of the European Union*, Case C-295/11; *Judgment of the Court (Grand Chamber) of 16 April 2013 in Joined Cases C-274/11 and C-295/11*.
Two other actions are currently pending against two Regulations (No 1257/2012 and No 1260/2012) – *Kingdom of Spain v Council of the European Union*, Case C-147/13; *Kingdom of Spain v European Parliament and Council of the European Union*, Case C-146/13.

Unitary Patent Regulation[353] and Translation Regulation[354].[355] Another landmark step was signing on February 19 2013 the Unitary Patent Court Agreement (the UPC Agreement), which established a unitary court system for participating EU-Members (a third pillar of the EU-patent system, next to the two regulations).[356]

The long-awaited unitary patent resembles a hybrid – it is comprised of four documents: the two regulations, the UPC Agreement and the EPC.[357] Article 24 of the Agreement defines the hierarchy of the sources, bestowing superiority to the EU regulations, followed by the Agreement, the EPC, and other international agreements and national laws[358] that cover diverse matters. For example,

---

Callens and Granata, *Introduction to the Unitary Patent and the Unified Patent Court. The (Draft) Rules of Procedure of the Unified Patent Court*, 12-13; Thomas Jaeger, "Shielding the Unitary Patent from the ECJ: A Rash and Futile Exercise," *IIC* (2013): 389; Matthias Lamping, "Enhanced Cooperation – A Proper Approach to Market Integration in the Field of Unitary Patent Protection?," ibid.(2011); Rudolf Teschemacher, "EU - Unitary Patent / Actions Spain and Italy Against Enhanced Cooperation Dismissed," http://www.eplawpatentblog.com/eplaw/2013/04/eu-unitary-patent-actions-spain-and-italy-against-enhanced-cooperation-dismissed-.html, accessed 22.01.2014.

353 "REGULATION (EU) No 1257/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection ", Official Journal of the European Union L 361/1, 31.12.2012.
The Regulation represents a *special agreement* in the light of the Article 142 of the EPC: "a special agreement that settles a European patent with a unitary character throughout the territories of contracting States, may provide that a European patent may only be granted jointly in respect of all those States." The EU would access first the EPC in order to grant EU-Patents under the EPC jurisdiction. Furthermore, the Regulation represents a regional patent agreement within the meaning of Article 45(1) of the PCT.
Callens and Granata, *Introduction to the Unitary Patent and the Unified Patent Court. The (Draft) Rules of Procedure of the Unified Patent Court*, 21; Jaeger, "Shielding the Unitary Patent from the ECJ: A Rash and Futile Exercise."

354 "COUNCIL REGULATION (EU) No 1260/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements," Official Journal of the European Union L 361/89, 31.12.2012.

355 Brandi-Dohrn, "Some Critical Observations on Competence and Procedure of the Unified Patent Court," 374.

356 The UPC Agreement is neither an EU-document, nor an EU-treaty; it is an international agreement between the EU Member States and requires ratification by at least 13 countries, including Germany, France, and the United Kingdom.
Prior to the UPC Agreement, the legal status of the proposed court system was contested on the grounds of its compatibility with the EU law. The interested parties were on hold for almost two years. Eventually, the Court confirmed the incompatibility and presented certain improvements, which were amended in accordance with the later (singed) version of the Agreement.
Opinion of the Court (Full Court) of 8 March 2011, Opinion 1/09.The application from 6 July, 2009; Callens and Granata, *Introduction to the Unitary Patent and the Unified Patent Court. The (Draft) Rules of Procedure of the Unified Patent Court*, 51; Winfried Tilmann, "Das Europäische Patentgericht nach dem Gutachten 1/09 des EuGH," *GRUR Int.* (2011); Jaeger, "Shielding the Unitary Patent from the ECJ: A Rash and Futile Exercise."

357 An engaging work on this subject-matter: "Hieronymus Bosch am Werk beim EU-Patent? Alternativen zur Einheitspatentlösung," *EuZW* (2013).
A theoretical scenario of a patent litigation under the UPC in Johnson and Westmacott, "Europe Has Spoken: Now It's Up to the Judges," 17-21.

358 Maximilian Haedicke, "Rechtsfindung, Rechtsfortbildung und Rechtskontrolle im Einheitlichen Patentsystem," *GRUR Int.* (2013): 612.

patentability requirements follow the provisions of the EPC (accordingly, the EPO will examine and grant the EU-Patent as stipulated in the EPC). [359] The UPC Agreement addresses the substantial law in terms of the direct and indirect use of an invention, as well as limitations to the effect of a patent. The latter were initially provided in Regulation 1257/2012; however, after multi-party discussions, they found their place in the UPC Agreement to assure greater uniformity of the new law.[360]

Legal questions surrounding the creation of the UPC and the transfer of a vast part of substantive law to its competences stirred broad debates. As commentators indicate, the EU legislator chose a rather complicated and unusual technique to establish the Unitary Patent. In that regard, it was questioned whether European law could be subjected to the construction under the auspices of an international court – the Unified Patent Court – with the aim of harmonizing EU law processes via international law.[361]

Furthermore, the proposal of enclosing substantive law in the Regulation has been met with the fire of critics concerned with the quality of judgements delivered by the Court of Justice of the European Union (the CJEU) in matters of intellectual property (like trademark law). It was claimed that patent law, a complex legal field, should be subjected to the competences of a specialised court (a standard practice in most countries). Ultimately, the interested parties did their best to

---

[359] The tasks of the EPO in Callens and Granata, *Introduction to the Unitary Patent and the Unified Patent Court. The (Draft) Rules of Procedure of the Unified Patent Court*, 23, 34-36.

[360] The transfer of substantial law into the UPC Agreement concluded intense debates on the aspects of the Unitary patent law that would remain within the competences of the CJEU. Commentators objected to the assignment of substantive law matters to the CJEU. They argued that the possible flood of preliminary rulings and, consequently, enormous delays together with substantial costs, would impede the effective enforcement of the unitary patent law; in a long term, it could also affect the EPC system itself. As argued by Prof Krasser, the CJEU as " a constitutional court should not be obliged to address individual issues in a specialized field, which above that can be hardly answered withour the assistance of technical experts." That mistrust was criticized in light of the oeuvre of the CJEU and the indisputable contribution in the success and stability of the EU legal framework.
Rudolf Kraßer, "Auswirkungen einer Einbeziehung von Vorschriften über Inhalt und Grenzen der Verbietungsrechte des Patentinhabers in eine EU Verordnung zur Schaffung eines einheitlichen europäischen Patentschutzes " (EPLAW Patent Blog1.11.2011); Callens and Granata, *Introduction to the Unitary Patent and the Unified Patent Court. The (Draft) Rules of Procedure of the Unified Patent Court*, 26-31; Jaeger, "Shielding the Unitary Patent from the ECJ: A Rash and Futile Exercise."; Haedicke, "Einheitliches Patentsystem," 614; Jochen Pagenberg, "Unitary Patent and Unified Patent Court - Resolution,"
http://www.eplawpatentblog.com/2011/November/EPLAW%2020Resolution%2020on%2020Regulation%202029%2020Oct%20202011%5B1%5D.pdf, accessed 22.01.2014; "EPLAW - The Unified Patent Court: EPLAW Resolution on the Draft Agreement," ibid. http://www.eplawpatentblog.com/eplaw/2011/09/eplaw-the-unified-patent-court-eplaw-resolution-on-the-draft-agreement.html, accessed 23.01.2014; "DIRECTIVE 2004/48/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on the enforcement of intellectual property rights. (Text with EEA relevance)," Offical Journal of the European Union L 195/16, 2.6.2004.

[361] Jaeger, "Shielding the Unitary Patent from the ECJ: A Rash and Futile Exercise," 390.

avoid the jurisdiction of the already much-mistrusted CJEU.[362] Professor Rudolf Krasser expressed the opinion that the CJEU as a "constitutional court of the EU" should not be obliged to address questions (prejudicial questions) in a specialised field.[363] The exact role of the CJEU in the unitary system remains unclear. The courts of first instance, i.e. central[364], local, and regional divisions, as well as the Court of Appeal in Luxembourg, may direct questions on the interpretation of EU law to the CJEU. Hence, the CJEU may decide upon elements of EU law incorporated in the unitary regime like the EU-Biotech directive or supplementary protection certificates.[365]

The catalogue of patent limitations provided in Article 27 is based on the CPC catalogue that was appended with the later-enacted corresponding exceptions. The extensions of the catalogue derive from the EU Law: 1) Directive 2001/82/EC[366] and Directive 2001/83/EC[367] in Article 27d – the *Bolar* exception; 2) Regulation 2100/94[368] in Article 27l – the multiplication of harvest for agricultural uses, 3) Directive 2009/24/EC[369] in Article 27k – interoperability. Notably, the principle of exhaustion of rights, well-founded within the EU-regime, enjoys double security: it appears in Article 29 of the Agreement, and in Article 6 of the Unitary Patent Regulation. To the surprise of many, important instruments like compulsory licensing and the prior use right remained within the jurisdiction of the national law of Member States.[370] The countries ought to decide now whether to adjust their national law to the unitary patent system or establish two parallel norms for two regimes on the same subject matter.[371] The question of norm interpretation remains open. Since the CPC has never entered into force, the CJEU has never opined on the scope of exceptions (and will not do so in the future).[372] The UPC Agreement constitutes a foundation for the Unified Patent Court (the UPC) that will be in charge of constructing norms. It is certain that the UPC will decide in

[362] ibid.; Matthias Eck, "Europaeisches Einheitspatent und Einheitspatentgericht - Grud zum Feiern?," *GRUR Int* (2014): 116.
[363] Kraßer, "Auswirkungen," 7.
[364] Paris, Munich, and London.
[365] Rainer Kuhnen, "The Proposed Structure of the Unified Patent Court System in Europe," *Patents in Europe 2015/2016. Helping business compete in the global economy* (2014): 28; Johnson and Westmacott, "Europe Has Spoken: Now It's Up to the Judges," 12.
[366] "DIRECTIVE 2001/82/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 November 2001 on the Community code relating to veterinary medicinal products," Official Journal of the European Communities L 311/1, 28.11.2001.
[367] "DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 November 2001 on the Community code relating to medicinal products for human use," Official Journal of the European Communities L 311/67, 28.11.2001.
[368] "COUNCIL REGULATION (EC) No 2100/94 of 27 July 1994 on Community plant variety rights."
[369] "DIRECTIVE 2009/24/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 April 2009 on the legal protection of computer programs," Official Journal of the European Union, L 111/16, 5.5.2009.
[370] Recital 10 of the Preamble of the Regulation 1257/2012 provides that national laws of Member States govern the regime of compulsory licensing. The same concerns the prior user rights, pursuant to Article 28 of the Agreement.
[371] Haedicke, "Einheitliches Patentsystem," 611.
[372] Kraßer, "Auswirkungen," 8.

all patent cases concerning both unitary patents and European patents. The Court will have competences in respect to patent infringement, patent revocation, and prior use of the invention (pursuant to Article 32). When the unitary patent comes into force (probably in 2016), it is only a matter of time before respective case law is carved out under the Unified Patent Court. The question is how much time has to pass before the Court makes significant decisions in this regard.

Forming a unified construction line for each exception will definitely be hard work, since it should be compatible with the current practice of the national courts, whether *liberal* or *conservative,* and unify all discrepancies. In that regard, the experimental use exception serves as a good example: German courts are considered to be "liberal" (i.e. exempt more uses under the national provision for experimental use, recognising commercial purposes), whereas Dutch courts are seen to render "conservative" judgements.[373] The input goes both *downwards*, i.e. from the EU level to national laws, and *upwards*. Certain terms of the EU-Patent must be determined *per analogiam* to national laws. Again, experimental use illustrates this matter well: the wording of Article 27(b) is the same as in the corresponding German provision (Section 11 (2) of the German Patent Act). Most probably, German court decisions will serve as significant guideposts in determining the scope and meaning of the provision. However, it remains an open question whether the German understanding will gain Europe-wide recognition.[374] So far, only the exhaustion principle, which is a well-established principle at the European level, stays firm within the given framework. In questions on the exhaustion for a unitary patent, the decisions of the ECJ shall be taken into account[375]; likewise, with regard to terms adopted form the EU law, e.g. the term *biological materials* corresponds to the term *Biopatent* from Directive 98/44/EC[376], or to the term *medicine* from Regulation 2001/83/EC.[377] The UPC as an international court is expected to make autonomous decisions, though it is impossible for the court to detach itself from established patent practice entirely.

The unification of the patent system did not cover certain instruments, such as compulsory licensing and prior use. Scholars claim that this exclusion appears to be inconsistent with the whole concept of a unitary patent: not only does it introduce a great portion of imbalance into the system, but also denotes a certain dose of misconception. If the creators of the unitary patent aimed at establishing a tool for promoting innovation and an effective market, they deprived it (and the

[373] Haedicke, "Einheitliches Patentsystem," 611.
[374] ibid., 614.
[375] ibid., 613.
[376] "DIRECTIVE 98/44/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 July 1998 on the legal protection of biotechnological inventions".
[377] "Einheitliches Patentsystem," 612.

public) of a unified protective measure for dependent inventions.[378] However, one should not forget that an instrument of compulsory license does not bear any practical implications – compulsory licenses are rarely granted, *if ever*. The same goes for the prior use right. European patent practice does not reveal an urgent need for the aforementioned tools to be harmonised within a unitary framework. Non-EU countries may address this issue with different EU-mechanisms. It seems the legislators have chosen a pragmatic approach and excluded this delicate matter from the unitary agenda.

There are still more questions than answers in regard to the unitary patent, because the system and its mechanisms must first be set in motion in order to observe and asses its pros and cons in practice. Certainly, the unitary system needs time to achieve its full operational shape. For the time being, patent practitioners and users must become acquainted with its features to make the correct (business) decisions: consider prosecution costs and all possible litigation scenarios. Legally and logistically, the unitary system is still a puzzle. Anxieties over the new form are all the more understandable in light of the fact that it introduces a further complexity layer to the existing models of European and national patents in Europe.

4.4 General Profiles of the Compared Patent Systems

The two European countries selected for the comparison, Germany and the UK, demonstrate many commonalities in their models of patent protection. As EU Members and active lawmakers on the international level, the two countries have legal systems with the same legal foundations, i.e., the EPC, the PCT, the TRIPS, the Strasbourg Convention, and the CPC, as well as provide similarly broad catalogues of exceptions. The CPC with its catalogue of patent limitations, though never enforced, affected the scope of protection in both systems, which have transposed its regulations into national orders for the purpose of further harmonisation with the EU law (and among the EU Members).[379]

In Germany, the patent system is governed by the Patent Act of 1981. The protection of intellectual propriety is further guaranteed in Article 14(1) of the Basic Law[380] that safeguards private property, and patents are recognised as such. The scope of the patent is curtailed in Article 14(3) when the public interest is at stake: “expropriation shall only be permissible for the public good.” Since

[378] Hilty et al., "The Unitary Patent Package: Twelve Reasons for Concern," 3.
[379] Kraßer, *Patentrecht*, 71.
[380] The Basic Law of the Federal Republic of Germany, 1948 [Grundgesetz für die Bundesrepublik Deutschland].

patent law serves society by fostering innovation and providing access to its fruits, the diminution (not the expropriation) of the patent right secures the trade-off between the patent holder and the third parties (accepted in light of Article 5(3)).[381] This finds its expression in Sections 9 and 10 of the Patent Act, defining the scope of patent protection, directly followed by Section 11, which stipulates limitations to the effect of a patent, and Section 12, which provides the prior use right.[382]

The UK patent system is regulated in the Patents Act of 1977, which is regarded as "the most complex piece of patent legislation ever enacted in the United Kingdom."[383] The enacted law was the answer of the British legislator to international legislative initiatives: the CPC, the EPC, and the PCT, and was followed by the adoption of subsequent international measures.[384] That harmonisation was triggered by ongoing changes in the industry, in the course of which IP protection was uplifted to an important aspect of business. Like in the German system, the scope of protection was balanced with the catalogue of limitations.

As an outcome, the Patents Act vastly regulates patent exceptions in Section 60(5) (following Articles 29-31 of CPC); and envisages the doctrine of exhaustion in Section 60(4) (pursuant to Article 81 of CPC).[385]

US patent law has a long legal tradition, with the first Patent Act being enacted in 1790 (the first in the world). Further legislation processes were eventful and dynamic. They were governed by the jurisprudence, which construed terms and established doctrines. The US patent system is anchored in the constitutional declaration on the protection of intellectual property (Article 1 Section 8), which proclaims the promotion of "the progress of science and useful arts by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."

Modern patent law is codified in Title 35 of the United States Code (35 U.S.C.) and grounded in the Act of 1952, which has been amended several times. A recent major modification took place in 2011 by enacting the America Invest Act (AIA)[386] that converted the US system from first-to-invent (existing until then only in the US) into first-to-file, what affected the whole system in numerous

---

[381] Tobias Timmann, *Das Patentrecht im Lichte von Art. 14 GG*, vol. 22, Geistiges Eigentum und Wettbewerbsrecht (Tubingen: Mohr Siebeck, 2008), 203-41.

[382] Roman Sedlmaier, *Die Patentierbarkeit von Computerprogrammen und ihre Folgeprobleme* (Munich: Herbert Utz Verlag, 2004), 223.

[383] Edward Armitage, "The New British Patent Legislation," *IIC* (1978): 207.

[384] ibid.

[385] ibid., 214.
"Section 130(7) stated that section 60 of the Patent Act 1977 was framed as to have as nearly as practical the same effect in the United Kingdom as the corresponding provisions of inter alia the Community patent Convention has in other Convention countries."
Smith Kline & French Laboratories Limited v. Evans Medical Limited, [1989] 1 F.S.R. 513, 523.

[386] *Leahy–Smith America Invents Act*.

ways.

Patent exceptions are seen as an inevitable necessity which safeguards important public policies:

> However, the real life imposed on the patent system the necessity to establish any kind of exemption for unlawful but socially beneficiary uses.[387]

However, 35 U.S.C stipulates patent limitations to a limited degree. Apart from the experimental use exception ("safe harbour") under Section 271(e)(1) and prior use provided in Section 273, the Act does not account for other tools similar to those seen in the presented European systems. The judicial doctrines supplement the picture with measures such as a repair doctrine or reverse doctrine of equivalents.

Learning from the best – that seems to be the Japanese patent[388]:

> We have looked about us to see what nations are the greatest, so that we can be like them. We said, 'What is it that makes the United States such a great nations? And we investigated and found that it was patents, and we will have patents.[389]

Throughout the last two centuries, French, German[390], English, and American legal institutions have shaped the current Japanese legal system. Japan offers a European-Anglo-American mix flavoured with Japanese practise derived from local culture, tradition, and comprehension.[391] The same spirit is reflected in the patent system which, while harmonised with international patent regulations, nonetheless managed to preserve the Japanese mindset.[392]

In Japan, patent-related matters are governed by the Japanese Patent Act (JPA) of 1959. The civil procedure law and the civil code are relevant sources in patent litigations, with jurisprudence contributing significant input to patent-law-making.[393] The patent exceptions have accordingly two sources: Article 69 of the Patent Act and the legal doctrine of permissible repair.

---

[387] *The House Report: H.R. Rep. No. 98-857 at 30 (1984), 1984 USCCAN 2714 fromIntegra Lifescience I, Ltd v. Merck KgaA, The Scripps Research Institute, 331 F.3d 860, *875 (2003).*

[388] Small inventions boosted Japan's technological success. Furthermore, Japan learned and improved foreign technology to overshadow previous "idols" and competitors. Rahn stresses the *intangible psychological factor strengthened* by the pro-IP policy that significantly contributed the success. See Guntram Rahn, "The Role of Industrial Property in Economic Development: The Japanese Experience " *IIC* (1983): 478-92.

[389] "Recht und Rechtsmentalitat in Japan," *Reihe Japanwirtschaft* 11(1981): 7.

[390] Bifurcated proceeding: the infringement proceeding at the civil court, the invalidation at the JPO. *Kilby 3*, Supreme Court vom 11.04. 2000 Hei 10 (O) 364, IIC 2004, 91, 95.

[391] "Recht und Rechtsmentalitat in Japan," 7-8.

[392] "The Japanese Experience," 449-92; Shozo Uemura and Hiroshi Kato, "Japan's History of Intellectual Property Policy and Patent Act," in *Patent Practice in Japan and Europe. Liber Amicorum for Guntram Rahn*, ed. Bernd Hansen and Dirk Schlussler-Langeheine (Aplhen, the Netherlands: Wolters Kluwer, 2011), 68.

[393] Eiji Katayama, *Japanese Patent Litigation* (Eagan, MN: West, 2009), 12.

4.5 Statutory Limitations

4.5.1 Private and Non-commercial Use

Limitation of private and non-commercial use constitutes one of the fundamental patent exceptions; it was conceived as far back as in the Paris Convention and is traditionally recognised in every patent regime. When we consider that patents are instruments which regulate the use of patented subject matter in the public and commercial domains, the exclusion of the private and non-commercial sphere appears a logical consequence of the application of law. Theoretical justifications for patents, such as the reward theory, accentuate that the economic implications of the private use of patents (investment recoup, remuneration) that do not have any commercial implications must stay free from the effects of patent monopoly. Furthermore, it would be unfeasible for patent owners to control the use of patented solutions by end-users and to force them to conduct research on the permissible scope of use for the given patented solution.

The German Patent Act stipulates the exception in Section 11(1). It covers two inseparable premises, i.e. private use and non-commercial exploitation – the exclusion of one makes the provision inapplicable. The underlying concept bespeaks that patents as instruments of public commerce cannot intrude on and regulate the private sphere, as this was not the purpose they were made for. Furthermore, an individual is released from the obligation to conduct patent due diligence before applying a product privately at home.[394]

The provision has a precise application scope and a defined target-group, i.e." individuals conducting acts upon the patented article privately." The first condition, *private use,* concerns acts performed within the private sphere (alone or with family), within individual sport activities, or for private or personal purposes.[395] The second criterion concerns the lack of economic profits from the utilisation of the patented solution – individuals exploiting patented articles in private, but generating income from the use, cannot shelter under the provision.[396] For example, a student who builds a patented device as part of their academic assignment, or downloads software for the same purpose, can refer to this section. The assistance of a neighbour, however, is questionable even when unpaid, since such assistance leaves the narrow ambit of permissible personal use and serves

[394] Sedlmaier, *Die Patentierbarkeit*, 225.
[395] Kraßer, *Patentrecht*, 786; Benkard and Editors, *Patentgesetz*, §11 at 3.
[396] An illustration: if one furnishes an apartment to rent (commercial character) with a patented object, e.g. a lamp, they infringe the patent. If, on the other hand, the exemplary lamp lightens one's private apartment, there is not patent infringement. Kraßer, *Patentrecht*, 786.

satisfying the needs of others.[397] Likewise, non-profit organizations, institutions, schools, and hospitals do not fall within the scope of the provision due to activities *coram populo*. The same concerns freelancers, e.g. attorneys and architects, who fall outside the exception due to the fact that in the pursuance of their profession, they exploit patented devices on a commercial basis.[398] Another illustration would be software made for private purposes, which supports other programs, e.g. open source software. Here, the private relation is automatically denied, because the use leaves the personal use sphere and is delivered outside to the *open* public. Invoking the Section in such cases is considered an abuse of the privilege.[399] However, no infringement occurs when the object purchased or produced for private and non-commercial purposes is re-sold.[400]

In the UK, this matter is regulated in Subsection 60(5)a, which is a verbatim implementation of the corresponding provision of the CPC.[401] The case law delivers interesting examples, including enterprises that invoke the aforementioned exception to protect and defend their business interests (unacceptable in the German system).

In *Smith Kline v. Evans,* Evans Medical, a long-standing pharmaceutical company, argued for the right to use the protected substance, i.e. to conduct in-house experiments that resulted in producing another patented substance, for private and non-commercial purposes.[402] The Court construed the provision as follows:

1) The term *privately* shall be understood conversely to the term *publicly*. Private use denotes an act done for a personal use. This includes both *secret* and *confidential* acts. The most crucial feature is the non-public character of an act.
2) The purpose of such acts requires a non-commercial motivation and outcome: "the word 'commercial' does not need the explanation and clearly includes any commercial

[397] Section 10(3). Benkard and Editors, *Patentgesetz*, §11 at 3; Sedlmaier, *Die Patentierbarkeit*, 225.

[398] *Glatzenoperation [Baldness treatment]*, BGH 26. 9. 1967 - I a ZB 1/65, NJW 1968, 197, 200; Benkard and Editors, *Patentgesetz*, §11 at 4.

[399] Sedlmaier, *Die Patentierbarkeit*, 225.

[400] Kraßer, *Patentrecht*, 785-86.

[401] Article 31 (a) of CPC:
"The rights conferred by a Community patent shall not extend to: (a) acts done privately for non-commercial purposes."

[402] *Smith Kline & French Laboratories Limited v. Evans Medical Limited*.
The plaintiff, Smith Kline & French Laboratories, sued the defendant for the infringement of three patents, all referring to the drug known as cimetidine. The three patents involved the Generic patent, the Master patent, and the Polymorph patent. The defendant, Evans Medical, acquired licenses of rights to the first two of them. The third patent, the Polymorph patent, was not available under licensing conditions. The plaintiff applied to amend the Polymorph patent what the defendant opposed in the course of in-house experiments: the results of tests on the master patent led to a product falling within the Polymorph patent.

purpose."[403] (The border between commercial and non-commercial purpose blurs when acts change their character in the course of operation.)

In the case in question, *Evans Medical* claimed that the purpose of experiments was *private*, but confirmed that the information could have been of commercial use. The Court asserted that the subsection applies even if the information obtained via experiments might eventually lead to commercial application. However, if the act has a hidden commercial purpose, the subsection does not exclude liability for patent infringement. *Evans Medical* argued that the sole purpose of the experiments was the preparation of the evidence for the amendment proceeding, and hence they were of private character (!). *Smith Kline* opposed this argumentation and asserted that the experiments had a dual purpose: 1) the collection of evidence for the proceeding, 2) the collection of commercial experience. The Court found that the scale and nature of the experiments suggested that they indeed had commercial motivation, because they intended to provide the company with a head start in applying for a license of right.[404]

In another case, *McDonald v Graham*[405], the Court confirmed the presented course. In the case, the defendant kept and used the promotional Z-Cards (patented as foldable sheet material) for the purposes of his business. In reference to an earlier case, *Smith Kline v Harbottle,* the Court acknowledged *keeping* as stocking goods for sale: "a keeping in some capacity and for a purpose other than that of a mere custodian or warehouseman."[406] The defendant attempted to persuade the Court that their keeping of the Z-card is private and non-commercial[407], but its attempts proved unsuccessful.[408]

When juxtaposed against the German construction of the exception, its application scope in the UK regime appears generous and liberal – its ambit stretches, surprisingly, over business entities. The provision admittedly applies to acts done in private, understood as acts conducted at home or in a laboratory, as long as they are kept secret and closed to the public view. The non-commercial character is a requirement of utmost importance, which must be met: an operation must be non-

[403] ibid., 517-19.
[404] ibid., 522.
[405] *McDonald v. Graham* [1994] R.P.C. 407.The patent at issue related to a manner of folding a sheet of material, which resembled a plastic credit card, marketed under the name Z-card. The plaintiff claimed that the defendant infringed the patent on folded sheet materials (Z-Cards) by keeping and using them for the purpose of his business. Above that, the plaintiff alleged the violation of copyright law in way of reproducing materials similar to original materials prepared for the promotion of Z-card.
[406] *Smith Kline and French Laboratories Ltd. v R.D. Harbottle (Mercantile) and Others*, [1980] R.P.C. 363, 373.
[407] Interestingly the defendant attempted the defence upon the experimental use exception. See *McDonald v. Graham* 431.
[408] ibid., 432.

commercial in the initial stage. However, if its profile changes with time into a commercial undertaking, which was not anticipated or intended, the provision may still find application.

US law does not provide any similar provision on this matter. It accepts, as presented in a further part of this work, private and non-commercial use within the framework of repair and maintenance activities. The research unveiled solely one case where the infringing use concerned a personal use. In *Beedle v. Bennett*[409], the defendant made and installed a patented driven well to draw water from the earth on his farm, an act which the patentee claimed to be infringing. The Supreme Court asserted that view and held that a use solely for personal convenience was an act of patent infringement.[410] The case highlights a restrictive approach in defining the scope of the free use of an invention. In the cited case, the defendant neither sold nor offered to sell the patented invention, but merely used it on his own farm – his actions did no economic harm to the patentee (apart from the fact that the defendant did not buy the invention, but made it himself). The decisive argument against the defendant was "personal convenience" from the use of the invention, which is the more surprising in light of the fact that undoubtedly any kind of infringing act conducted by individuals bears the signs of personal convenience. From this perspective, US law does not make place for private and non-commercial uses, as they are known in the European systems.

The JPA does not provide any provision on private and non-commercial acts. The reading of Articles 68[411] and 101[412] provides some indications in favour of this kind of use. They stipulate that unlawful workings on the patented invention must have a commercial character, "as a business," to constitute an infringement.[413] However, no judicial decision has been rendered to clarify this term, hence the academic doctrine serves as the only source of interpretation. The term *as a business* refers to *industrial activities* that are neither individual nor domestic.[414] Industrial activities generate profits and "relate to business." Therefore, enterprises, public work projects, medical services, legal practice are seen as industrial activities. [415] Based on this understanding of the term, an exception for private and non-commercial acts must be construed narrowly and solely concern conducts performed individually, i.e. domestically, which are not affected by any commercial use. The scope of application of the exception resembles its construction in the German order.

---

[409] *Beedle v. Bennett*, 122 U.S. 71(1887).

[410] Ronald D. Hantman, "Experimental Use as an Exception to Patent Infringement," *Journal of the Patent & Trademark Office Society* 67, no. 12 (1985): 636.

[411] Article 68 (Effect of patent right).

[412] Article 101 (Acts deemed to constitute infringement).

[413] Georg Andreas Rauh, "Mittelbare Patentverletzung in Deutschland, Japan und den USA," *GRUR Int.* (2010): 466.

[414] AIPPI, "Japan. Report Q202. The Impact of Public Health Issued on Exclusive Patent Rights," 1.

[415] ibid.

4.5.2 Experimental Use

Experimental use is the most important and the most debated patent exception which is implemented in every patent regime. Its importance manifests itself in blocking the effect of a patent over scientific experimentation on the patented subject matters, i.e. testing for the purpose of finding new applications and their new adaptations – a safety valve for enhancements and betterments. In that regard, the experimental use exception plays a central role in retaining a delicate balance in the patent system; without this instrument, a single patent would be too powerful. Intense public and academic debates on the scope of the exception result from the fact that it curtails the effect of a patent over activities that might bear commercial potential, e.g. by developing new products.

The exception is of particular importance to the pharmaceutical and biotechnological sectors, in which substances are constantly scrutinised with the purpose of finding new applications. In this context, the experimental use exception emerges in discussions on research *with* an invention and the extension of the exception to cover such uses – in the literature, the problem appears in the context of questions on research tools. The matter is relevant with patentisation stretching over the results of the basic research, which may hinder scientific workings.[416]

The exception goes a step further than private and no-commercial use, because it permits uses conducted in the public domain, i.e. by public institutions, business entities, universities, communities (1), and accepts commercial intentions behind experiments (2), albeit only in some jurisdictions.

The latter underscores the variability in norm interpretation between jurisdictions, despite consensus over the inevitability of the exception to ensure the balance of interests.

[416] Chris Dent, "The TRIPS Agreement and an Experimental Use Exception for 'Research Tools'," *Australian Economic Review* 44, no. 1 (2011); Janice M. Mueller, "No Dilettante Affair: Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools," *Washington Law Review* 76, no. 1 (2001); John P. Walsh, Ashish Arora, and Wesley M. Cohen, "Effects of Research Tool Patents And Licensing on Biomedical Innovation," in *Patents in the Knowledge-based Economy*, ed. Wesley M. Cohen and Steven A. Merrill (Washington, DC: The National Academy Press, 2003).

4.5.2.1. Germany

German law situates this exception in Section 11(2), stipulating that "acts done for experimental purposes relating to the subject matter of the patented invention are exempted from the scope of patent protection."[417] The provision is anchored in the constitutional protection of research and teaching (Article 5(3) of the Basic Law) and constitutes a limitation of the patent right justified in light of Section 14(3) of the Basic Law.[418]

The norm recognises tests, trials, and experiments that measure the patented object with the aim of gaining new data and information, as lawful experimental uses. New information gained in the course of such experiments pertains to new indications, substance characteristics, or dosing proportions. Conducts carried out to clarify uncertainties in the applications of patented substances fall within the ambit of the provision as well. In principle, experimental undertakings with the main objective of securing new findings and gaining knowledge are exempted; tests that examine the technical application and the innovativeness of a given patent are also situated within the exception. Experimental use allows for reverse engineering, which is an inevitable part of every analysis of patented matter. Besides testing, experimental use includes manufacturing and using the patented device; however, these cannot be exceeded the scope and amount recognisable as experimental. The provision does not indicate any quantitative limitations but the Court might challenge extensive and "oversized" experiments.[419] Experimental conducts might be carried out by the user or delegated to a specialised agency (if it does use the patented technology for its own benefits).[420]

Two decisions of the Federal Supreme Court landmarked a liberalisation trend in applying the experimental use exception, which was of high importance in basic-research, where "blocking" patents curtail research operations, as it takes place in the biotechnological sector.[421]

---

[417] The old Patent Act of 1968 lacked the respective provision on experimental use. The regulation was appended to the new Patent Act of 1981 in the literal wording of the Article 31b of the Agreement relating to Community Patent of 1975 (Art. 27 b, 1989; 89/69/EEC). See Peter Ruess, "Accepting Exceptions: A Comparative Approach to Experimental Use in the U.S. and German Patent Law," *Marq. Intell. Prop. L. Rev.* 10, no. 81 (2006): 95-97.

[418] Art. 5 (3) of The Basic Law:
"Arts and sciences, research and teaching shall be free. The freedom of teaching shall not release any person from allegiance to the constitution."

[419] Benkard and Editors, *Patentgesetz*, §11 at 6; compare with *Monsanto Co. v. Stauffer Chemical Co.*, [1985] R.P.C. 515; Rolf Pietzcker, "Patentrechtliche Fragen bei klinischen Untersuchungen - eine Erwiderung," *GRUR* (1994): 320; *Klinische Versuche*, BGH 11.7.1995 - X ZR 99/92, NJW 1996, 782, 785-86.

[420] Benkard and Editors, *Patentgesetz*, §11 at 6-7.

[421] *Klinische Versuche*; *Klinische Versuche II*, BGH 11.4.1997 - X ZR 68/94, NJW 1997, 3092; Wolfang Von Meibom and Johann Pitz, "Experimental Use and Compulsory Licence Under German Patent Law," *Patent World* (1997): 29-30.

The patents in question concerned inventions in the field of biotechnology: 1) preparation of human immune interferon[422] and 2) production of erythropoietin[423]. The Court delivered two important statements: it did not object to the testing of patented substances for governmental approvals[424], nor to the patenting of the results thereof, because the intention to patent an improvement cannot disqualify from the exception.[425] It was stressed that that the objective of the provision is further development and the expansion of knowledge and understanding, which can be safeguarded only when experiments are carried out *on* the patented article. Hence, tests with the objective of discovering new indications, features of the substances, or a form or a dosage the substance must be provided in to treat certain disorders would fall within the ambit of the regulation. For the same reason, the experiments carried out to clarify uncertainties in the application of patented pharmaceutical substances are deemed permissible.

What does not comply with the scope of provisions are conducts that measure the market potential of new derivatives: demand, price, and production conditions.[426] Likewise, trials that serve *dusting around* with the aim of hiding the genuine purpose of experiments, e.g. the incorporation of patented technology into one's own strategy, cannot be exempted. Not only do they deprive the patentee of economic benefits, but they also contradict the purpose of the regulation.[427] The use of patented matter as a *research tool* is also not considered to fall within experimental use, because such use relies on the technical teaching embedded in the patented subject matter, and hence negatively affects the economic interest of the patentee.[428]

---

[422] The plaintiff was the exclusive licensee of a patent covering human immune interferon (interferon gamma). One of the defendants imported the active ingredients and used them to produce the pharmaceutical “Polyferon,” which is the only pharmaceutical with the active interferon-gamma approved in Germany (used in the treatment of classic rheumatoid arthritis). The defendants were conducting clinical studies with the inferno gamma with a view to identify additional, conceivable indications. *Klinische Versuche*.

[423] The plaintiff was the exclusive licensee of a patent for producing erythropoietin (patented EPO).The defendant conducted clinical trials on the substance, which contained recombinant human EPO – where the sequence of amino acids was identical with the patented EPO – to confirm the results from animal tests and to generate data for regulatory approval. *Klinische Versuche II*.

[424] "Experimental Use," 29-30. Some commentators do not recognise the two cases as “a gross about-turn,” since the Supreme Court did not dissociate from the general trend observed in Europe. See J.K. Jochen Pagenberg, "Clinical Trials I - Comment," *International Review of Intellectual Property and Competition Law* (1997).

[425] *Klinische Versuche II*, 3094.

[426] *Klinische Versuche*, 784; *Ethofumesat*, BGH 21.02.1989 X ZR 53/87, GRUR 1990, 997.

[427] *Klinische Versuche II*, 3094-95; Sedlmaier, *Die Patentierbarkeit*, 228-29; Pietzcker, "Patentrechtliche Fragen " 320.

[428] Benkard and Editors, *Patentgesetz*, §11 at 7; Joseph Straus, "Zur Zulässigkeit klinischer Untersuchungen am Gegenstand abhängiger Verbesserungserfindungen," *GRUR* (1993); Rudolf Teschemacher, "Die Benutzung patentierter Erfindungen zu Veruschs- und Forschungszwecken," *GRUR Int.* (1987); Thomas Hieber, "Die Zulässigkeit von Versuchen an patentierten Erfindungen nach § 11 Nr. 2 PatG 1981," *GRUR* (1996); Peter Chrocziel, "Zulassungshandlungen mit patentierten Arzneimttelerfindungen durch Zweitanmelder in der Bundesrepublik Deutschland und den USA," *GRUR Int.* (1984).

German jurisprudence and commentators stress that the exception constitutes a tool for examining the feasibility and the practicability of inventions, as well as generating new information or clarifying uncertainties, with the objective of introducing betterments or new inventions on the market.[429] As long as trials provide new knowledge and deepen the understanding of the patented teaching, the stimulus behind scientific curiosity, patent application, and patent commercialisation is irrelevant; experiments remain within the scope of the section.[430]

4.5.2.2 The United Kingdom

The UK system adapts a similar construction of the experimental use exception. It is included in Subsection 60(5)(b), which covers acts of both commercial and non-commercial character.[431] The first condition of the exception is that experiments must be conducted "on" a patented subject matter to see how it can be made, improved, or how it works – research tools do not fall within the ambit of the provision.

In *Smith Kline v Evans,* the Court perceptively examined the meaning of the wording "relating to the subject-matter of the invention." It pointed out that use of "the" and not "an" invention indicates that the subject matter of the invention refers to the claims of the patent in question.[432] The relationship with the invention must be "real and direct." That means trials should pertain to the properties of the claimed invention itself. Experiments with the objective of evaluating other substances or products, challenging or improving upon their validity, fail to comply with the premise of a direct relation with the invention; they also deprive the patentee of the just commercial compensation for using the claimed patent.[433] An excessive interpretation of the exception to cover trials with patented matter would rid the subsection of its original intention by applying it to all possible experimental cases:

> It cannot have been the intention of the legislature to include in the exemptions form infringements of paragraph (b) of section 60(5) tests or trials intended, as their purpose, to promote the commercial prospects and acceptability of a product, ex hypothesi an infringing product, with a view to its wider or better marketing by the infringer when he should be free to market it, as, for instance, when the patent expires.[434]

---

[429] Kraßer, *Patentrecht*, 787.

[430] *Klinischer Test*, LG Berlin 25.09.1984 16 O 644/84, GRUR 1985, 375; *Feldversuche [Field Experiments]*, LG Düsseldorf 5.3.1985 4 O 419/83, GRUR Int. 1986, 807; *Atenolol*, Hoge Raad, 18.12.1992, GRUR Int., 1993, 887.

[431] *Smith Kline & French Laboratories Limited v. Evans Medical Limited*, 522.

[432] ibid., 524.

[433] ibid., 523; *Monsanto Co. v. Stauffer Chemical Co.*, 522.

[434] *Monsanto Co. v. Stauffer Chemical Co.*, 523.

This approach confirmed the interpretation baseline adopted in earlier judicial decisions.[435]

In *Inhale v. Quadrant*, the Court indicated that experiments must be carried out for an *individual* purpose, and dismissed the experimental use defence due to the fact that:

> (…) the defendant did not exploit its products or technology for its own experimental purposes. In all cases, the defendant was trying to exploit and sell its technology to third parties. This is not experimental use.[436]

Conducts with the purpose of generating "statistics for further commercial exploitation" are another excluded category:

> But trials carried out in order to demonstrate to a third party that a product works or, in order to amass information to satisfy a third party, whether a customer or a body such as PSPS or ACAS[437], that the product works as its maker claims are not, in my judgement, to be regarded as acts done for experimental purposes.[438]

In the aforementioned case, obtaining named non-statutory approvals was aimed at expanding the market of an herbicide, TOUCHDOWN, which had already been manufactured by the defendant. The Court of Appeal held that the party went beyond the permissible scope of experimental use.

The two analysed European jurisdictions adopt analogous constructions of the experimental use exception: the conducts must provide new information on and allow for improvements of the patented subject matter; they may have commercial motivation, but they should preponderantly have an experimental purpose. Due to the general nature of the exceptions, it is safe to assume that this *liberal* construction applies equally in all sectors of technology.

4.5.2.3 The United States

The strict comprehension of the experimental use in the US doctrine sharply differs from the presented European approaches. The exception[439] in the US has a well-established legal tradition,

---

[435] ibid.Also Frearson v Loe [1878] 9 CH. D. 48, 66; Hoe & Co. V Foster & Sons [1899] 16 R.P.C.33, 38; Hudson, Scott & Sons Ltd. V Barringer Ltd. [1906] 23 R.P.C. 79, 87; J.Lucas (Batteries) Ltd. V. Gaedor Ltd. [1978] R.P.C. 297, 384.

[436] *Inhale Therapeutic Systems Inc. v. Qudrant Healthcare PLC*, [2002] R.P.C. 21, 463.

[437] The two institutions are regulatory bodies: Pesticides Safety Precaution Scheme (PSPS) proves the safety of agricultural materials, Agricultural Chemical Approval Scheme (ACAS) tests their efficacy. Both are non-statutory regulatory bodies, but it is a common practice to apply for clearance and /or approval from them to commence marketization. See *Monsanto Co. v. Stauffer Chemical Co.*, 520.

[438] ibid., 542; *Auchincloss v. Agricultural & Veterinary Supplies Ltd* [1999] R.P.C. 397, 405.

[439] The experimental use defence shall not be confused with the experimental use exemption provided in Section 102, which serves the protection of an inventor prior to filing a patent application.
Robert L. Harmon, *Harmon on Patents. Black-letter Law and Commentary* (Arlington: BNA Books, 2007), 409-14; *Elizabeth v. Pavement Co.*, 97 U.S. 126(1877); *Deutrim Co. v. The United States* 19 Cl. Ct. 624, *631

with the first judgement made as far back as 1813. However, thus far the exception has not been worded in a codified form.

In *Whitmore v. Cutter*[440], the Court formulated the experimental use exception for the first time. Its scope was very narrow and strictly limited to actions exercised "solely for amusement or to satisfy idle curiosity or for a strictly philosophical inquiry."[441] In this precedent-setting case, the Court gently unsealed patent exclusivity and sanctioned actions undertaken with the aim of deepening knowledge:

> (…) it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.[442]

The philosophical and idle character[443] of the inquiries was (and is) understood literally, which means that the exception should be understood narrowly. This was affirmed in *Sawin v. Guild*[444], in which the Court asserted that unlawful making must be performed with the intention of depriving the patentee of their just reward for the invention; acts for "mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification" were not deemed to be *making*:

> The making of a patented machine to be an offence within the purview of the statute, must be the making with an intent to use for profit.[445]

The Court unequivocally excluded any option of the commercial application of the obtained results. It divided experimental uses into two categories: 1) philosophical (i.e. scientific) experimentation and 2) verification of the verity and exactness of the specification.[446] The Court accentuated that the activity could not deprive the patentee of his or her legitimate economic reward. In "The Law of

---

(1990); *Pfaff v. Wells Elec. Inc.*, 525 U.S. 55(1998); *Eli Lily & Co. v. Zenith Goldline Pharm Inc.*, 471 F.3d 1369(2006).

[440] *Whittemore v. Cutter*, 29 F. Cas. 1120(1813).

[441] *Harmon on Patents*, 151-52; *John M.J. Madey v. Duke University*, 307 F.3d 1351, *1360-61 (2002); *Embrex, Inc. v. Service Engineering Corp.,* , 216 F.3d 1343, *1349 (2000); *Roche Products Inc. v. Bolar Pharmaceutical Co., Inc.*, 733 F.2d 858, *863 (1984).

[442] *Whittemore v. Cutter, *1121.*

[443] As clarified by Mueller, the term *philosophical experiments* might be rather bewildering in the context of the contemporary understanding of a technical solution, but then the meaning of *philosophical started to lean toward natural philosophy,* which today is simply referred to as *science*.
Janice M. Mueller, "The Evanescent Experimental Use Exemption from United States Patent Imfringement Liability: Implications for University and Nonprofit Research and Development," *Baylor Law Review* 56(2004): 929; *Integra Lifescience I, Ltd v. Merck KgaA, The Scripps Research Institute*, *874.

[444] *Sawin at al. v. Gulid*, 21 F. Cas. 554, No. 12,391(1813).

[445] ibid., *555.

[446] ibid.

Patents for Useful Inventions" (1890), Robinson explains that unlawful use must be hostile and harmful to the patentee's interests, which could be converted into financial gain in other proprietary manners.[447]

The analysis of case law proves that US Courts did not shift away from the direction of philosophical curiosity, relentlessly safeguarding "the truly narrow" margin of flexibility. The modern doctrine has tightened its scope to an even further degree. One of the most persuasive and significant cases was *Pitcairn v. the United States*[448], where the Court introduced the term *legitimate business* as an important indicator of the lawfulness of experiments and trials.

In the said case, the US government purchased 2,200 helicopters manufactured to order. The order extended from 1946 to 1964 and involved the amount of $639 million (which was used in determining the compensation claims). The claim concerned the similarity (and non-similarity) of some 40 models of ordered aircraft in regard to which the Court asserted infringement. The defendant, US government, urged the Court to exclude aircrafts used for "testing, evaluation, demonstrational or experimental purposes." The Court did not consent to the argument:

> Obviously, every new helicopter must be tested for lifting ability, for the effect of vibration on installed equipment, flight speed and range, engine efficiency, and numerous other factors. Tests, demonstrations, and experiments of such nature are intended uses of the infringing aircraft manufactured for the defendant and are in keeping with the legitimate business of the using agency. Experimental use is not a defense in the present litigation.[449]

The legitimate business of the defendant was the military defence for which the aircrafts were designed and tested. The Court clearly stated that the experimental use exception was not conceived to serve the business interests of the infringer. Moreover, the use of a minimal sample does not release from liability (as it was suggested in *Douglas v. United States*[450]):

> (…) an infringement is not a question of degree. Even the use of a small amount of substance or to a small extends may bear substantial lost on the side of the patentee.[451]

However, the strict and narrow scope of the doctrine's application did not guarantee the level of reliability that one would wish for.[452] The US practice does not allow for a use if it can be construed

[447] Hantman, "Experimental Use as an Exception to Patent Infringement," 622-23.
[448] *Stephen Pitcairn, Agent v. The United States*, 547 F.2d 1106(1976).
[449] ibid., *198.
[450] *Douglas v. The United States*, 510 F.2d 364(1975).
[451] *Deutrim Co. v. The United States* *630.
[452] Mueller, "No Dilettante Affair," 5.

as *using* the patented invention in light of 35 U.S.C. §271 [453] When examined through the parameters of contemporary scientific research, it is demonstrable that the exception has met with little success.[454]

Universities and research institutions used to enjoy the benefits of the (almost limitless) experimental use exception; many found this fact to be self-evident, and this conviction was further supported by the jurisprudence. For example, in *Ruth v. Stearns-Roger Mfg. Co.,*[455] the Colorado School of Mines, one of the recipients of allegedly infringed mining machines and their parts, was released from patent liability, since the use of the patented machinery was experimental – the parts were used in laboratory machines and were changed from day to day.[456] Hence, academic scientists were strongly convinced to be immune from patent infringements, as they utilised patented tools in university labs for "strictly philosophical inquiry." That has changed with *Madey v. Duke*, in which "legitimate business" won over the criterion of "idle curiosity."

In *Madey v. Duke University,*[457] the court dismissed the experimental use exception, since the activities performed on the patented devices remained in accordance with the objective of Duke's *legitimate business*, i.e. providing higher educational services:

> (…) these projects unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects. These projects also serve, for example, to increase the status of the institution and lure lucrative research grants, students and faculty.

The determining factor was Duke's patent licensing policy, from which it derived substantial revenues. The court emphasised that even the "slightest commercial implication"[458] disqualifies the application of the experimental use exception. The scope of applying the exception was constrained by the notion of legitimate business, which remained the main axis of all concerns. The legitimate business objective in the case was the educational benefit for which the patented device was operated: students were *consumers* who paid for that educational opportunity. Therefore, Duke's

---

453 *Patent Law*, 533.

454 "The Evanescent."

455 *Ruth v. Stearns-Roger Mfg. Co.*, 13 F. Supp. 697(1935).

456 ibid., 703.

457 Dr. John M.J. Madey was director of the free electron laser research laboratory at Duke University. He was also an inventor and the owner of two U.S. patents on laser devices – inventions patented during Madey's tenured position at Stanford University. In 1989, lured by the Duke's offer, he moved to Duke and took the laser lab with him. In the aftermath of a dispute between Madey and Duke concerning the management of the labd, Madey resigned from the position in 1998. The laser equipment stayed in the Duke lab and scientists continued to operate on it. In effect, Madey sued the university for patent infringement due to the unauthorised use of the patented equipment.
John M.J. Madey v. Duke University, *1352-54.

458 See *Stephen Pitcairn, Agent v. The United States*; *Roche Products Inc. v. Bolar Pharmaceutical Co., Inc.*

utilisation of the patented device did not qualify for the experimental use exception. Moreover, the patented device was used for the purpose it was made for, and not in order to improve its design and functioning.[459]

In light of the presented cases, it appears that hardly any conduct carried out in the university lab or in any other place might be deemed to be of experimental nature. The criterion of legitimate business has shrunk the ambit of the exception to some minute activities done for "idle satisfaction" – trifling, "dilettante affairs."[460]

Therefore, one would not be mistaken to consider the experimental use doctrine as almost non-existent in the US system. From the perspective of R&D practice, the majority of trials are conducted with the idea (intention) of bringing an ultimate solution to the market (to recoup the out-laid investment) – which constitutes normal business behaviour, as acknowledged in the German and UK jurisdictions. The acceptance of the commercial nature of experimental activities in the European systems results from the basic assumption that a trial must uncover an unknown aspect of a patented solution, i.e. it provides new information and moves forward the state of the art. That a certain conduct might lead to a marketable product, and an entity or an individual desires to carry out trails which lead to such an outcome, does not deprive the conduct of its *experimental* character. However, the US doctrine puts the stress not on the outcome of such experiments, but on their purpose, i.e. scientific curiosity, which could have been a reasonable approach in the 19th century, but not in the context of science and research in the 21st century. Under the conditions of intense competition between companies and universities (for research grants), all entrants must deliver "faster, newer and better products" – how to achieve this goal if not by testing and measuring existing products? A further question arises on how to disentangle one invention from another. Technological progress is grounded in improvements on earlier solutions.[461] Hantman's case-law analysis exposed another aspect of this issue. Cases in which the experimental use was allowed concerned uses where no monetary damages occurred on the side of the patentee, only because the defendant neither sold nor manufactured the patented solutions in question, although such attempts and intentions vividly existed.[462] Further remarks concern the concepts of curiosity and idle satisfaction, which should literally serve the gratification of one's own philosophical and scientific interests – is it not equal with an act of personal convenience? If the use of a driven well for one's own domestic supply is considered to be an act of personal convenience

[459] *John M.J. Madey v. Duke University*, *1360-63.
[460] *Patent Law*, 534; "No Dilettante Affair."; *Roche Products Inc. v. Bolar Pharmaceutical Co., Inc.*, 863.
[461] Suzanne Scotchmer, "Standing on the Shoulders of Giants: Cumulative Research and the Patent Law," *The Journal of Economic Perspectives* 5, no. 1 (1991).
[462] Hantman, "Experimental Use as an Exception to Patent Infringement," 625-26, 32-34.

(like in *Beedle v. Bennett)* and is thus regarded to be infringing, why is this not the same for philosophical inquiries?[463] This can be interpreted as an inconsistency in the application of the law.

4.5.2.4 Japan

In Japan, the experimental use exception found its statutory expression in Article 69(1):

> A patent right shall not be effective against the working of the patented invention for experimental or research purposes.[464]

The provision was introduced as far back as 1909 – a considerable head-start over other countries[465] – at the time of an intensive technological development based on reverse engineering.[466] In spite of a long legal tradition, the notion of **"**experimental and research purposes" has not been clarified in the Patent Act, and hence must be supported by academic doctrine and judicial decisions. To classify a given conduct as experimental use, it must comply with certain requirements:

1) the subject-matter must be patentable,
2) the working must contribute to scientific development by verifying the properties of an invention, improving it, or ascertaining its economic advantages.[467]

The exception also covers tests carried to obtain data for the governmental registration (known as the *Bolar* exception).

Japanese courts reluctantly accepted the extension of research exception on regulatory approvals. In *Monsanto v. Stoffer Japan K.K.*[468]*,* the Court dismissed the explanation of the defendant (Stoffer Japan) that experiments were performed with the intention of securing agrochemical registration, which was required for the sale of the herbicide.[469] The court stated:

> Agrochemical experiments carried out for the purpose of securing government registration of the herbicide are not intended to advance technology and

[463] Richard Bee, "Experimental Use and an Act of Patent Infringement," *J. Pat. Off. Soc'y* 39, no. 5 (1957).
[464] "Unofficial Translation of Japan's Patent Act (Act No. 121 of 1959) ", http://www.jpo.go.jp/shiryou_e/s_sonota_e/fips_e/mokuji_e.htm#japan, accessed 17.12.2012.
[465] E.g. in Germany the exception was introduced only in 1981.
[466] Katsuya Tamai, "The Experimental Use Exception: a Japanese Prespective," *CASRIP Symposium Publication Series: Reconciling Competing Interests in Intellectual Property*, no. 7 (2002): 14-15.
[467] AIPPI, "Japan. Report Q202," 2.
[468] *Monsanto Co. v. Stauffer Japan K.K.*, 1246 Hanrei Jiho 128 (Tokyo Dist. Ct. 1987), IIC 1989, 91.
[469] ibid., 94.

therefore do not fall within the scope of the experiment or research exception to an otherwise infringing use.[470]

The Court followed the prerequisite that research and trials "are inherently intended to advance technology to the next stage and not for purposes associated with the manufacture or marketing of a patented product."[471] Accordingly, experiments providing data for governmental registration do not contribute to technological progress.

Primary producers welcomed the Monsanto decision and consequently flooded Japanese Courts with infringement claims against Japanese generic companies.[472] The Monsanto approach was equally applied and rejected. In a number of cases[473], Courts judged in favour of pharmaceutical companies, highlighting the requirement of technological advancement. Some judgements[474], however, deviated from this construction and approached the exception more liberally to include clinical trials (the *biological equivalence test*[475]) within the experimental use exception under Sec. 69(1).[476]

The *liberal* reasoning was threefold:

1) generic tests contributed to scientific development;
2) market exclusivity resulted from a patent terminates with the lapse of a patent and as such cannot be extended above that time, otherwise it would be with the detriment to the fair market competition;

---

[470] ibid., 91.

[471] ibid., 94.

[472] 1) Galaxo-Wellcome PLC sued Sawai Seiyaku, Taiyo Yakuhin K"gy", and Kayaku; 2) Sandoz sued Sagami Kasei Kogyo, Shiono Chemical, Permachem Asia, YIC, Taiyo Yakuhin K"gy", MF, Medisa Shinyaku, Taiko Seiyaku and Toyo Pharmacy; 3) Bayer-Yakuhin Ltd. Toyama Seiyaku K"gy", Ikeda Mohando, Ryukakusan, Taiyo Yakuhin K"gy", MF, Maeda Yakuhin K"gy", Kyowa Yakuhin K"gy", Yoshindo, and Fukui Seiyaku. From *Synthelabo*, Nagoya Distric Court 06.03.1996, IIC 1997, 398, Comment, 399.
Due to the pricing policy of the Japanese Health Ministry, generic drugs constituted (only) 7-8% of the total pharmaceutical sales, which was up to 4 times less when compared with the European or US markets: there the total sale amounted to 30-40%. Ibid.

[473] Synthelabo – five suits were filled by French Synthelabo S.A. to Nagoya District Court (3 suits) and Nagoya High Court (2) against generic companies: 1)Toyo Pharma K.K. & Yoshindo K.K., 2) Daito K.K. & Nihon Pharmaceutical K.K., 3) Horita Pharmaceutical Synthesis K.K., 4) Malco Pharmaceutical K.K., 5) Taiyo Pharmaceutical K.K.; Daiichi Pharmaceutical Co. Ltd v. Shiono Chemical K.K. & Choseido Pharmaceutical K.K.; Kyorin Pharmaceutical Co., Ltd. V. Hotta Yakuhin Gosei K.K..
See ibid.; Jennifer A. Johnson, "The Experimental Use Exception in Japan: a Model for U.S. Patent Law?," *Pacific Rim Law & Policy Journal Association* 12, no. 2 (2003): 513-15; Jinzo Fujino, "Latest Developments in Japan IP Cases," *AIPPI Journal* (Nov. 1997): 299.

[474] Ono Pharmaceutical K.K. v. Kaigai Pharmaceutical K.K., Otsuka Pharmaceutical K.K. v. Towa Yakuhin K.K., Wellcome Foundation Ltd. V. Sawai Pharmaceutical K.K. From Johnson, "Experimental Use in Japan," 515.

[475] Tamai, "Experimental Use Exception," 15.

[476] Johnson, "Experimental Use in Japan," 510-18; *Procaterole*, Tokyo High Court March 31, 1998, IIC 1999, 454.

3) anyone can freely utilize the invention after the patent is not in force anymore.[477]

The extension of the experimental use exception over generic tests caused a great deal of confusion and, as has been claimed by commentators, might in fact turn out to be to the detriment of the provision by deforming its initial concept. In Japan, the acceptance of generic tests occurred without the implementation of a separate provision to the Patent Act. Many practitioners could not understand whether the criterion of scientific advancement in regard to the experimental use exception lowered its significance or was completely abandoned, and whether it applied in other fields of technology, outside the pharmaceutical sector.[478]

4.5.3 Permissible Conducts on Patented Medicinal Products

The limitation, widely known as the *Bolar* exemption[479], was named after a US case that signalised the necessity of such an exception, and has been adapted in numerous jurisdictions[480] Because of its specific and clear context, its construction is almost similar in all of the analysed systems. *Roche v. Bolar* is a case with probably the greatest international resonance on patent legislation. It initiated worldwide legislative changes, which approved experiments for the purpose of regulatory approval, either as a separate provision or, like in Japan, within the scope of the general research exception.[481]

In short: Bolar tested the properties of a patented pharmaceutical of *Roche*, Valium, shortly before its expiration, in order to compare them with the properties of the generic product and, consequently, apply for FDA approval. Roche wanted to enjoin Bolar and argued that the use of a patented drug for federally mandated premarketing tests is a use and violates patent law. Bolar opposed the accusation by interpreting the experimental use exception very liberally and claiming that ”public policy favours generic drugs and thus mandates the creation of a new exception in

---

[477] Tamai, "Experimental Use Exception," 15.

[478] Johnson, "Experimental Use in Japan," 517-18; Tamai, "Experimental Use Exception," 16.

[479] *Roche Products Inc. v. Bolar Pharmaceutical Co., Inc.*

[480] "DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 November 2001 on the Community code relating to medicinal products for human use"; "DIRECTIVE 2001/82/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 November 2001 on the Community code relating to veterinary medicinal products": with further amendments; "REGULATION (EC) No 1901/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 001/83/EC and Regulation (EC) No 726/2004".

[481] WIPO, "Patent Related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels," (CDIP/5/4 Rev., http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=1316292010), 24.

order to allow FDA required drug testing."[482] The Court denied the exception due to Bolar's business motivation behind generating data for FDA approval:

> It is no trifle in its economic effect on the parties even if the quantity used is small. It is no dilettante affair (…) We cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of "scientific inquiry," when that inquiry has definite, cognizable, and not insubstantial commercial purposes.[483]

The case exposed the inadequacy of the legal construction. It was not correct to block generic companies in testing original drugs, because that delayed the entrance of generics on the market and extended patent protection beyond the standard patent term. That loophole was promptly improved by the Congress, which introduced an explicit exception for experiments on patented pharmaceuticals for statutory approvals, informally named the Hatch-Waxmann Act (Drug Price Competition and Patent Term Restoration Act), which was incorporated into the US patent law under Section 271(e)(1).[484]

In German law, the exception is included in Section 11(2b) and is applied primarily to generics[485] and biosimilars[486]. This provision has a wider scope than 11(2) since it exempts practically all

---

[482] *Roche Products Inc. v. Bolar Pharmaceutical Co., Inc.*, *862.

[483] ibid.

[484] Gerald J Mossinghoff, "Overview of The Hatch-Waxman Act and Its Impact on the Drug Development Process," *Food & Drug LJ* 54(1999); Wendy H. Schacht and John R. Thomas, "CRS Report for Congress The "Hatch-Waxman" Act: Selected Patent- Related Issues " (2002); "Symposium: Striking the Right Balance between Innovation and Drug Price Competition - Understanding the Hatch-Waxman Act ", (Food & Drug Law Journal Vol. 54, 2, 1999).

[485] The direct reference to generics can be found in the preamble of the Regulation 764/2004 under No. 9: "(…) It is also appropriate to allow access to this procedure for medicinal products which, although not innovative, may be of benefit to society or to patients if they are authorised from the outset at Community level, such as certain medicinal products which can be supplied without a medical prescription. This option may be extended to generic medicinal products authorised by the Community, provided that this in no way undermines either the harmonisation achieved when the reference medicinal product was evaluated or the results of that evaluation."

[486] Biosimilars mean similar biological medical products (also called "follow-on biologic" or "biogenerics" in the US). They are medicinal products submitted for statutory approval prior to the expiry of the original biopharmaceutical. Due to a similar legal status, they might be easily confused with generics, but the biochemical distinction leaves significantly less space for doubt. Generics are equivalents of low-molecular-weight drugs: they are comprised of "small molecules with well-defined, and generally stable chemical structures." Biopharmaceuticals and their biosimilars are "comparatively large peptides or proteins with complex structures." The first bio-drugs were introduced in the 1980 and were mainly "copies of endogenous human proteins, such as erythropoietin (EPO), insulin, growth hormones and cytokines." They are developed by one of the following biotechnology methods: rDNA, controlled gene expression, or antibody methods. Due to "their high molecular weights, their complex three-dimensional structures, the dependence of biological activity on structural integrity, the complexity of their manufacturing processes," they constitute unique products. The pharmaceutical differences between the

conducts on the patented subject-matters as long as they are performed with the purpose of obtaining the regulatory approval, e.g. the production of generic, market analysis.[487] Likewise, the UK Patent Act was appended with a corresponding provision in Section 60(5)i. However, the UK construction of the provision is narrower and exempts acts performed solely for the purpose of governmental authorisation.[488]

In the US, the introduction of the provision spurred numerous court decisions, in which various legal schemes have been examined. In some sense, the Bolar exception satisfies a narrow interpretation of the experimental use exception by recognising as permissible uses of a commercial character, which otherwise would not have been regarded as experimental.

Merck v Integra[489] focused on the application of Section 271(e)(1) for pre-clinical experiments.[490]

---

two types of patent-equivalents bring us back to legal issues that require regulation, with the main question being how much testing is required.

The first legislative attempts to regulate this complex subject-matter were undertaken almost a decade ago in Directive 2004/27/EC (Art. 10 No. 4), with Annex I, and in Directive 2003/63/EC. Subsequently, the European Medicine Agency (London) and its scientific Committee for Medicinal Products for Human Use (CHMP) developed guidelines précising the requirements with respect to clinical and non-clinical trials.

The first biosimilar were marketed in 2006. Biosimilars that have been approved by the European Commission include 1) a version of recombinant somatropin – Omnitrope and Valtropin, 2) recombinant of human EPO (erythropoietin n) – Abseamed, Binocrit and Epoetin alfa Hexal 3) recombinant filgrastim – Biograstim, Filgrastim, Ratiopharm, Ratiograstim, and Tevagrastim: Filgrastim Hexal and Zarzio.

Huub Schellekens and Ellen Moors, "Clinical Comparability and European Biosimilar Regulations," *Nature Biotechnology* 28, no. 1 (2010); Daan Crommelin et al., "Pharmaceutical Evaluation of Biosimilars: Important Differences from Generic Low-Molecular-Weight Pharmaceuticals," *Eur J Hosp Pharm Sci* 11, no. 1 (2005); H. Mellstedt, D. Niederwieser, and H. Ludwig, "The Challenge of Biosimilars," *Annals of Oncology* 19, no. 3 (2008); GaBI Generics and Biosilimars Initivative, "Biosimilars Approved in Europe," http://gabionline.net/Biosimilars/General/Biosimilars-approved-in-Europe, accessed 11.07.2015; "Biosimilars-Info.de," www.biosimilars-info.de, accessed 28.02.2013; "DIRECTIVE 2004/27/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use," Official Journal of the European Union, L 136/34, 30.4.2004; "COMMISSION DIRECTIVE 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use," Official Journal of the European Union, L 159/46, 27.6.2003.

487 Benkard and Editors, *Patentgesetz*, §11 at 10.

488 Terrell and Editors, *The Law of Patents*, 327; Nicole Dinaut and Stephanie White, "Experimental Use or Infringement? Location Matters," *Intellectual Asset Management*, no. 59 (July/August 2013): 115-16.

489 *Integra* owned five patents on a tri-peptide segment of fibronectin/amino acids (Arg-Gly-Asp, referred to as RGD peptides). When bound to avB3 receptors, the peptides should enhance wound healing and increase the biocompatibility of prosthetic devices. Dr. Cheresh, a highly renowned professor at the Scripps Research Institute, discovered that blocking integrin avB3 inhibits the growth of tumour cells. *Merck KgaA,* a German company, offered to support Dr. Cheresh's research and entered into an agreement with him and other Scripps scientists. The project was aimed at developing a drug candidate and launching clinical trials within three years. The research succeeded in the discovery of cyclic peptide EMD 66203 and its derivatives. The extensive tests also covered the RGD peptide and its therapeutic effects. When Integra learned about the project, convinced of its commercial character, it proposed Merck licences, which rejected calling on safe harbour within 35 U.S.C. Sec. 271 (e)(1).
Integra Lifescience I, Ltd v. Merck KgaA, The Scripps Research Institute, *862-64.

490 Merck intended to apply for an Investigatory New Drug application (IND), which is a regulatory requirement by the FDA at the preclinical stage of developing new drugs. The IND is a prerequisite for

The Court of Appeal upheld the infringement claim, stating that performing tests on a number of patented compounds with the aim of selecting one particular compound as a drug candidate did not relate to gathering information for FDA approval. The defendant carried biomedical research with no relation to FDA submission of any tested peptides.[491] The Supreme Court, however, permitted the application of the safe harbour onto pre-clinical, trials because nothing in the statue indicates that the safe harbour is limited to a particular development stage. It also affirmed that basic research performed without the intention of developing drugs, with the belief that the screened compound would have some physiological effect that the researcher intends to induce, could not enjoy the privilege of the safe harbour:

> It does not follow from this, however, that § 271(e)(1)'s exemption from infringement categorically excludes either (1) experimentation on drugs that are not ultimately the subject of an FDA submission or (2) use of patented compounds in experiments that are not ultimately submitted to the FDA. Under certain conditions, we think the exemption is sufficiently broad to protect the use of patented compounds in both situations.[492]

In the post-*Merck* period, only once did the Court rule in favour of the defendant.[493] In *Classen Immunotherapies v. King Pharms*[494]*,* the defendant tested Skelaxin, a muscle relaxant drug, using what *Classen* claimed was its patented method of identifying new drug uses. Later, Elan submitted a citizen petition and a labeling supplement to the FDA presenting results of its study on drug bioavailability. The Court accepted the defendant's argumentation that the use of Classen's patent reasonably related to the FDA submission. The Classen process presented a *research tool*[495]. The Court acknowledged the application of the safe harbour for such process tools when they serve the aim of generating data for FDA application.[496]

---

later clinical testing in humans to support an application for a new drug. See John Carlin and Colin Cabral, "Hatch-Waxman Safe Harbor Construed in 'Merck v. Integra'," *New York Law Journal* 234, no. 5 (2005).

491 *Integra Lifescience I, Ltd v. Merck KgaA, The Scripps Research Institute*, *867-68, 72; Ruth Freeburg, "No Safe Harbor and No Experimanl Use: Is It time for Compulsory Licensing of Biotech Tools," *Buff.L.Rev.* 351, no. 53 (2005-2006): 355-56.

492 *Merck KGaA, Petitioner v. Integra Lifesciences I, LTD, et al.*, 545 U.S. 193, *206 (2005).

493 Patrick Gattari and Nicole Grimm, "Federal Courts Debate Safe Harbour Exemption for Patent Infringement under 35 U.S.C 271(E) Following Merck v. Integra," http://www.mbhb.com/pubs/xpqPublicationDetails.aspx?xpST=PubDetail&pub=247, accessed 05.02.2014.

494 *Classen Immunotherapies, Inc. v. King Pharms., Inc,*, 466 F.Supp.2d 621(2006).

495 Research tools are patented inventions that are used to discover or measure other substances or products. The application (and patenting) of research tools is of particular concern in pharmaceutical and biotechnological sectors. Several questions arise in this context, e.g. the scope of "the safe harbour" of experimental use, reach-through royalties (license fees from the sale of discovered substances).
Mueller, "No Dilettante Affair."; Walsh, Arora, and Cohen, "Effects of Research Tool Patents And Licensing on Biomedical Innovation."; Gerald J. Flattmann and Kaplan Jonathan M., "Licensing Research Tool Patents," *Nature Biotechnology* 20(2002); Dent, "The TRIPS Agreement and an Experimental Use Exception for 'Research Tools'."

496 *Classen Immunotherapies, Inc. v. King Pharms., Inc,*, *625.

In *Proveris Scientific Corp. v. InnovaSystems,* the Court held that the provision was not designed to protect parties that do not seek FDA approval.[497] In *PSN v. Abbott,* the Court asserted that the provision does not apply to ANY activity.[498] Further case law shows that post-approval tests are legitimate only if they serve the purposes of the FDA, i.e. they are required to maintain FDA approval.[499]

In conclusion, the Courts tend to dismiss infringement claims whenever they find a genuine intention to obtain (or maintain) FDA approval. They even accept the use of a patented solution as a research tool with the FDA proceeding in the background – this illustrates the privileged position of the pharmaceutical sector.

4.5.4 Permissible Uses of Plant Materials (Research and Discovery)

For centuries, plant breeding had not been recognised as inventive work because the process rested upon creating conditions in which plants could reproduce and mix. However, modern science has delivered leverages to control the process, including the multiplication of plants on the DNA level. To that end, plant breeding has become technically specialised and complex, or, in other words, ”patentable.”[500] This shift was followed by the introduction of a proprietary regime over plant breeding, via either patents or plant variety certificates[501]. Both forms provide the owner with the advantage of being free from competition for a limited term. Patent law provides the said limitation in the form of a research exception, which constitutes a specialised norm within the classic experimental use exception. It exempts uses of biological material for research purposes, such as breeding, discovering, or developing other plant varieties.

The German Patent Act lays down the exception in Section 11(2a), which clearly accentuates its relation to the experimental use conceived in Section 11(2). The provision covers the discovery, breeding, and development of new plant varieties, under the reservation that the obtained

---

497 *Proveris Scientific Corp. v. InnovaSystems, Inc.*, 536 F.3d 1256, *1265 (2006).

498 *PSN Illinois, LLC v Abbott laboratories and Abbott Bioresearch Center, Inc*, U.S. Dist. LEXIS 108055, *17 (2011).

499 See *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057(2011); *Momenta Pharma, Inc. v. Amphastar Pharma., Inc.*, 686 F.3d 1348(2012).

500 1919 – a landmarking discovery of techniques for hybridizing corn. See Craig Borowiak, "Farmer's Rights: Intellectual Property Regies and the Struggle over Seeds," *Politics and Society* 32, no. 4 (2004): 515.

501 See Bernard Le Buanec, "Protection of Plant-Related Innovations: Evolution and Current Discussion," *World Patent Information* 28(2006); Max Thiele-Wittig and Paul Claus, "Plant Variety Protection - A Fascinating Subject," ibid., no. 25 (2003); Robert Tripp, Niels Louwaars, and Derek Eaton, "Plant Variety Protection in Developing Countries. A Report from the Field," *Food Policy* 32(2007); Oliver Mills, *Biotechnological Inventions. Moral Restraints and Patent Law* (Farnham: Ashgate, 2010).

materials cannot be commercially exploited. The term *plant variety* is construed as provided in the Council Regulation 2100/94[502]. In other words, the exception covers trials on plant varieties of all botanical genera and species, including hybrids; it exempts genetic workings on the genome (the independent parallel development of clones of protected genes, reprocessing for breeding purposes), and on the subject-matter of the invention. To reiterate, the experiments must deliver a new plant variety instead of disclosing one which is already known. In that regard, the subsection directly corresponds with the "classic" experimental use, certain questions can be answered therefrom. The current scope of the provision allows plant breeders to provide finished products on the market after the patent expires (or lapses), which bear a significant economic meaning when considering the enormous potential of the decorative plants market (e.g. roses, orchids). Some commentators indicate that the exception resembles a compulsory license, despite its systematic location under Sec. 11(2).[503] The amendment of the Subsection solved the matter of the collision between patent law and the law on the protection of plant varieties[504]. A plant breeder must decide which type of protection is more suitable for the given solution: a patent or a plant variety certificate.[505] The legislator amended the law on the basis of the declaration of the German delegation for the minutes in the Internal Market Council of 27 November 1997[506] when implementing the *Biopatent* Directive[507] to diminish the risk of collisions and secure the further development of plant varieties.[508]

The UK Patents Act does not provide any corresponding regulation. Experiments performed on plant varieties are exempted in Section 8(b) of the Plant Varieties Act of 1997. If a certain plant variety is granted with patent protection, experimenting, i.e. discovering and developing new derivatives, underlies the experimental exception as laid down in Section 60(5)(b). However, in light of the upcoming entrance into force of the UPC Agreement, the UK legislator intends to introduce a corresponding breeders' exception as stipulated in Article 27 of the Agreement. The aim of the

---

[502] Article 5(2): "For the purpose of this Regulation, „variety" shall be taken to mean a plant grouping within a single botanical taxon of the lowest known rank."
"COUNCIL REGULATION (EC) No 2100/94 of 27 July 1994 on Community plant variety rights ", Official Journal of the European Communities, L 227/1, 1.9.1994.

[503] Michael A. Kock, Susann Porzig, and Eva Willnegger, "Der Schutz von pflanzenbiotechnologischen Erfindungen und von Pflanzensorten unter Berücksichtigung der Umsetzung der Biopatentrichtlinie.," *GRUR Int.* (2005): 190; Kraßer, *Patentrecht*, 790.

[504] "The Plant Variety Protection Law (consolidated text of December 19, 1997)," PVP Gazette 86, December 1999.

[505] Kock, Porzig, and Willnegger, "Der Schutz von pflanzenbiotechnologischen Erfindungen," 190; Benkard and Editors, *Patentgesetz*, §11 at 9.

[506] WIPO, "Questionnaire on Exceptions and Limitations to Patent Rights. Germany," (http://www.wipo.int/scp/en/exceptions/replies/germany.html), 21.

[507] "DIRECTIVE 98/44/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 July 1998 on the legal protection of biotechnological inventions".

[508] The Plant Variety Protection Law envisages a similar exception in Section 10(1)(3).

amendment is the creation of a unified catalogue of patent exceptions that would be applicable to all patents valid in the UK.[509]

In the US system, breeders' privilege has found its expression in 7 U.S.C. §2544, which exempts activities on protected varieties for the purposes of plant breeding and research and underlies the regime of the Plant Variety Protection Act (7 U.S.C. §2321 *et seq.*)[510]

Japan's applicable law does not include any provision on this subject-matter.

4.5.5 Medical Treatment and Derivatives (Extemporaneous Preparation of a Medicine)

Liability for patent infringement is taken away from medical practitioners in regard to their treatment of patients. The origins of the exceptions are to be found in the patentability exclusion of medical therapeutic methods. An international standard is laid down in the TRIPS Agreement in Article 27 (c), which exempts from patentability diagnostic, therapeutic, and surgical methods for the treatment of humans or animals. The article "copies" a corresponding norm from Article 52(4) of the EPC. The question of what constitutes "medical treatment" gives rise to discrepant legal interpretations and numerous judicial decisions[511], as well as "inventive" claim writing[512]. The subject is complex, as it fuses patent and medical law with ethical considerations.[513] Regardless of the scope of exclusion and related discussions (that are not handled in this chapter[514]), its

[509] WIPO, "Questionnaire on Exceptions and Limitations to Patent Rights. The United Kingdom," (http://www.wipo.int/scp/en/exceptions/replies/uk2.pdf).

[510] W. Lesser, "Valuation of Plant Variety Protection Certificates," *Review of Agricultural Economics* 16, no. 2 (1994): 231.

[511] Colm Murphy, "Methods of Treatment: Is There Any Protection Available in Europe?," *Nature Biotechnology* 19(May 2001); Martin Todd, "Patentability of Methods of Medical Treatment: a Comperative Study," *J. Pat. & Trademark Off. Soc'y* 82(2000): 389.

[512] E.g. presenting a method in the form of a product, or claiming a dosage regime instead of therapeutic use. Nahoko Ono illustrates the diverse practices of the patent office on the example of a patent which was submitted to three patent offices: USPTO, JPO, and E PO. Only in the USPTO could the patentee claim his invention as a medical method. In the JPO he filed four different applications covering separate medial uses of medicaments for treating arterial disease, brain infarction, diabetes, and disease X.
See Nahoko Ono, "Better than Nothing: Japan's Next Move on Patentability of Medical Methods," *IIC* (2006): 201-05; Murphy, "Methods of Treatment: Is There Any Protection Available in Europe?."

[513] Todd, "Patentability of Methods of Medical Treatment: a Comperative Study," 381; Doris Thums, "Patent protection for medical treatment - a distinction between patent and medical law," *IIC*, no. 27 (1996).

[514] See Todd, "Patentability of Methods of Medical Treatment: a Comperative Study."; O. Mitnovetsk and D. Nicol, "Are Patent for Methods of Medical Treatment Contrary to the Ordre Public or morality or "generally inconvenient"?," *J Med Ethics*, no. 30 (2004); Michael Davis, "Excluding Patentability of THerapeutic Methods, including Methods Using Pharmaceuticals, for the Treatment of Humans under Trade Related Aspects of Intellectual Property Rights Article 27(3)(A)," *Hofstra L. Rev.*, no. 43 (2014-2015);

derivative provides patent space for medical practitioners (i.e. doctors) using medical methods and pharmacists preparing medicine for an individual patient within a specific medical treatment, and has been adopted in various jurisdictions.

German law regulates this matter in Section 11(3), which excludes the preparation of medicine for the purposes of the medical treatment of a single patient. The norm directly corresponds to Section 2a (1) of the Patent Act (as well as to Art.53(c) EPC), which prohibits patentability of "methods for the surgical or therapeutic treatment of the human or animal body or for diagnostic methods used on the human or animal body"[515].

The provision addresses solely pharmacists and does not extend to doctors. The exception does, however, pertain to the preparation of medicine for a single patient and not for a greater number of patients at the same time. It covers the prescription, production, and use of pharmaceutical products in individual cases. The preparation of a medicine is considered to be a part of the therapeutic treatment of the human body, and not as an element or part of a procedure to produce a certain substance applicable in the course of medical treatment.[516]

The UK patent act stipulates this rule in Subsection 60(5)c and covers the same conditions. Its addressees are registered medical or dental practitioners. It corresponds to Section 4(2), which does not allow for patenting methods of treatment, diagnosis, and therapies pertaining to human and animal bodies.[517]

The US patent law also limits the ability of the patentee to enforce the patent with regard to patented medical procedures that are practised by medical practitioners (doctors) in treating patients. 35 U.S.C. §287(c)[518] stipulates an exemption for "medical practitioners performing a medical activity on a human or a laboratory animal." Medical procedures concern the medical treatment of humans and animals, surgeries, therapies, and diagnostic tests, but do not extend to drugs or reagents. This subsection was introduced as recently as in 1996 at the request of the House of Delegates of the American Medical Association and the medical doctors' lobby, and

---

Alison Hill, "Ambiguous Regulation and Questionable Patentability: A Toxic Future for in Vitro Companion Diagnostic Devices and Personalized Medicine," *Wis. L. Rev.* (2013).

[515] The prohibition does not apply to "products, in particular substances or substance mixtures, for use in one of the above-mentioned methods."

[516] *Carvediol II*, BGH, 19.12.2006 - X ZR 236/01 (BpatG) GRUR 2007, 404, 405; Peter Mes, *Patentgesetz. Gebrauchmusterrecht.*, 3 ed. (Munchen: C.H. Beck, 2011), §11, Rn.6; Kraßer, *Patentrecht*, 791.

[517] Terrell and Editors, *The Law of Patents*, 326 (8-49).

[518] Section 616 of the Omnibus Consolidated Appropriations Act of 1996, codified as 35 U.S.C. §287 (c).

eventually harmonised US law with foreign systems, considering that the exception is established on the international level (Article 27 (3) TRIPS).[519]

In Japan, pursuant to Article 69(3), a patent right for the invention of a medicine does not affect the manufacture of a medicine (a product or a process) as prescribed by a physician or a dentist. The provision defines "the invention of a medicine" as a product used for diagnosis, therapy, treatment, or the prevention of human diseases. The provision relates to Article 2.1.1 of the *Examination Guidelines for Patent and Utility Model*[520], which enumerates medical inventions that do not comply with the requirement of industrial applicability.[521]

The objective of protecting medical treatments constitutes an argument against the patentability of medical methods of treatment. In 2002, the Tokyo High Court rendered a judgement in the appeal to the JPO's rejection of a patent application for "process and device for the reproducible optical representation of a surgical operation." The rejection was justified on the following grounds:
1) the invention did not comply with the requirement of industrial applicability under Article 29 (1), because the claimed invention was a surgical and diagnostic method pertaining to human beings and;
2) the invention lacked inventiveness[522].

The Tokyo High Court upheld the rejection, arguing *inter alia* that medical doctors must freely utilize their skills when treating patients, and not be preoccupied with the peril of possible patent infringement. The exclusion of medical activities from patentability under Article 29(1) complements Article 69(3). However, the Court signalized that no legal rationale exists to exclude medical methods from patentability, and that this matter requires the re-consideration of the existing patent policy.[523]

---

[519] Fariba Sirjani and Dariush Keyhanii, "35 U.S.C. 287(C): Language Slightly Beyond Intent," *Buffalo Intellectual Property Law Journal* 3, no. 13 (2005).

[520] "Examination Guidelines for Patent and Utility Model in Japan, as of April 2012," http://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/1312-002_e.htm (accessed 17.6.2013).

[521] A comprehensive list covers methods of surgery therapy or diagnoses of humans (e.g. method of contraception or delivery), therapies, or diagnoses practiced on animal bodies, surgical treatments, the use of devices inside the human body, preparatory treatment for surgery, cosmetic surgical operations, implantations, methods of preventing a disease.
AIPPI, "Japan. Report Q202," 5; "Examination Guidelines for Patent and Utility Model in Japan, as of April 2012": Part II Requirements for Patentability, Chapter 1 Industrially Applicable Inventions.

[522] Article 123(1) of the Patent Act stipulates the material requirements for patent invalidation. They concern: 1) administrative deficiencies in patent applications (i, ii, iv, v, viii), 2) non-compliance with patentability requirements (ii), 3) non-patentable subject-matter (ii), 4) a person who is not entitled to enjoy patent rights or becomes unable to hold the right (ii, vi, vii), 5) violation of a treaty (iii). With the exception to Article 123(1)(iii), the invalidated patents are deemed so *ex tunc*, and might be judged so even after the lapse of a patent.

[523] Ono, "Better than Nothing," 200-01.

4.5.6 Permissible Conducts on Vessels, Vehicles, and Aircraft (Temporary Presence)

A set of rules exempts from patent liability conducts on patented devices on land vehicles, vessels, and aircraft which entered the territory of another country on a temporary or accidental basis. The reduction of the scope of a domestic patent right protects unauthorised uses of a patented technology necessary for the further operation of a vehicle or a vessel involved in international conveyance. Historically, the temporary presence exception goes back to the 19th century, with the adoption of the norm in 1852 in England and 1856 in the US. The exception gained international recognition in the first half of the 20th century with the appearance of the Convention Relating to the Regulation of Aerial Navigation in 1919, with the amendment to the Paris Convention in 1925 (the Hague Revision of the Paris Convention) in Article 5ter, which ultimately reinforced the norm as an international standard of patent practice.[524] Another provision that complements the "temporary presence" exceptions relates to the Chicago Convention on International Civil Aviation form 1944, Article 27 of which limits the patent liability to construction operations such as repair, storage, and installation of spare parts performed on the patented device. The determinants of the protection are the nationality of the conveyance, e.g. whether the country of the flag is the signatory of the Paris Convention, and the temporariness of the entrance onto the territory.

Under German patent law, the effect of a patent does not stretch to a number of actions conducted on international vehicles that enter the territory of German. These actions are stipulated in three sections of the Patent Act: 11(4)-(6). They adopt international regulations in this matter: Article 5ter of the Paris Convention in Sections 11(4) and (5); and Article 27 in Section 11(6).

Section 11(4) exempts the use of patented subject-matter onboard vessels which enter the inland waters of Germany, under the condition that the patented devices are used exclusively for the needs of the vessel. Section 11(5) allows for the temporal or accidental stay of aircrafts and land vehicles within the territory of Germany. The temporal or accidental stay shall not exceed the scope of several days, but can be repeated.[525] Section 11(6) exempts aircraft from seizure or detention on the grounds of patent infringement. The same applies to the storage of spare parts and equipment.

The UK Patents Act stipulates similar rules in Subsections 60(5)d-f: for vessels and vehicles which enter the territory of the UK accidentally or temporarily. The first amendment to the patent law

[524] Jonas Anderson, "Hiding Behind Nationality: The Temporary Presence Exception and Patent Infringement Avoidance," *Mich. Telecomm. & Tech. L. Rev.* 15(2008): 7-11.

[525] Mes, *Patentgesetz*, §11 at 7-9; Kraßer, *Patentrecht*, 791; *Stapelbarer Transportwagen*, OLG Düsseldorf 01.04.1993 2 U 96/92, GRUR 1994, 105; *Pflanzen-Transportwagen*, Hanseatisches Oberlandesgericht Hamburg 18.02.1988 3 U 159/87: GRUR Int 1988, 781.

providing the exception was introduced in 1852, and required reciprocity to protect the English shippers.[526]

The provisions pertain to a "relevant ship, aircraft, hovercraft or vehicle" and concern a ship, aircraft, hovercraft, or vehicle not registered in the UK, but in another country which is a signatory of the Paris Convention and a member of the World Trade Organisation. The exception covers only "the exclusive needs" of such vessels or vehicles, i.e. uses that are necessary to safely continue the transport. The term *temporal or accidental stay* refers to a transient stay or a stay for a limited period of time, whether occasional or causal. Frequency, persistence, and regularity of the stays are not determinative.[527] In *Stena Rederi v Irish Ferries*, the Court held that the intentions of the operator of the vehicle at the time of entry determine the qualification of a stay as temporal.[528]

The US system implements the norm of "temporary presence" in Section 272 35 U.S.C.[529]. Like Article 5ter, it includes the reciprocity provision, but it does not differentiate between the conveyance types and does not include the aspect of *construction,* as laid down in the Chicago Convention. Due to the sparse legislative record on the adoption of the provision, it can be assumed that the legislator relied on the domestic construction of the exception from 1856[530], which was found to be sufficient.[531] In *Brown v. Duchesne*, the Supreme Court addressed the question of whether an element patented under the US system, which constitutes part of a foreign vessel, can be improved upon without the consent of the patentee when such vessel entered the territory of the US temporarily for the purpose of commerce. The Court stated that US patent law did not extend to foreign vessels lawfully harboured in US ports, even when such practice was with to the detriment of the interests of the patentee, e.g. resulting in their financial loss. In addition, it was argued that a private person cannot exercise "a political power," which would be the case if a patentee could enforce the patent right against foreign vessels, because that would "curtail the treaty-making power of Congress."[532] In a later case, *Cali v Japan Airlines, Inc.*[533], the Court interpreted a temporal presence to include all instances of entering the US territory "for the purpose of completing a voyage, turns about, and continuation or commence of a new voyage."[534]

---

526 Anderson, "The temporary presence exception," 7.
527 Terrell and Editors, *The Law of Patents*, 326-27.
528 *Stena Rederi AB v. Irish Ferries Ltd.*, [2002] R.P.C. 50, at 77.
529 Amended in 1952.
530 *Brown v. Duchesne*, 60 U.S. (19 How.) 183(1856).
531 Anderson, "The temporary presence exception," 16.
532 ibid., 8-9.
533 *Cali v. Japan Airlines, Inc.*, 380 F. Supp. 1120(1974).
534 "The temporary presence exception," 17-18.

In the Japanese Patent Act, the exception is included in Article 69(2)(i), which limits the effects of a patent on vessels or aircrafts merely passing through Japan, as well as the effects of machines, apparatus equipment, or other products used therefor. Like in other jurisdictions, this provision incorporates Article 5ter of the Paris Convention and the provisions of the Chicago Convention. In the unofficial translation of the Patent Act, temporary presence is expressed as "passing through Japan," which can be interpreted as making an entrance for a finite duration with the purpose of international commerce. The distinction between vessels and aircrafts remains clear in light of Japan's geographical location. Analyses of Japan's law indicate that the country does not depart from the established standards on international transportation.

4.5.7 Permissible Agricultural Uses (Farmers' Privilege)

Another class of exceptions, here treated as one type, concerns the so-called *farmers' privilege*, which immunises uses of patented plant or animal material for agricultural purposes. This form of patent exceptions followed the introduction of patents on biological materials ("living matters"), which partially affected the practices of traditional farmers, e.g. seed saving and sharing.[535] The objective of farmers' privilege is to allow the farmers to use the products of their harvest for further agricultural work, with the exclusion of commercial activities.

On the EU level, the privilege is safeguarded in Articles 11(1)-(2) of the Biopatent-Directive[536] and in Articles 27(i)-(j) of the UPC Agreement for unitary patents, established on the basis of Article 14 of the Council Regulation 2100/94[537]. The latter allows for the propagation or multiplication of the harvest, provided that the material was purchased for agricultural use with the consent of the patent proprietor.

The German Act includes this provision in Section 9c (1)[538], with an analogous exception applicable to breeding livestock included in Section 9c (2)[539]. The exceptions concern the reproduction of plant or animal material for agricultural, but not commercial (reproduction) activities. Section 9c (3) excludes the applicability of Section 9a in regard to reproduced biological material that was obtained accidentally, or the reproduction of which was technically unavoidable, e.g. the

[535] Borowiak, "Farmer's Rights: Intellectual Property Regies and the Struggle over Seeds."
[536] "DIRECTIVE 98/44/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 July 1998 on the legal protection of biotechnological inventions".
[537] "COUNCIL REGULATION (EC) No 2100/94 of 27 July 1994 on Community plant variety rights ".
[538] Article 11(1) of Biopatent-Directive 98/44/EC.
[539] Article 11(2) of Biopatent-Directive 98/44/EC.

unintentional crossing of seeds.[540] Brewing serves as a good illustration of the exception: the multiplication of seeds is inevitable in production of beer. For that reason, the limitation exempts the second tranche of reproduced seed. The objective of the exceptions is to allow farmers to pursue their harvesting or breeding activities, including the propagation of patented material, for agricultural purposes.

The UK Patent Act regulates this matter in a similar manner.

1) Subsection 60(5)g allows for the use of harvest material for propagation or multiplication, but applies solely to plant varieties specified in Schedule A1 (Subsection 60(6A)), which names the requirements for the violation, such as plant species, equitable remuneration to the patent proprietor, information provided by a farmer, a seed processor, and the existence of a rightsholder.

2) Subsection 60(5)h permits the use of an animal or animal reproductive material for the agricultural breeding of stock or other animal reproductive material, which constitutes or contains a patented invention. Section 60(6B) excludes the sale of the material, as well as any commercial reproduction activity which falls within the scope of the provision (it does not impose any limitations upon the variety of animals, i.e. the subsection applies to all animal varieties).

US patent law does not provide any similar provision which would regulate uses for agricultural purposes. However, since 1970, the US has granted certificates of plant variety protection[541], the law of which provides corresponding farmers' and breeder's privileges. 7 U.S.C. §2543 stipulates the right to save seeds obtained from an authorised source for further seeding purposes, as well as the right to use saved seeds in the production of a crop for use on the farm or for sale. A *bona fide* sale should be for a reason other than reproductive purposes and should be carried out via other channels. Such a sale concerns small quantities of seeds that are not labelled by a variety name.[542] A purchaser who uses such seeds for seeding purposes infringes the right. Notably, US law departs from the legal practice adopted in the European system by legitimising the sale of seeds, which is excluded in other regimes that solely allows farmers the use and the reproduction of protected varieties on their own farms.[543]

[540] Kraßer, *Patentrecht*, 792.
[541] 7 U.S.C. §2321 et seq.
[542] Lesser, "Valuation of Plant Variety Protection Certificates," 232.
[543] ibid.

The applicable law in Japan does not include any provision corresponding to farmers' privilege.[544]

4.5.8 Permissible Use of Biotechnological Inventions

In Article 27(l), the UPC Agreement permits, laconically expressed, acts pursuant to Article 10 of the *Biopatent* Directive. The said provision introduces the exhaustion principle in regard to biological materials, which in practice means that the purchasers of propagation material have the right to grow it (with market circulation in mind). This solution applies to the second generation of biological material obtained from the propagation and multiplication of the patented material, placed on the market (within the EU or the EEA) by the patent holder or with his or her consent, and with the intention of further propagation or multiplication. The exception does not absolve the user from patent liability if he or she further sells the obtained material for further propagation and multiplication, and does not cover third generation material.[545]

The German legislator implemented this rule in Section 9b of the Patent Act. The UK Patent Act includes the exception in Schedule A2 in Section 10, which is a verbatim translation of Article 10 of the Directive.

No directly related solutions in US and Japan applicable laws have been found.

4.5.9 Permissible Use of Computer Programs

The UPC Agreement presents a novel approach by incorporating an exception on computer programs for the purpose of decompilation and interoperability into the catalogue of patent limitations. German and UK legislators have not implemented similar instruments in their patent systems (to date); but regulate this subject matter via copyright law in reference to Articles 5 and 6 of the Software Directive[546]: Sections 69d and 69e of the German copyright act, and Sections 50A(1-

[544] WIPO, "Questionnaire on Exceptions and Limitations to Patent Rights. Japan," (http://www.wipo.int/scp/en/exceptions/replies/japan_2.pdf), 14.
[545] Kraßer, *Patentrecht*, 792; Benkard and Editors, *Patentgesetz*, §9c at 2-5.
[546] "DIRECTIVE 2009/24/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 April 2009 on the legal protection of computer programs".

3) and 50B of the UK act.[547] The same concerns the two other analysed jurisdictions, the US and Japan.

The provisions of the Directive relevant to the named purposes concern the observation, study, and testing of the program's functioning with the aim of determining the ideas and principles underlying the program or its specific elements (similar to experimental use). The authorisation of the rightholder is not required to reproduce and translate the code for the purpose of achieving the interoperability of an independently created computer program with other programs. The acts can be performed by the licensee or another person authorized to use a copy of a program. The information to achieve interoperability has not previously been readily available; the permissions extend solely to those parts of the original program which are necessary in order to achieve interoperability.

Almost automatically, a chain of questions arises as to how and why transpose these norms in the environment of patents. The *obtained information*, which pertains to the source code (an interface), is protected under the copyright regime, whereas a patent covers a technical solution expressed and realized with a computer program (concerning primarily the quell code). When we consider that patents which cover the functioning of interfaces, or patents with protected elements contain interoperable information, does the patent interoperability exception apply instead of the corresponding copyright provisions, or does it complement it? More questions are to come. If the interoperability is achieved on the operation level by modifications of the source code “as such,” even if this induces certain patented technical results, but the code “as such” remains non-patentable and falls within the ambit of the copyright regime, are we faced with a schizophrenic situation in which we accept the patenting of software “as such” despite clear exclusions in patent law? Why, then, would the decompilation of code constitute patent infringement and require insurance against such conducts in the form of a patent limitation? One should also consider that the legislator might have chosen the lesser of two evils and introduced the exception as “a backdoor” solution for patent infringements involving interoperability matters. …Time will tell.[548]

---

[547] Reto Hilty and Christophe Geiger, "Towards a New Instrument of Protection for Software in the EU? Learning the Lessons from the Harmonization Failure of Software Patentability " *Max Planck Institute for Intellectual Property & Competition Law Research Paper No. 11-01* (2011).

[548] See John Palfrey and Urs Gasser, *Interop. The Promise and Perils of High Interconnected Systems* (New York: Basic Books, 2012); Karl H. Pilny, "Schnittstellen in Computerprogrammen. Zum Rechschutz in Deutschland, den USA und Japan," *GRUR Int.* (1990); Thomas Vinje, "Die EG-Richtlinie zum Schutz von Compterprogrammen und die Frage der Interoperabilitaet," ibid.(1992); Michael Lehmann, "Die Europaische Richtiline uber den Schutz von Computerprogrammen," ibid.(1991); Ulla-Maija Mylly, "An Evolutionary Economics Perspective on Computer Program Interoperability and Copyright," *IIC* (2010); Sally Weston, "Software Interfaces - Stuck in the Middle: The Relationship Between the Law and Software Interfaces in Regulating and Encouraging Interoperability," ibid.(2012); Begona Gonzales Otero, "On the

4.5.10 Prior Use

The prior use right constitutes a separate category of patent limitations: it applies to a unique scenario in which a patented idea has been in use by a third person before the patent application has been filed, and does not require the permission of the patentee.[549]

The main objective of the norm is the protection of legitimate possession and its economic status against destruction by the subsequent patent application of a third party.[550] The prior use exception applies to commercial uses and serves the protection of the investment. It begins from the moment of the first use of the later-patented solution, and no from the recognition by the patent owner, who is not entitled to any remuneration for such use.[551] In the first-to-file systems, where a party which decided not to patent an invention or was slightly behind the party which filed a patent application, would have to cease all operations and incur financial losses, the functionality of the prior use right is of particular concern, as it serves the overall fairness and the balance of interests.

The prior use exception constitutes an original and separate right from the patent itself; it is neither equal to a patent license, nor represents any burden to it.[552] Notably, in *Helitune v Steward Hughes,* the UK Court held that a prior use right can be recognised as "a statutory licence"; however, the conferred right does not entitle the licensee to grant further licences and does not constitute a license on a contractual basis – it only permits the aforementioned action(s).[553] Any kind of contractual binding between the inventor and the user – e.g. an employment contract or a supply order – eliminates the possibility of invoking the prior use defence.[554]

Prior use is a well-recognised instrument, which has been adopted in multiple jurisdictions. In the course of long-term practice, many aspects of the privilege have been unified among the legal systems.

Fence of Article 27(K) of the UPC: The Software Interoperability "Limitation"," http://kluwerpatentblog.com/2014/11/14/on-the-fence-of-article-27k-of-the-UPC-the-software-interoperability-limitation.html, accessed 24.04.2015; Amy Cullen, "Software, Patents and Interoperability - The UPC Regime and UK Implementation," Bristows. Law Firm, http://www.bristows.com/articles/software-patents-and-interoperability-the-upc-regime-and-uk-implementation
accessed 24.04.2015.

549 Kraßer, *Patentrecht*, 819-20.

550 Benkard and Editors, *Patentgesetz*, §11 at 2.

551 Kraßer, *Patentrecht*, 819-20; Benkard and Editors, *Patentgesetz*, §12 at 6.

552 *Lacktränkeinrichtung*, BGH 07.01.1965 Ia ZR 151/63, GRUR 1965, 411, 415-16.

553 *Helitune v. Stewart Hughes* [1991] F.S.R. 171, 207, 206.

554 *Fullstoff* BGH 10.9.2009 - Xa ZR 18/08, GRUR 2010, 47; *Patentgesetz*, §12 at 12; Kraßer, *Patentrecht*, 821.

The UPC Agreement lays down the limitation in Article 28, which does not regulate prior use on a EU-wide basis, but subjects it to national regimes. The exclusion of prior use from the unification process has been criticised for the incoherence of the undertaken steps. It seems that the lawmakers avoided a troublesome issue that the prior use constitutes, considering its derogating function of patent exclusivity and significant economic ramifications. On the other hand, the reason for removing the privilege from the unification agenda could be its low practical meaning, and procedural hurdles, such as the meticulous evidence that is associated with older materials.[555]

The German Patent Act regulates the prior use right in Section 12 providing that a patent has no effect against a person who, at the time of the application's filing, had already begun to use the invention in Germany, or had made the necessary arrangements for doing so.

In the UK system, the use of an invention by a third party before the priority date used to constitute an infringement and did not enjoy any protection in the Patents Act of 1949. With the enactment of the Patents Act of 1977, such uses were exempted from infringement by conferring a *continuation* right in accordance with Section 64.

The US patent law allows for claiming the prior use defence in regard to commercial activities performed in the US, which is stipulated in 35 U.S.C. §273. The norm exempts from infringement commercial activities in good faith that occurred at least a year before the filing or disclosure date[556] of the invention (whichever is earlier).

Prior to the American Invents Act (AIA)[557] the prior use defence applied solely to business method patents. Currently, the prior use exception applies to every technology: "a subject matter (…) consisting of a machine, manufacture, or composition of matter used in a manufacturing or other commercial process."[558] This change resulted from the major modification of the US patent system introduced by the AIA, namely the shift to the first-to-file model: the system had to provide a defence mechanism to a party that used, but did not disclose, an invention.[559] The defence applies to commercial uses and other specific uses, such as non-profit uses by research laboratories or other entities, such as universities or hospitals, to ensure that the public may benefit from the

[555] Lise Osterborg, "Gedanken zur Vereinheitlichung des Vorbenutzungsrechts fur Erfindungen im Gemeinsamen Markt," *GRUR Int* (1983); Jan Busche, "Das Vorbenutzungsrecht im Rahmen des deutschen und europaischen Patantrechts," *GRUR* (1999).

[556] Section 273(2)(B).

[557] *Leahy–Smith America Invents Act*.

[558] Harmon, *Harmon on Patents*, 149. This concerns patents that were granted on or after 16 September, 2011.

[559] David J. Kappos and Teresa Rea Stanek, "Report on Prior User Rights," (USPTO, 2012), 49.

privilege.[560] It also covers the premarketing regulatory view, during which the safety or efficacy of the subject matter is established (including any period specified in Section 156(g)[561]).

Japan's Patent Act implemented the prior use right in Article 69, which stipulates in subsection (2)(ii) that a patent right is not effective in regard to products which were in existence before the time of patent application. This rule corresponds with Article 79, which regulates the prior use right as a non-exclusive license. The provision states that a person who made or learned about the existence of an invention identical to the claimed in a patent application and has been using or preparing to use the said invention at the time of the patent application's filing, shall have a non–exclusive license to use the patented invention. The license is restricted solely to the invention itself and the purpose for which the invention has been used or prepared. The activity must take place solely in Japan.

Comparisons between the prior user rights in the analysed systems demonstrate many commonalities. The condition for invoking the application of the privilege is the commercial character of the undertakings. Private and non-commercial use excludes the application of the prior use right. The prior use exception applies when the innovative idea in possession was recognized, used, and (or) manufactured.[562]

This assumes certain advancement in the workings on or the commercialization of the claimed invention. The UK provision clearly indicates that preparations must be *effective* and *serious*; intentions alone do not suffice to comply with the provision. Preparations must indicate certain advancement in accomplishing a given undertaking, e.g. business negotiations entering the contractual stage. Experimental trials may be considered to constitute serious preparations[563]:

> That conclusion can be illustrated by considering a person who had in good faith imported an infringing product. The section enables him to continue to import the product but not to sell it unless the importation amounted to an effective and serious preparation to sell it.[564]

[560] Section 273(c)

[561] Section 156(g) regulates the extension of patent terms on following products: (1) new drug, antibiotic drug, human biological product; (2) food additive or colour additive; (3) medical device; (4) product which is new animal drug; (5) veterinary biological product. The provision explains the calculation of the review period for each product group.

[562] Kraßer, *Patentrecht*, 825-26; Benkard and Editors, *Patentgesetz*, §12 at 10.

[563] Terrell and Editors, *The Law of Patents*, 329-31.

[564] *Helitune v. Stewart Hughes*

When it comes to a legal dispute upon the prior user right, the party which invokes the privilege has to provide outstanding, flawless, and convincing evidence[565] on the development of the invention, together with evidence on the attempts to put it into circulation – the advanced state of preparations for commercialization is of particular advantage in claiming the prior user exception. All materials on the trade secrecy of the invention in question play a role, not only those relating to the claimed patent (or certain patent claims). For example, in the US the prior use defence involves an extensive (and costly) discovery procedure, including covering other entities of the company. In addition, the prior use defence introduces the risk of establishing patent infringement if the evidence does not effectively prove advanced workings and use in *good faith*. In the course of proceedings, the court examines the patent claims and the similarities between the patented invention and the "prior use" object, along with the rectitude of technology acquisition and the development process.[566]

The principle of *good faith*, i.e. an independent and rightful *prior* development of the patented solution without the intent to infringe, is a core determinant of prior use.[567] It corresponds with the underlying purpose of the norm that addresses the use of an invention, completed without the knowledge of patent application, or granted patent protection, which safeguards fairness and justice in regard to a party that was "behind in filing the application."[568]

A prior user enjoys a wide privilege to exploit the invention for his or her own company, including the permission to change of the type of use. For example, if the prior user has manufactured products, but, despite intending to do so, has not succeeded in their commercialisation, the use may *extend* onto further business activities.[569] The analysed norms do not explicitly limit the scope of the exercised right in a quantitative or qualitative manner. Modifications of the patented product are permissible if they do not substantially depart from the technical teaching embedded in the patent – the right covers working and modifications of the claimed use, provided that such modifications do not change the identity of the prior use product. [570] The use cannot extend to forms that do not relate to the state of the object at the time when the prior use was claimed. E.g., an exporter cannot claim a manufacturing right over the patent at issue.[571] Likewise, the privilege does not allow its holder to change an act into e.g. importing or materially modifying the nature of

[565] 35 U.S.C. §273 (b), (e), (f).
[566] Johann Pitz, *Patentverletzungsverfahren*, 2 ed. (Munich: Beck, 2010), at 62.
[566] Kraßer, *Patentrecht*, 823; Benkard and Editors, *Patentgesetz*, §12 at 8.
[567] Kraßer, *Patentrecht*, 823; Benkard and Editors, *Patentgesetz*, §12 at 8.
[568] WIPO, "Questionnaire on Exceptions and Limitations to Patent Rights. Japan," 5.
[569] Alfred Keukenschrijver, "Zur sachlichen Reichweite des Vorbenutzungsrechts," *GRUR* (2001): 945.
[570] Kappos and Stanek, "Report on Prior User Rights," 26.
[571] Pitz, *Patentverletzungsverfahren*, at 63; Kraßer, *Patentrecht*, 826; *Desmopressin*, BGH 12.6.2012 - X ZR 131/09, GRUR 2012, 895, 896.

the prior use. The privilege, however, allows for the continuation of a given act and qualitative adjustments to the product, e.g. placing the product on the market and modifying it during its lifetime – otherwise, the objective of the prior use would only be illusory.[572]

The prior use right constitutes personal use and cannot be bestowed to a third party; it can be, however, transferred or assigned with the entire business in which the prior use occurred. [573] The prior use privilege cannot be licensed, but it can be transferred only in conjunction with a business, which also includes transfer in the form of a general succession like inheritance.[574]

Notably, US law reserves that no prior use right can be invoked in regard to patents owned by or assigned to universities or technology transfer institutions[575]. Otherwise, prior use could impair the ability of such institutions to license their research results.[576]

The prior use defence serves the protection of non-patented innovations and trade secrecy. The legislator has acknowledged the fact that an inventor need not apply for a patent protection to pursue a business activity. The USPTO Report on the prior use right defence indicates that the defence does not affect the patent system by reducing the incentive to seek patent protection, as is claimed by its critics. The prior use defence calibrates the balance between different inventors of the same invention, providing the one who did not apply for a regulatory protection, but nonetheless used the invention commercially for a longer period of time, the privilege to continue the business.[577]

In the light of theoretical considerations, the prior use exception represents a desired legal instrument that rightfully solves a conflict between the patentee and the prior user of an invention. It also constitutes a powerful instrument that delineates the market exclusivity granted with patent. In regard to the latter, an EU-wide prior use right could provide the prior inventor with an immense advantage e.g. by allowing for their business expansion in other countries, in which the patentee could have already "prepared" the conditions for commercial activities. This would build direct competition on the same subject matter in the whole common market578 – an unwanted outcome of EU-wide prior use despite the high saturation of patents on similar and overlapping

[572] Terrell and Editors, *The Law of Patents*, 329-31.
[573] Section 273 (e) (1), Section 12 of the German Paten Act.
[574] Section 64(2) of the Patents Act of 1977, Article 94(1) JPA. Kappos and Stanek, "Report on Prior User Rights," 26.
[575] Section 273 (e)(5).
[576] Kappos and Stanek, "Report on Prior User Rights," 7.
[577] ibid.
[578] The exhaustion principle does not allow the prior user the freedom to exercise the prior use right, e.g. by establishing producing subsidiaries in other countries, where he did not formally obtain the privilege.

solutions. Under the current strong patent mindset, such a solution definitely could not have been adopted. Even when, in practical dimensions, prior use is a rare ground for patent litigations (patent revocation certainly represents a more promising strategy).[579]

4.5.11 Exhaustion of Patent Rights

The principle of the exhaustion of patent rights is widely acknowledged in the respective national legal orders. However, it has not been codified thus far, and works on the level of the legal doctrine itself. It appears under the statutory limitation, as the UPC Agreement incorporates the principle in Article 29.

The exhaustion of patent rights occurs when an authorised person enters the patented product into commercial circulation, for which he or she obtains remuneration.[580] In that moment, the supervision of the patentee over a product or a process is terminated. Exhaustion is a legal rule *ipso iure* and constitutes an immanent restriction within the patent law.[581] Substantially speaking, the principle, like other patent limitations, serves the balance of interests. More particularly, it ensures the free movement of goods, and stresses that a patentee should not be able to exercise boundless control over the use on of a protected sold product. It also limits the potential demands of the patentee for additional compensations once he or she obtains a reward.[582] Until the product enters market circulation, the patentee enjoys all privileges of the patent to determine the price and the sale conditions; however, once the article is sold, the patentee cannot instruct the lawful purchaser on the use, distribution, or the re-sale of the given product (the relation resembles an exclusive license over a sold product).[583]

---

[579] Osterborg, "Gedanken zur Vereinheitlichung des Vorbenutzungsrechts fur Erfindungen im Gemeinsamen Markt."

[580] Exhaustion may occur even when the product is put into circulation without the consent of its patent holder. E.g. in the German system it happens under the conditions of the exploitation right (Sec. 23), subsequent exploitation right (Sec. 12, 123 No. 5), a compulsory licence (sec. 24), or a governmental exploitation order (Sec. 13). The right is not exhausted when a licensee is authorised only to produce a certain product, but also delivers it to the market and sells. *See* Kraßer, *Patentrecht*, 796-97.

[581] ibid., 795. If all requirements of exhaustion are met, the principle cannot be restricted or revoked.

[582] This corresponds with the single-compensation rule, which means that one cannot request the application of further instruments once the damages have been recouped. For example, if the infringed party receives full compensation calculated either upon the damages incurred or the profit the infringer has made, or upon the equivalent of license fees the infringer would otherwise have to pay, the party cannot demand injunction upon the use or sale. *See* ibid., 796.

[583] *Karate*, BGH, 14. 12. 1999 - X ZR 61/98, JuS 2000, 612, 613.

The exhaustion principle as such has not been enforced internationally.[584] However, the principle has a regional effect within the territory of the EU and the European Economic Area.[585] In practice, it pertains to the fact that when a product is put on the market in one of the EU Member States with the authorisation of the patent holder, patent rights exhaust automatically in all Member States. *De jure*, the principle arises from Article 34 of the TFEU, which prohibits quantitative restrictions on imports and equivalent measures between the Member States.

The territoriality principle within the EU with respect to the exhaustion principle was abandoned to stimulate trade and commerce between the Member States, and to strengthen the Common Market, with the objective of achieving stronger competitiveness within the EU market with the US and other leading economies.[586]

In the German order, the principle evolved as a scholarly doctrine founded upon the principles of Josef Kohler.[587] The right of use obtained by the purchaser used to be explained on the grounds of an implied license, but that approach proved insufficient in clarifying the patentee-purchaser relationship. Kohler replaced it with the concept of *Zusammenhang der Benutzungsart* (the context of the type of use), and initiated the evolution of the modern exhaustion principle. His theory acknowledged e.g. the replacement of spare parts if the identity of the product was to remain unchanged.[588] Later, Lindenmaier introduced an understanding which regarded the exhaustion

---

[584] The international exhaustion remains an open question and a very delicate issue since there is still no consent between countries: the emerging countries accede upon it, whereas the developed countries reject the idea. The TRIPS-Agreement sanctions the exhaustion principle as an open question.
Article 6 of TRIPS reads as follow: "For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."
A voice in favour of international exhaustion: Stanislaw Soltysinski, "International Exhaustion of Intellectual Property Rights under the TRIPs, the EC Law and the Europe Agreements," *GRUR Int.* (1996); and a voice against: Joseph Straus, "Bedeutung des TRIPS für das Patentrecht," ibid.

[585] The exhaustion constitutes an important element of the EU economic policy. Formulated by the ECJ with regard to the Articles 28, 29 of the TEC (Articles 34 and 36 of the TFEU), the rule contributed to the improvement of free movement of goods and the strengthening of the Internal Market. The underlying judiciary oeuvre comprises decisions: *Parke, Davis & Co. v. Probel and Others*, C-24/67; *Centrafarm BV and Others v. Sterling Drug ("Negram 2")*, C-15/74; *Terrapin v. Terranova* C-119/75; *Merck v. Stephar and Exler ("Modurethik")*, C-187/80.
"The exhaustion principle is next to the community patent, which introduction has not been yet successful, a way to limit the perils for the internal market that results from the territoriality principle binding for intellectual property rights." Andreas Leßmann, "Erschöpfung von Patentrechten bei Konzernvertrieb," *GRUR* (2000): 744.

[586] "Erschöpfung von Patentrechten bei Konzernvertrieb," 744.

[587] Josef Kohler, *Handbuch des Deutschen Patentrechts in rechtsvergleichender Darstellung* (Mannheim: Bensheimer, 1900).

[588] ibid., 545; Fritz Lindenmaier, "Über Erschöpfung des Patentrechts, Ausbesserung, Wiederherstellung und Ersatz in Verkehr gebrachter patentgeschützter Vorrichtungen und ihrer Teile " *GRUR* (1952): 294; *Förderrinne*, BGH 21.11.1958 I ZR 129/57, GRUR 1959, 232, 233; Mineko Mohri, *Maintenance,*

principle as a special principle which applied only to protected articles put into circulation.[589] The exhaustion allowed for the further exploitation of a patented product, its repair, and re-sale; but did not exclude the patent right when the use exceeds the scope of permissible patent utilization.

The German Patent Act does not conceive a general principle of exhaustion, with the exception of the propagation of biological material, which implements Article 10 from the Biopatent Directive. No general exhaustion rule has been codified to govern other cases. As mentioned above, exhaustion occurs as a well-established doctrine on a national level, with a strong grounding in EU law (a regional European exhaustion).

UK Law applies the doctrine of an implied license, which functions as the exhaustion doctrine. The latter was introduced to the Patents Act as an implementation of corresponding CPC rules, but remains out of force.[590] Similar to German law, a regional exhaustion applies within the EEA territory under Articles 34 and 36 of TFEU.

The implied license doctrine was established in *Betts v Willmott*[591] and pertains to a situation in which the patent holder transfers a license to exercise control over a particular patented product to a purchaser in the course of a sale. Unless the patentee expresses certain restrictions, the user enjoys by the virtue of an implied license the right to freely use the product.[592] Once an implied licence is given, it cannot be withdrawn to curtail the use of the good:

> If not limited licence was imposed at the time of the supply on the person originally supplied then no amount of notice to that person or persons deriving title form him could turn the general licence into a limited licence.[593]

The implied license can be overridden once an authorised person sets conditions defining the permissible use of a patented product upon is sale, which apply to all purchasers.[594]

An implied license allows the purchaser to have the article repaired, but does not extend as far as renewal.[595] If some elements of machinery tend to wear out easily, the use can have them replaced

---

Replacement and Recycling - Patentee's Rights in the Aftermarkets. Germany, the U.S. and Japan (Munich: Herbert Utz Verlag, 2010), 38.

589 Lindenmaier, "Über Erschöpfung des Patentrechts," 295.

590 Ammîrām Binyāmînî, *Patent Infringement in the European Community* (Weinheim VCH, 1993), 290, Footnote 14.

591 *Betts v. Willmott*, LR 6 Ch App 239(1871).

592 Terrell and Editors, *The Law of Patents*, 324-25.

593 *Roussel Uclaf U.S. v. Hockley Inernational and Ltd. and Anr.*, [1996] R.P.C. 14, 441, 442.

594 *Dunlop v. Longlite Battery*, R.P.C. 473(1958); *National Phonograph Company v. Menck*, 28 R.P.C. 229(1911).

within the bounds of the implied license, or even order a greater number of parts for unanticipated breakdowns.[596]

In one recent case, *DataCorporation v. Eagle Technologies*[597], the Court merged the application of the implied license with the exhaustion principle. The Court asserted the implied license to claims 19[598] and 22[599], and infused into the reasoning on the implied licence the notion of patent exhaustion, by stating that claimant rights exhausted with the unrestricted first sale of the device:

> (…) those purchasers had an implied licence to work the invention of claims 19 and 22; or the claimant's rights in respect of those two claims had been exhausted by sale of the printers. It relied on the fact that there were no conditions on the sale of the claimant's printers restricting the user to using only ribbons sold by the claimant.[600]

In the US system, the exhaustion doctrine, better known as the *first sale doctrine*, originates from the old English common law "disapproving imposing any restraints on the personal property"[601]. The doctrine introduces balance into the patentee-purchaser relation and has a strong pro-competitive meaning.[602]

In a precedent-setting case on repair and reconstruction, *Wilson v. Simpson*, the Court vocalized the notion of the exhaustion of rights:

> The right to replace them [cutting-knives] was a part of the invention transferred to the assignee for the time that he bought it (…). It has not been contended, nor can it be, that such can be a limitation of the assignee's right in the use of the invention.[603]

An unconditional sale exhausts the patent monopoly over the manufactured article: it hands "the

---

595 *British Leyland Motor Co. v. Amstrong Patents Company Ltd.*, [1986] F.S.R. 221, 237; *United Wire Ltd. v. Screen Repairs Services (Scotland)*, [2001] R.P.C. 24, 439; *Sirdar Rubber Co. Ltd. v. Wallington, Weston & Co.*, [1907] 24 R.P.C. 539; *Solar Thomson Engineering Co. Ltd. v. Barton*, [1977] R.P.C. 537.

596 *British Leyland Motor Co. v. Amstrong Patents Company Ltd.*, 256.

597 *DataCorporation v. Eagle Technologies* [2011] R.P.C.17, 443.

598 "The inventive concept lays in the cooperation between the spindles of the carrier, the pins at the end of the spindles and the features of the supply item- a method claim." Ibid., 502.

599 "The inventive concept lays in the cooperation between the spindles of the carrier, the pins at the end of the spindles, the feature of the supply item and the support structures in the printer. In general, it is a product claim." Ibid.

600 ibid., 449.

601 Frank Porcelli, "Bowman v. Monsanto and an Introdcution to the Patent Exhaustion/First Sale Doctrine in the United States," *GRUR Int.* (2013): 27; see also David H. Horowitz, "The Record Rental Amendment of 9184: a Case Study in the Effort to Adapt Copyright Law to New Technology," *Colum.-Vla. J.L. & Arts* 31, no. 12 (1987).

602 Binyāmînî, *Patent Infringement in the European Community*, 292.

603 *Wilson v. Simpson*, 50 U.S. 109, *124 (1850).

absolute dominion" over the sold product to the purchaser, who has the right to use the device "until it is worn out," to repair it or improve upon it "as he pleases, in same manner as if dealing with property of any other kind."[604] In return, the patentee obtains a satisfying compensation – a gratification for the invention:

> Patented implement or machines sold to be used in the ordinary pursuits of life become the private individual property of the purchasers, and are no longer specifically protected by the patent laws of the States (…).[605]

In *Mallinkrodt v. Medipart*, the court stressed that "no restrictions can be imposed on patented goods after their sale (…) and [a restriction] could not convert (…) a sale into a license. The principle of exhaustion does not affect a conditional sale to change it into an unrestricted one."[606]

A conditional sale restricts the purchaser's rights – the purchaser is not entitled to go beyond the given limitation. The conditions of such a sale must be lawful and mutually accepted; however, if the patentee exceeds the legitimate scope of patent exclusivity, the doctrine of patent misuse may restore the proper balance. This applies to conducts that represent lawful measures, but have an anticompetitive strength and are against the public interest, e.g. tying restrictions and price fixing.[607]

The difference between the two principles derives from the type of conduct trigger: the exhaustion principle arises from the fact of selling a product, whereas an implied license results from the conduct of a party (its intentions), e.g. an acquiescence, equitable estoppel, or legal estoppel.[608] One does not exclude the other. In *Quanta*, the Court affirmed:

> It is axiomatic that the patent exhaustion doctrine, commonly referred to as the first sale doctrine, is triggered by an unconditional sale.[609]

Failure to understand the circumstances involved in certain conduct may result in the erroneous and unlawful application of an implied licence. In the famous case *Monsanto v. Scruggs*, the legal argument of the defence, which was based on the implied license doctrine, was not confirmed by the findings of the Court. The defendant attempted to expand the concept of the implied license

---

[604] *Mitchell v. Hawley*, 84 U.S. 544, *548 (1872).

[605] ibid.

[606] The Court of Appeals acknowledged that certain types of restrictions are enforceable if they remain within the reward a patentee is entitled to by a patent. *Mallinckrodt Inc. v. Medipart Inc.* , 976 F.2d 700, *703-05 (1992); *Goodyear v. Beverly Rubber* 10 F. Cas. 638, *640 (1859); *Keeler v. Standard Folding Bed Co.*, 157 U.S. 659, *666 (1895); *Adams v. Burke*, 84 U.S. 453, *457 (1873).

[607] *Mallinckrodt Inc. v. Medipart Inc.* , *703-05.

[608] Amber Hatfield Rovner, "Practical Guide to Application of (or Defense against) Product-Based Infringement Immunities under the Doctrines of Patent Exhaustion and implied License," *Tex. Intell. Prop. L.J.*, no. 12 (2003-2004): 246; Harmon, *Harmon on Patents*, 623.

[609] *LG Electronics Inc., v. Quanta Computer Inc.*, 453 F.3d 1364, *1369 (2006).

over the second generation of the self-replicating seeds. He argued to have an implied license on replicated seeds. However, the structure of Monsanto's license agreements excluded any possibility of implied licensing, since every link in the distribution chain, as well as the use thereof, were under license conditions. The Federal Circuit panel affirmed that "in order to establish an implied licence the circumstance of the sale must plainly indicate that the grant of a licence should be inferred." In the case, Monsanto's licenses were classic licensing agreements. They imposed significant restrictions on the seed sellers, who were not permitted to sell seeds to growers unless they signed one of Monsanto's licence agreements.[610] The seed distributors were not authorised to grant any sort of a licence[611]:

> Without the actual sale of the second generation seed to Scruggs, there can be no patent exhaustion. The fact that a patented technology can replicate itself does not give a purchaser the right to use replicated copies of the technology. Applying the first sale doctrine to subsequent generations of self-replicating technology would eviscerate the rights of the patent holder.[612]

Likewise, while in Japan the exhaustion of a patent right has not been proclaimed in the JPA, it nonetheless remains a well-known institution in the legal doctrine.

However, unlike in the other presented jurisdictions, the old statutory patent law, the Patent Act of 1922, based the norm on the principle the implied license.

It stipulated that a lawful purchaser was entitled to use, sell, and allow others to use the protected product. Some scholars merged the implied license with the patent exhaustion, arguing that "it could be thought to be the expiration of the right due to the achievement of the right."[613]

It was not until 1997 when in *BBS Wheels*[614] the Supreme Court set forth the principle of domestic patent exhaustion.

---

[610] The growers could use seeds with Monsanto's biotechnology for planting a single crop only ("exclusivity provision"). The transfer or re-use of seeds, as well as research or experimentation, were prohibited (*no replant policy* and *no research policy*). Last but not least, the growers had to pay a technology fee.

[611] *Monsanto Co v. Scruggs*, 459 F. 3d 1328(2006). See also *Monsanto Co. v. McFarling*, 302 F.3d. 1291(2002); Porcelli, "Bowman v. Monsanto and an Introdcution to the Patent Exhaustion/First Sale Doctrine in the United States," 29; *Monsanto v. Bowmann*, 686 F. SUpp. 2d 834, *839 (2009).

[612] *Monsanto Co v. Scruggs*, *1336.
In another case involving Monsanto, the Court repeated the same principle: "No unconditional sale of the Roundup Ready 9R trait occurred because the farmers could not convey to the grain dealers what they did not possess themselves. (…) The grain elevator/dealer from whom Bowmann bought the soybeans had not right to plant the soybeans and could not confer such a right on Bowmann." *Monsanto v. Bowmann*, *839.

[613] Mohri, *Maintenance, Replacement and Recycling*, 50.

The case involved a German manufacturer, BBS, which produced a certain type of car wheel with patents in Germany and Japan. The defendant obtained the wheels in Germany and imported them to Japan. The import was not restricted by BBS: notifications neither on the products nor on the purchase were given or expressed. BBS wanted to prevent the defendant from importing its product and claimed damages. In the first instance, the Tokyo District Court consented to the plaintiff's claims. In the appeal, the Tokyo High Court dismissed the claim, arguing that the plaintiff was sufficiently compensated upon the act of the first sale. BBS appealed from the decision to the Supreme Court. The defendant raised the principle of international patent exhaustion. The Supreme Court rendered a judgement in favour of the defendant:

> However, if patented products are sold domestically, either by the patentee or with his consent, the patent is deemed exhausted because it has fulfilled its purpose.[615]
>
> (…) It is assumed that the patentee who has transferred the ownership of patented goods abroad has also endowed the transferee or any subsequent purchaser with the right to undertake further transactions with third parties, including the importation to Japan, use in Japan, and transfer of ownership on our domestic market.[616]
>
> (…) The importation of products covered by a domestic patent and marketed abroad by the patentee is only infringing if the patentee has clearly excluded such importation.[617]

The Court accentuated the overall benefits of patent exhaustion:

a) the balance between the patent protection and the public benefit,
b) unimpeded free movement of goods,
c) fair and just reward for an inventive effort.[618]

The construction of the exhaustion principle does not depart form acknowledged standards and legal practice: provided the seller explicitly indicates that the distribution of goods in Japan is restricted or prohibited, the exhaustion of rights does not occur and a double reward is permissible.[619]

The exhaustion rule does not derogate the rights from a patent completely. Such rights remain only unenforceable as long as the exploitation stays within the scope of law. It plays a role in debates on

---

[614] *BBS Wheels 2*, Tokyo High Court 23.03.1995 Case No. Hei 6 (ne) 3272; *BBS Wheels 3*, Supreme Court 01.07.1997 H6-(Ne)-3272, IIC 1998, 331.
[615] *BBS Wheels 3*, 333.
[616] Ibid., 334.
[617] ibid., 331.
[618] ibid., 333.
[619] Etuso Doi, "U.S. Supreme Court Judgment on Patent Exhaustion Rendered - A Comparative Overwiev with Japanese Patent Law - Quanta Computer, Inc. v. LG Electronics, Inc.," *Patents and Licensing* (Jun 2008): 37. See also *Canon Injekt Printer*, IP High Court 21.01.2006 Hei 17 (ne) 10021, IIC 2006, 867, 868.

the permissible acts of the end users, such as the scope of the repair doctrine, where the effectiveness of the principle terminates if the conduct in question manifests the preponderance of infringement indications, i.e. the reconstruction of a patented device.

4.6 Non-statutory Limitations

4.6.1 Repair v. Reconstruction Doctrines

> Whether and to what extent an improvement, re-manufacturing and replacement of elements that relate to any patented product, device, arrangement (composition) or a process and its results, is covered by the patent, was always one of the most complicated patent questions. [620]

Drawing clear and concise boarders between permissible repair and impermissible re-manufacturing is "a hard nut to crack" in the patent practice.[621] Apart from the definition of repair itself, i.e. all conducts performed on a product that prolong its usefulness, other issues pertaining to repair remain complicated.[622] Certain guidelines can be extracted from case law; however, not a single case can be determined *a priori* without a detailed examination of patent claims and the circumstances of the conduct in question.

Not without reason, the question of permissible repair arises together with the issue of indirect infringement[623]: control over the spare-parts market is a much sought-after prize.[624] Indirect (contributory) infringement occurs when without the patentee's consent a third party offers or supplies to unauthorized persons "means relating to an essential element" of an invention with the intention of making or using the invention, if either the third party knows or it is obvious from the circumstances themselves that such means are suitable and intended for the use of the invention.[625] An element can be recognised as relating to an essential feature of the invention on a

---

[620] Lindenmaier, "Über Erschöpfung des Patentrechts," 294.

[621] Clemens Rübel, "Patentschutz bei Reparatur- und Ersatzteilfällen," *GRUR* 7(2002): 565.

[622] Klaus Haft et al., "Die Erschöpfung von Rechten des Geistigen Eigentums in Fällen des Recyclings oder der Reparatur von Waren (Q 205)," *GRUR Int.* (2008): 946.

[623] For example, Section 10 of the German Patent Act; Section 60(2) of the UK Patents Act.

[624] Niels Hölder, "Mittelbare Patentverletzung und Erschöpfung bei Austausch- und Verschleißteilen Die „Flügelradzähler"-Entscheidung des BGH," *GRUR* (2005).

[625] This is similar in the UK doctrine: pursuant to Section 60(2), a person infringes a patent if he or she supplies or orders to supply a person not entitled to work the invention with means relating to an essential element of an invention for putting the invention into effect in the UK. The infringement occurs if the person knew that those means are suitable and intended for putting the invention into effect, i.e. a supplier knows that the end user intends to work the invention. The place of infringement: "putting the invention into effect in the United Kingdom," is defined by the place of operation of the end users.
Intellectual Property Office UK IPO, "Manual of Patent Practice," (2013), http://www.ipo.gov.uk/pro-types/pro-patent/p-law/p-manual/p-manual-practice/p-manual-practice-pat1977.htm

functional basis when, together with one or more claimed elements, it contributes to the realization of the technical concept of the invention.[626] Its identification remains an indispensable condition of rendering fair judgement in every case on indirect infringement.

4.6.1.1 Germany

In old German patent law, such "essential" parts had to meet the requirement of *erfindungsfunktionellen Individualisierung* (invention-related functional individualization), which referred to elements that demanded special invention-related adjustment due to the fact that alone, i.e. when separated from the given invention, the elements did not fulfil the invention-related function.[627] This abstruse approach was abandoned and replaced with the concept of *functional cooperation*.[628] As determined by jurisprudence, an element is essential "when it functionally supports the realization of the inventive concept."[629] If the element in question fulfils the above criterion, its supply can be considered indirect infringement. However, that still does not clarify whether the replacement of the essential element constitutes permissible repair. However, such an approach nonetheless takes each case a step further, because understanding the essentiality of an element constitutes an important reference in the repair-reconstruction dichotomy.

German courts examine how changes introduced in the course of the alleged repair correspond with the identity of the invention; how the element in question contributes to the technical teaching; last but not least, how the repair affects the balance of interest. The courts investigate the following issues:

1) the identity and essentiality of an element (a technical solution embedded in the device),
2) the technical teaching (defined in patent claims),
3) the trade-off.

Small nuances between cases have proved sufficient in shifting the judgements in a different direction. This fact introduces a certain dose of unpredictability and uncertainty when anticipating the judgements.

---

www.gov.uk/government/publications/patents-manual-of-patent-practice: 60.19-60.20.

[626] *Flügelradzähler [Impeller flow meter]*, BGH 4.5.2004 - X ZR 48/03, GRUR 2004, 758; Hölder, "Mittelbare Patentverletzung," 21-22.

[626] *Flügelradzähler [Impeller flow meter]*, 761; *Schutz (UK) Ltd v. Werit UK Ltd.*, [2010] F.S.R. 22, 553, 554.

[627] Lindenmaier, "Über Erschöpfung des Patentrechts," 298-99; *Förderrinne*, 234.

[628] *Rigg*, BGH 10.12.1981 X ZR 70/80, GRUR 1982, 165, 165-67; Michael Nieder, "Die mittelbare Patentverletzung - eine Bestandsaufnahme," *GRUR* (2006): 979.

[629] *Flügelradzähler [Impeller flow meter]*, 761; *Schutz (UK) Ltd v. Werit UK Ltd.*, 554.

The following list of most relevant decisions highlights how Courts handle this subject-matter in various scenarios:

a) *a replacement of one element in a patented device comprising of two elements*

In *Impeller flow meter*[630], the patent at issue concerned a device designed to measure water consumption, which comprised of two elements: housing (a capsule) and a removable measuring unit (a filter mesh). The defendant made and sold measuring capsules compatible with the patented housing.

The Court found the party guilty of infringement, since the replaced part, a measuring capsule, functionally corresponded with the features of the patent claims – it was covered by patent claims; and had significant meaning for the technical teaching embedded in the invention, and for that reason was ruled to be an essential element. The measuring capsule directly interoperated with the housing (claim no. 1); as well as enabled non-rotational admission flow and lowered the risk of clamping the two elements together (*Gesamtvorrichtung*).

The replacement of the measuring capsule constituted an unlawful re-manufacturing.

b) *A replacement of an element of no technical and functional effect upon the patent solution*

In *Flanged Tire*[631], the plaintiff was the owner of a patent for a rail vehicle wheel. The defendant supplied the plaintiff's customers with flanged tires produced according to drawing of the plaintiff provided for the purposes of maintenance.

The Court stated that the ultimate receiver of the flanged tires, i.e. the customer, was a lawful receiver and had the right to restore the utility of the device after this had been worn-out. It also admitted that there was a functional cooperation between the flanged tire and the rubber ring, which sufficed to qualify the supply of flanged tires as indirect infringement, but this did not serve as evidence to qualify the replacement as a reconstruction. The exchanged part did not add any value to the technical effects of the invention and did not reflect any of them. Therefore, the replacement of a worn-out part constituted permissible repair.

[630] *Flügelradzähler [Impeller flow meter]*.
[631] *Laufkranz [Flanged Tire]*, BGH 3.5.2006 - X ZR 45/05, GRUR 2006, 837.

The case *Pallet Container*[632] concerned the refurbishment of a worn-out inner part of a pallet container, which constituted direct infringement in light of Section 9(2). Not only did the the defendant replace a used part, he also produced new ones. However, the replacement of a used container represented a lawful use of a device in light of the exhaustion principle. Otherwise, the device would be of no use for its buyers.

The Court found no functional relation between the container and the patented structure, and stressed that containers did not contribute to the technical teaching of the invention. The exchanged container had no impact on the identity of the invention, which comprised of the outer coat designed to improve the stability of the inside container. No reference regarding any particular arrangement with the container was introduced into the patent claim. The replacement of the container was thus ruled to be permissible.

c) *A replacement of an easily wearing-out part (within a daily use of a device)*

In *Pipette system*[633]*,* the patent suit covered a manual pipette system. The defendants supplied syringes suitable for the plaintiff's device.

The Court regarded the claimed syringes as a non-significant and subordinate element of the invention, since they did not contribute to the technical solution of the invention whatsoever. The syringes interoperated with other elements of the invention, and for that reason constituted a part of a functioning unit (*Funktionseinheit*), which sufficed to fulfil the premises of indirect infringement. However, the product qualified neither as a reconstruction, nor as a repair; it was qualified as the replacement of a part wearing-out on a daily basis within the ordinary use of a device – a syringe was a part that solely interoperated with an improved locking system.

The Court referred to the balance of interests and asserted that it cannot be expected from the purchasers to be satisfied with a device, the lifespan of which would be limited to the number of syringes provided with the device by the manufacturer. Protecting the interest of the manufacturer (here, the patentee) by ensuring the position of an exclusive supplier of syringes would go beyond the inventive concept and the preservation of the identity of the patented solution.

[632] *Palettenbehälter 2 [Palett Container 2]*, BGH 17.7.2012 - X ZR 97/11, GRUR 2012, 1118.
[633] *Pipettensystem*, BGH 27.2.2007 - X ZR 38/06, GRUR 2007, 769.

The *Nespresso* case[634], highly awaited due to its economic impact on the coffee-capsules market, had a similar outcome[635]. The patent at issue concerned a system for extracting coffee from a capsule. The plaintiff argued that non-Nespresso capsules infringed its patent.

The Court asserted that the capsules, though indispensable for the use of machines, neither embodied nor referred in any manner to the technical teaching of the machine. The interoperability of capsules with a machine was clear: the device would be useless without the coffee capsules it was made for. However, the invention concerned solely the mechanical process of extracting the coffee from the inserted capsules, which was improved by simplifying the extraction. The capsules themselves did not require any improvement. The patent at issue did not determine their form and structure; they were indicated as an exemplary embodiment. The Court upheld that the replacement of capsules constituted an ordinary use to maintain the usefulness of a machine (see *Pipetten System*). The exhaustion took place – the Court evaluated whether the patentee was properly remunerated for placing the invention, defined through patent claims, on the market.

Nespresso, however, insisted on the court acknowledging the replacement of capsules to be re-manufacturing, since capsules are its main business: after all, the company is known as the biggest maker of coffee capsules, and not the coffee machine producer.[636] The capsules market keeps growing.

The following guidelines can be *extracted* from the analysed decisions:

1) the patent claims are the departure point – they indicate the technical solution and the identity of the invention;

---

634 *Nesspresso Capsules*, LG Düsseldorf 18.8.2012 4b O 81/12; BeckRS 2012, 17607.

635 The encapsulated coffee is "the fast-growing segment of the coffee market: pods now account for 20 to 40 percent of the value of ground sales in the $17 billion European coffee market according to Euromonitors International." See Liz Alderman, "Nespresso and Rivals Vie for Dominance in Coffee War," http://www.nytimes.com/2010/08/21/business/global/21coffee.html, accessed 14.02.2013.
Nespresso carries a fierce war over the dominance on the market of "encapsulated' coffee with e.g. Tassimo by Kraft and Senseo by Sara Lee. It fortified its position with 1700 patents – some of them expired already in 2012; the position of Nespresso remains strong. As the Nestle's spokesperson said, "There are no patent expires in the foreseeable future that would lessen the current protection of the intellectual property of our current capsules or product range." *See* Tom Mulier, "Nespresso Will Survive `Plethora' of Knock-Offs, Inventor Says," http://www.bloomberg.com/news/2011-01-30/nespresso-will-survive-plethora-of-knock-offs-inventor-says.html, accessed 14.02.2013; Reuters, "Nestle Wins Nespresso Patent Battle," http://www.reuters.com/article/2012/04/19/nestle-nespresso-idUSL6E8FJE0F20120419, accessed 14.02.2013.

636 Nespresso sales almost tripled within just four years: from $1.4 billion in 2010, to $3.2 billion in 2010. It is estimated that almost one-fifth of the coffee may be made from capsules. *See* Mulier, "Nespresso Will Survive."

2) if an ordinary use of the invention requires the recurrent replacement of an element, this will be recognised as a permissible action;
3) if measures go beyond the necessary scope of restoring the normal utility of the device, the introduced changes are regarded as a reconstruction, since they affect the identity of the patented device and exceed the inevitable ambit of maintenance;
4) the number of parts replaced does not play any role as long as their replacement does not change the identity of the invention;
5) the functional relation of the element to the invention is not determinative (see syringes in *Pipetten System*);
6) how the element contributes to the technical teaching affects the court rendering – patent claims are the reference.

4.6.1.2 The United Kingdom

The distinction is as challenging in the UK doctrine:

> The principle is quite clear, although its application is sometimes difficult; you may prolong the life of a licensed article but you must not make a new one under the cover of repair[637].

Again, the simplicity of the definition indicates a troublesome application: repair is everything "which does not amount to an act of making a patented article anew."[638] In other words, a repair is each action apart from manufacturing: "repair was one of the concepts (like modifying or adapting) which shares the boundary with "making" but did not trespass on its territory."[639]

This approach opens up an endless spectrum of repair models; repair is determined as a matter of degree (it may be simple and complex) and a question of facts.[640] Similar to the German courts, the UK courts screen the patent claims and analyse the modification in the identity of an invention and its impact on the technical teaching. In fact, courts from both countries often reach the same conclusions:

a) The replacement of an element in a two-element patented device

[637] *Sirdar Rubber Co. Ltd. v. Wallington, Weston & Co.*, 543.
[638] *United Wire Ltd. v. Screen Repairs Services (Scotland)*, 442; *Canon Kabushiki Kaisha v. Green Cartridge Co. (Hong Kong) Ltd.*, [1997] A.C. 7285, 7356.
[639] *Sirdar Rubber Co. Ltd. v. Wallington, Weston & Co.*, 543.
[640] *United Wire Ltd. v. Screen Repairs Services (Scotland)*, 448-50; *Solar Thomson Engineering Co. Ltd. v. Barton*, 547, 55.

In *United Wire v Screen Repair*[641] (German *Impeller Flow meter)*, the claimant argued that the process of replacing meshes amounted to re-making the screens by re-assembling, cleaning, and, in the end, exchanging certain parts with new ones. A permissible repair, in his view, would consist of "filling up holes in the mesh with rubber compounds."[642] The Court of Appeal agreed with the argumentation and found the replacement infringing and falling within the patent claims. Meshes were enclosed in patent claims and truly reflected the inventive idea. As the invention consisted of two elements, they presented a true combination; the Court stressed that a device consisting merely of two parts can hardly exist when one part is removed.[643]

b) The replacement of an element of no contribution to the technical teaching

In *Schutz v Wire*[644] (German *Pallet Container*), the Court clarified that the relation between a replaced element and the rest of a product can be determined if "what was left embodied the whole of the inventive concept of the claim"[645]. The claimant argued that containers were integrated products and could not serve their function without the "filling" bottle. That was insufficient to convince the Court, which stated that the inventive concept was embodied in the *Schutz* cage, which retained that concept even without the bottles. The plastic bottles did not contribute in any way to the technological teaching that concerned the improved resistance of the cage – particularly the joints of the rods.[646] The fact that the specification demonstrated that the inner containers were intended to be "interchangeable" or "exchangeable" spoke against the patentee.[647]

Solar Thomson Engineering v. Barton[648] (corresponding with the German *Flanged Tire)* concerned a patented pulley with an easily replaceable elastomeric ring in its peripheral groove. The alleged infringer was replacing the used rings based on patentee's drawings. The plaintiff did not offer the rings for sale, since his economic calculation showed it to be unprofitable and excessively troublesome. Neither did the first defendant, who sub-contracted the replacement due to insufficient manufacturing capacities. However, re-fitting worn parts was common practise in the steel industry.

---

641 *United Wire Ltd. v. Screen Repairs Services (Scotland)*.
642 ibid., 451-52.
643 *Schutz (UK) Ltd v. Werit UK Ltd.*
644 ibid.
645 ibid., 570.
646 The two EP-patents referred: 1) to the inner side of the cage lying closely against the bottle and 2) to the alleviation of forces. Ibid., 554.
647 ibid., 559.
648 *Solar Thomson Engineering Co. Ltd. v. Barton*.[1977] R.P.C. 537

The Court held that the replacement of the rings did not fall within the patent scope. The inventive idea resided in the facilitated removal of the split mould without dismantling the whole apparatus in order to e.g. to re-fit the worn rubber parts. As in *Schutz v. Wire*, the specification itself suggested the rubber ring is readily exchangeable.[649] The Court brought up the notion of an implied license and asserted that the users were accordingly licensed by the plaintiff, which could be easily inferred from the facts, and so the defendant was entitled within the bounds of the implied license to perform the repairs requested by the first defendant.

In conclusion, the following aspects of the Courts' analyses can be accentuated:

1) patent claims are the focal point and define the degree of permissible repair;
2) in some cases the specification clarifies whether certain elements can be exchanged, and it gives clear indications in regard to the manners in which the elements in question can be re-fitted;
3) if a given part constitutes an essential element of the invention, its replacement is infringing;
4) contribution of the element to the technical teaching plays a role in establishing infringement;
5) "No repair would be deemed as an infringement as long as it does not infringe the patentee's right to prevent other form making the product"[650];
6) whether a user had an implied license or the patent right had exhausted plays a secondary role when the act under investigation constitutes a prohibited making – neither an implied license nor exhaustion can exempt the act from patent liability.[651]

4.6.1.3 The United States

In the US doctrine, the concept of repair derives from the common acceptance of the belief that nobody should be penalised merely for repairing a worn-out element. Permissible repair is further justified by the first sale doctrine (or implied license), which exhausts the rights of the patentee over the invention. Due to the non-existence of the private and non-commercial exceptions in the US system, the repair doctrine can be regarded as a form of a permissible personal use for non-commercial purposes.

[649] ibid., 542.
[650] *United Wire Ltd. v. Screen Repairs Services (Scotland)*, 458.
[651] ibid., 458-59.

Permissible repair comes dangerously close to the infringing act of making something anew (reconstruction) – the borderline between the two remains vague and unclear. Two instrumental questions which should be considered in this regard are: *how much is allowed,* and *how much is too much*.[652]

The jurisprudential origins of the doctrine date back to 1850, when in *Wilson v. Simpson* the Supreme Court upheld that the replacement of a worn-out part represent a permissible repair:

> When the wearing or injury is partial, then repair is restoration, and not reconstruction.[653]

The Court asserted that when a device is completely broken or worn-out and can no longer be used, any attempt to restore the entire device constitutes an infringing reconstruction. It introduced two additional criteria to scrutinise the degree of changes: the essentiality and the intentions of the inventor. In the aforementioned case, the replaced parts were cutting knives with a short lifespan (of 60-90 days), which constituted an essential part of the invention. Without them, the users could not operate the machine. However, as the court affirmed, replacing them at short intervals was intended by the inventor, and hence the inventor could not complain about the purchaser's behaviour, which consisted of restoring these parts on a regular basis. New knives prolonged the life of the machine and maintained the "identity of the machine." In other words, the purchaser did exactly what the inventor intended them to.[654] Ultimately, the *essentiality* of an element was categorised as being lower than what the inventor intended, as expressed in the patent itself. (The court did not consider the relation between the knives and the technical solution.)

Cotton Tie v. Simmons was the first case in which the Court ruled impermissible reconstruction. The defendant combined an old buckle, originally used to confine the cotton bales, with a new band with the aim of making a new cotton-bale tie. The court recognized the action as the unlawful reconstruction of a patented article, which the inventor designed as a single-use product: as "[the tie] left the bale it could not be used again as a tie." Above that, defendants obtained a licence to use the invention and, once it has worn-out, discard it.[655] The licensing condition spoke against the

---

[652] *Mallinckrodt Inc. v. Medipart Inc.* , *709.

[653] *Wilson v. Simpson*.

[654] ibid., *122-24.
The decision in *Wilson v. Simpson* was criticised for elusive analysis and ambiguous standards in regard to the repair-reconstruction dichotomy. Mark D. Janis, "Tale of the Apocryphal Axe: Repair, Reconstruction, and the Implied License in Intellectual Property Law," *Maryland Law Review* 58(1999): 440-41.
In *Morgan Envelope v. Albany Perforated Wrapping Paper*, the Court analysed the invention of a toilet paper dispensing machine, where the replacement of perishable rolls of toilet paper occurred according to the inventor's arrangement. The act represented neither a repair nor a reconstruction. *See Morgan Envelope Co. v. Albany Perforated Wrapping Paper Co.* , 152 U.S. 425(1894).

[655] *Cotton Tie Company v. Simmons*, 106 U.S. 89(1882).

defendant, but the inventor's intention was the key factor in affirming infringement.

In *Aro Manufacturing v. Convertible Top Replacement*[656], the court challenged the question of whether the replacement of one unpatented part in a combination patent constituted infringement. The patented structure was a "convertible folding top with automatic seal at rear quarter." The invention comprised of supporting structures, a closing mechanism, and a top covering fabric. All of the elements were unpatented and merely their combination was filed as the invention. The first two court instances affirmed infringement; the Supreme Court reversed it. The pivot of its examination rested upon the status of an individual unpatented piece (a cover textile) within the patented combination. None of the elements – the shape, the colour, and the fabric – were claimed in the patent; only the complete *arrangement* was under patent protection. Hence, the Court decided that the patentee could not require the protection on each part taken separately:

> The fact that an unpatented part of a combination patent may distinguish the invention does not draw to it the privileges of a patent. That may be done only in the manner provided by law. However worthy it may be, however essential to the patent, an unpatented part of a combination patent is no more entitled to monopolistic protection than any other unpatented device.[657]

Additionally, the perishable character of the element in question could suggest to the purchaser that its replacement merely constituted the repair of the product. The court referred to *Wilson v. Simson* and reaffirmed that the purchaser buys "the use of the whole" of the combination and thereby has right to replace a worn or broken part to restore the utility of the device.[658]

The court contested the *multi-factor test*[659], suggested in earlier decisions[660], for its inaccuracy. The application of the test would erroneously establish that the replacement of the piece constitutes reconstruction. The fabric was a major and expensive component which wore out after a longer period of time; hence the owner would consider the replacement of a cover to be a major reconstruction rather than a repair.[661] The Court rejected the *heart-of-invention* approach, arguing that an unpatented element, regardless of its *essentialness*, cannot usurp the privileges of the patent. It focused on *spentness* as the determinative factor in the repair-reconstruction dichotomy:

---

656 *Aro Manufacturing Co. Inc. v. Convertible Top Replacement Co., Inc.*, 365 U.S. 336(1961).
657 ibid., *338.
658 ibid., *342.
659 The multi-factor test includes: 1) the life of the part in reference to the expect life of the whole product, 2) the importance of the replaced element, 3) costs, 4) common sense, 5) the intension of the patent owner, 6) the buyer's intension. See ibid., Justice Brennan's concurring opinion, *362; "Tale of the Apocryphal Axe," 444-46.
660 *Wilson v. Simpson*; *Heyer v. Duplicator Manufacturing*, 263 U.S. 100(1923).
661 *Aro Manufacturing Co. Inc. v. Convertible Top Replacement Co., Inc.*, *343.

> We hold that maintenance of the "use of the whole" of the patented combination through replacement of a spent part, unpatented element does not constitute reconstruction.[662]

Notably, in *Wilbur-Ellis v Kuther* the Court recognised as a repair an act of extensive refurbishment involving re-sizing of certain parts with the intention of extending the useful lifespan of the original device.[663] However, as a disclaimer it should accentuated that, in pre *Manufacturing*, which governed the said case, the extensive modifications were performed on unpatented elements (the patent covered a combination of fish-canning machine):

> When six of the 35 elements of the combination patent were resized or relocated, no invasion of the patent resulted, for as we have said the size of cans serviced by the machine was no part of the invention; nor were characteristics of size, location, shape and construction of the six elements in question patented.[664]

Likewise, repair is asserted when a patented combination device is dismantled, renovated, injured parts are replaced, and then reassembled with original parts that remain serviceable.[665]

The US jurisprudence applied various approaches when ruling in repair-reconstruction cases, such as *the identity of an invention*[666], *the heart of invention*[667], the *multifactor-test*[668], and *spentness*[669].[670]

In *Husky*[671], the Court listed three primary repair-reconstruction circumstances:

1) the entire patented invention is spent, and a user reconstructs it to make it usable again – when the invention is intended by the patentee to be used only once and be destroyed afterwards, the use constitutes an infringing **reconstruction**[672];
2) only a spent part is replaced – the part has a shorter lifespan than other parts and/or the whole combination, and so it should be assumed that replacement was accounted for by the patentee – **a repair**; especially when[673];

---

662 ibid., *345.
663 *Wilbur-Ellis Co. v. Kuther* 377 U.S. 422(1964).
664 Ibid., *424-25.
665 *General Electric Company v. United States*, 572 F.2d 745(1978); *Dana Corporation v. American Precision Co.,* , 827 F.2d 755(1987).
666 *Wilson v. Simpson*.
667 "Tale of the Apocryphal Axe," 451-52.
668 *Aro Manufacturing Co. Inc. v. Convertible Top Replacement Co., Inc.*
669 ibid.; *Husky Injection Molding Systems Ltd. v. R&D Tool & Engineering Co.*, 291 F.3d 780(2002); *Jazz Photo Corp. v. United States ITC*, 264 F.3d 1094(2001).
670 "Tale of the Apocryphal Axe," 448-76.
671 *Husky Injection Molding Systems Ltd. v. R&D Tool & Engineering Co.*
672 *Cotton Tie Company v. Simmons*; *Aro Manufacturing Co. Inc. v. Convertible Top Replacement Co., Inc*; *Husky Injection Molding Systems Ltd. v. R&D Tool & Engineering Co*; *Heyer v. Duplicator Manufacturing*; *Jazz Photo Corp. v. United States ITC*.
673 *Wilson v. Simpson*. *Wilson v. Simpson*.

3) a part is not worn out, but replaced with a part to perform a different function – a situation "**akin to repair**, with a reservation that the replaced part is not a patented part of the invention."[674]

In conclusion, any attempts at shaping general standards applicable in diverse types of cases appear futile due to the immense diversity of innovations[675]:

> It is impracticable, as well as unwise, to attempt to lay down any rule on this subject, owing to the number and infinite variety of patented inventions.[676]
>
> Thus, there may be some concept of proportionality inherent in the distinction between repair and reconstruction.[677]

4.6.1.4 Japan

Japanese practitioners and scholars also struggle with the dilemma in question. As each time, the definition itself remains plain and simple: maintenance of a patented product (a check-up or the repair of worn-out elements) with the intent of preserving its utility is lawful. Lawful repair neither achieves the purpose of a patented invention, nor modifies the identity of the protected product, and hence does not constitute the *use* of the invention. Under the principle of patent exhaustion, a purchaser has the right to *consume* the acquired product by replacing and repairing broken parts.[678]

When examining the conducts performed upon patented products, Japanese courts exercise two methods: 1) *substantial analysis employing comprehensive standpoints* to understand the type of the act, 2) *the limit of exhaustion analysis – the two-exception test.*[679] Courts apply them interchangeably, which leads to discrepant outcomes, like in the case of the *Canon Injekt Printer.*[680] (Japanese courts a lack clear policy in this regard.)

---

674 *Wilbur-Ellis Co. v. Kuther* ; *Husky Injection Molding Systems Ltd. v. R&D Tool & Engineering Co.*
675 *Jazz Photo Corp. v. United States ITC*, *1102. *Jazz Photo Corp. v. United States ITC*, *1102.
676 *Goodyear Shoe Machinery Co. v. Jackson*, 112 F. 146, *150 (1901).
677 *Husky Injection Molding Systems Ltd. v. R&D Tool & Engineering Co.*, *786.
678 Osaka District Court, 20 July 2006, 164 Hanrei Jiho 1968; Hammer for a san- making machine, Osaka District Court, 24 April 1989, 1315 Hanrei Jiho 120 from Mohri, *Maintenance, Replacement and Recycling*, 98 -100.
679 ibid., 100.
680 Canon Inc. v. Recycle Assist Co., Ltd.; *Canon Injekt Printer*.

The named case concerned repaired (or re-used) ink cartridges originally manufactured by Canon, which were later refilled by a Chinese company seated in Macao, and subsequently imported to Japan by the Tokyo-based company Recycle Assist.

The Tokyo District Court applied the *substantial analysis* and dismissed the claim, arguing that the defendant did not create a new patented product. The Court considered a number of issues, such as the intention of Canon, the structure of the patented products, the patentable subject-matter, and the distribution.[681] It asserted that the ink tank was still usable when emptied, i.e. it had a longer lifespan than the ink itself. Moreover, "*filling with the ink up to the top of the ink tank is an inevitable method of filling it, and ink is not a patented part*".[682] Otherwise, the ink tank would have to be discarded after one use, which would be detrimental from an ecological and an economic point of view.[683]

The IP High Court employed the *two exceptions test* and overruled the previous judgement. It introduced two new standards in which the exhaustion does not occur:

> However, a patent right is not exhausted and the patentee can enforce its right in the following situations:
>
> *Scenario 1:* When a patented product is reused or recycled after the patented product has fulfilled its original service life and thus fulfilled its function, or
>
> *Scenario 2:* When a third party adds or exchanges part or all of the substantial elements of the patented invention of the patented products.[684]

In this particular case, Scenario 1 did not apply, since the Court did not assert the fulfilment of the product when the original ink had been consumed. The refilling of an empty ink tank represented the replacement of a consumable part, and not the *use* of the product itself. The analysis confirmed Scenario 2: the defendants modified elements that were essential to the patented invention. Patent infringement arose in the process of refilling the liquid container. The Court asserted that the defendant employed the same process as claimed in the patent.[685]

During the appeal to the Supreme Court, the identity of the infringed product was scrutinized by employing (again) *substantial analysis* and the *comprehensive standpoint*. The following features were provided as reference points:

1) the attributes of the patented product,

---

[681] *Maintenance, Replacement and Recycling*, 102.
[682] ibid.
[683] ibid.
[684] *Canon Injekt Printer*, 868.
[685] ibid., 868-69.

2) the substance of the patented product,
3) the description of fabrication and replacement of parts,
4) the actual condition of distribution/transaction.

The Court concluded that the patentee did not intend the ink to be refilled, and hence the cartridges were not provided with any opening to facilitate the refilling. Consequently, it deemed the refilling as a "deformation of the ink tank."[686] The Supreme Court stated that the rule of patent exhaustion applied solely to the sale of patented products under the condition that they remain unchanged. Processing or replacing part of the patented product leads to the creation of a new product, which I distinct from the original one. Therefore, the patent did not exhaust.[687]

The judgement worked solely in favour of the printer producers by bestowing on them the exclusivity on the ink cartridge market and excluding other suppliers. The judgement does not feel correct because the analysis concerned the sold product "as such" and not the patent and the scope of protection granted. Moreover, the Court introduced into the analysis a rather vague notion of public perception which should not be anyhow a yardstick for rendering a judgment on patent infringement. Illustratively, from a European perspective refilling of an ink tank is considered as a common practice– more cost-effective and much more reasonable than buying a new cartridge. Such a public perception might comply with a judgment as long as ink refilling is not confirmed to be protected with a patent. Finally, yet importantly, the interests of third parties and the pragmatic examination of the patent effects were not considered in this litigation.[688]

A brief overview of Japanese case law shows that the approach of the courts is not satisfactory: they lack a unified approach and a comprehensive understanding of patents with their (immense) economic impact.

In *Tissue Paper*[689], the patented invention related to a tissue paper dispenser that hospitals were supplied with. The patentee imposed an obligation on the buyers to obtain tissue paper only through the patentee. The defendant was the company that refilled the patentee's dispensers with tissue paper. The first instance upheld the patentee's claim; the appeal court rendered a contradictory judgement based on the exhaustion principle. The perspective of patent exhaustion is

[686] *Maintenance, Replacement and Recycling*, 104-05.
[687] Doi, "U.S. Supreme Court Judgment on Patent Exhaustion," 30-31.

[688] See Christopher Heath and Mineko Mohri, "Ending is Better than Mending - Recent Japanse Case Law on Repair, Refill and Recycling," *IIC* (2006): 862-64.
[689] Osaka High Court, 1 December 2000 (unreported), Case WA 11089/1998 from ibid., footnote 14.

surprising, considering that the tissue paper did not contribute to the patented solution itself.[690] In *Hammer*[691], the patented invention concerned a device for crushing stone. It was designed to last a couple of years, but the battering plate lasted for approximately a week. The Court acknowledged the replacement as an infringement.[692]

The most commented *Fuji case*[693] concerned the infringement of Fuji single-use cameras after inserting a new film and a battery into used devices. The Tokyo District Court employed the *comprehensive standpoint* and found infringement in the act of replacing an essential element of the invention and making a new product which is identical with its original patented counterpart:

> Once a patented product has fulfilled its function, the patentee is allowed to re-enforce its patent rights over these used patented products. (…) Once the defendant exchanges the main component which comprises a substantial part of patented invention, and thus manufactures new products, the patentee can enforce its patent rights over such products to the extent that these are products identical to the original patented products the patentee has sold.[694]

The Court recognized the permissible replacement of minor components such as batteries, filters, or parts with a shorter lifespan than the product itself, e.g. light bulbs. The replacement in question does not amount to the re-manufacturing of the patented invention. The Court explained that the lifespan of a patented product should be estimated from a comprehensive standpoint, "encompassing the function, structure, material, usage of the patented product and actual conditions of the distribution."[695]

The Court measured the product and its use, but did not measure the patented invention embedded within it. The invention related to the winding mechanism and the whole device (a single camera). The replaced elements: a battery and a film, remained unrelated to the claimed invention – an important aspect missed by the Court.[696] The Court remarked on the level of destruction and difficulties by opening the back cover, as if this possibility were an invitation to perform permissible repair or a reconstruction. The Court made a reference to the public perception of single-use disposable cameras that gained a wide public recognition. However, as correctly noted by commentators, *the common understanding in society* can be manipulated by the

690 ibid., 860.
691 Hammer for a sand-making machine, Osaka District Court, 24 April 1989, 1315 Hanrei Jiho 120 from Mineko Mohri, "Patents, Repair and Recycling from a Comparative Perspective," ibid.(2010): footnote 39.
692 Christopher Heath and Mineko Mohri, "Ending is Better than Mending - Recent Japanse Case Law on Repair, Refill and Recycling," ibid.(2006): 860.
693 Tokyo District Court, 31 August 2000, (unreported) – Fuji Camera from ibid., footnote 18.
694 ibid., 861.
695 Mohri, *Maintenance, Replacement and Recycling*, 107.
696 Heath and Mohri, "Ending is Better then Mending," 861-62.

influx of information. The patent claims demonstrate that the winding mechanism could be re-used, but the patentee's intention was to block the reuse by making the removal difficult.[697]

Japanese Courts performed complicated (convoluted) legal analyses and reached (disappointingly) perplexing conclusions. Comparing the original product with the "re-made" product seems to be one-way street in favour of the patent holder. A "repaired" product is and should be identical with the original one: that is the main purpose of repair. An issue which needs to be addressed here is the extent to which a patented solution (described in patent claims) is changed due to the replacement of worn-out parts. The overview of available cases and corresponding comments suggests that in this subject matter Japanese jurisprudence introduces more confusion than clarity.[698]

4.6.2 Defence Against Claims on Equivalents

Infringement liability can arise when infringing embodiments cover the patented solution functionally and technically, i.e. fall within the zone of equivalent solutions.

Despite differences between jurisdictions in defining the notion of what is equivalent. In general, it can be said that an equivalent is an element that solves the problem of the invention with means that objectively have identical effects, based on the literal meaning of patent claims. The literal meaning pertains both to the plain and the strict meaning of words as found in dictionaries, and to their comprehension by a person skilled in the art.

The reading of patent claims is determinative in infringement lawsuits. Their interpretation and ambit may evolve and alternate despite the *first* construction of the patent office. The alternation does not imply a complete shift from the initial construction, but relates to the extension in the patent construction over embodiments that have not been anticipated before the patent infringement.

[697] Mohri, *Maintenance, Replacement and Recycling*, 107.
[698] ibid., 111-12.

Patent claims build the boundaries of patent exclusivity. Their wording must be extremely well-weighted – not too broad, and not too narrow, or otherwise mistakes might be very costly.[699] Claims do not stand-alone in and of themselves, but are supported by a description (a specification) and drawings, which can clarify ambiguities in regard to the formulation of patent claims.[700] This a widely accepted approach, which is codified in the European system (e.g. Section 69 EPC and the Protocol[701])[702], and confirmed in US jurisprudence[703]. Once patent claims are defined, an accused device is scrutinised "claim-by-claim" in light of the patented solution with the said "boundaries as the reference," to determine the type of infringement: literal or non-literal (i.e. equivalent).[704] To that end, every patent, regardless of the grade of precision to which it has been drafted, covers more than it explicitly says.

Doctrines governing the defence of non-equivalents do not constitute a patent limitation in the classical meaning, unlike all of the above-mentioned instruments, as they apply solely to post-infringement procedures (*ex post)*. They do not create a space free from the effects of a patent, but have a strictly litigation-related purpose. They derogate and limit patent exclusivity when it could be misappropriated by claims over forms and uses outside the scope of protection.

The delimitation of the protection scope constitutes the main axis of every patent lawsuit, and all the pre-trial considerations on the probability of infringement. Certain skilfulness in reading patent claims is required to map out the boundaries of the monopoly, with the ultimate interpretation being made by the court itself. The legal practice established multiple tests, questions, and approaches that guide the construction of claims, which in the end demand a scrupulous reading of

---

[699] The case *Radio Broadcasting System* illustrates cases of misfortune in the drafting of patent claims. The patent at issue covered a radio transmission system intended for car radios with the intent of transmitting traffic information. The patent claims encompassed the transmitting device, but not the receiver that was produced by the defendant. The Court held the complaint unfounded, since receivers were not included in the subject matter of the patent at issue. The Court doubted whether the receiver could adopt the features of the invention. See
Radio Broadcasting System, BGH 24.3.1987 X ZR 20/86, IIC 1988, 811; Jochen Pagenberg, "New Trends in Patent Claim Interpretation in Germany - Good-bye to the "General Inventive Idea"," *IIC* (1988): 788-93.

[700] Klaus Grabinski, "„Schneidmesser" versus „Amgen" Zum Sinn oder Unsinn patentrechtlicher Äquivalenz," *GRUR* (2006): 714; *Schneidmesser I [Cutting Blade I]*, BGH 12.03.2002 - X ZR 168/00, IIC 2002, 873.

[701] "Protocol on the Interpretation of Article 69 EPC," (the new text adopted 28 June 2001).
Section 69 of the EPC Agreement (and the Protocol): "the patent protection is determined by the terms of the patent claims, with the description and drawings used to interpret the claims."

[702] Pursuant to the Section 14 of the German Patent Act, patent claims are determinative for the scope of patent protection. If any ambiguities arise, specifications and drawings assist in clarifying them. Kraßer, *Patentrecht*, 706-07; Grabinski, "„Schneidmesser" versus „Amgen"," 714; *Formstein [Moulded Curbstone]*, BGH 29.4.1987 X ZR 28/85, IIC 1987, 795, 799; *Radio Broadcasting System*, 813; *Windsurfing International*, Court of Justice of the European Communities, Decision vom 25.02.1986 - Case No. 193/83, IIC 1986, 362.

[703] E.g., *General Electric Company v. United States*.

[704] Mueller, *Patent Law*, 446-49.

claims and an investigation into the features of the infringing embodiment. Experience and knowledge are the best advisors.

In terms of making, equivalency comes into play in the likelihood of patent infringement. The following presentation on equivalency determination intends to present a broad picture of principles and doctrines, with the focal point set on the defence of non-equivalents.

4.6.2.1 Germany: Formstein Defence – The Free State of the Art[705]

The German doctrine delivers an interesting perspective on the interpretation of the patent scope. Historically, there have been two concepts: the two-tier theory (*Zweiteilungslehre*), and the three-tier theory (*Dreiteilungslehre*[706]).

In short, after 1940 patent law [707] distinguished three layers of a patent within the *three-tier theory*: 1) the direct subject matter of an invention (*der unmittelbare Gegenstand der Erfindung*), 2) the subject matter of the invention (*der Gegenstand der Erfinung)*, and 3) the general inventive idea (*allgemeinere Erfindungsgedanke)*. The first layer denoted the narrowest scope, the third the broadest.[708] The term *direct subject matter* referred to an inventive idea in its literal meaning (unimpeachable). The second layer covered the technical teaching derived from patent claims, drawings, and the specification by an average person skilled in the art. It stretched over the most obvious equivalents, and was recognised as the most relevant. The general inventive idea expanded the protection over other equivalents a person skilled in the art could infer from the content of the patent without inventive endeavours, simply based on his or her knowledge and experience.[709]

The *Formstein*[710] decision brought back the two-tier system (*Zweiteilungslehre*) [711], which takes into account: 1) the subject matter of the invention (its identity), and 2) the general idea of the

---

[705] Historical insight into discussions upon the free state of art in Paul Ströbele, *Die Bindung der ordentlichen Gerichte an Entscheidungen der Patentbehoerden* (Köln: Heymann, 1975), 92-97.

[706] Kraßer, *Patentrecht*, 708; Hans Dieter Gesthuysen, "Der „Formstein"-Einwand bei einer nach der Entscheidung „Befestigungsvorrichtung II" äquivalenten Ausführungsform," *GRUR* (2001): 910.

[707] Applicable to patents granted based on the Patent Act of 1968. Ströbele, *Die Bindung der ordentlichen Gerichte an Entscheidungen der Patentbehoerden*, 81. Ströbele, *Die Bindung der ordentlichen Gerichte an Entscheidungen der Patentbehoerden*, 81.

[708] Gesthuysen, "Der „Formstein"-Einwand," 910; Eduard Reimer, "Für Professor Dr. jur. Dr.-Ing. e. h. Fritz Lindenmaier zum 75. Geburtstag Äquivalenz, Erfindungsgegenstand, allgemeiner Erfindungsgedanke in Theorie und Praxis," *GRUR* (1956).

[709] Kraßer, *Patentrecht*, 708-09; Gesthuysen, "Der „Formstein"-Einwand," 910-11; Reimer, "Äquivalenz, Erfindungsgegenstand," 392-95.

[710] *Formstein [Moulded Curbstone]*, BGH 29.4.1987 X ZR 28/85; IIC 87, 795.

[711] Applied before 1940.

invention (the equivalent field). The identity of an invention covers the meaning of the patent claims together with the description and drawings, as well as the prior art provided in the patent application. The equivalent field covers all application forms with at least one patented feature which fulfils the requirement of inventiveness.[712]

As provided in Section 14 of the Patent Act, which corresponds to Article 69 EPC, patent claims are recognised as the essence of the protection: the basis is construed as the literal meaning of the wording together with the meaning comprehended by the person skilled in the art. Figures, numbers, or dimensions also underlie the interpretation of *content*, i.e. if the person skilled in the art identified other numbers or figures having the same effect to the ones named in the patent claims, then they are regarded as equivalents.[713] Embodiments named by the expert that go beyond the literal meaning constitute absolute equivalents. Non-absolute equivalents, which cannot be deduced by patent examiners, emerge during the infringement proceeding.[714]

In the landmark BGH case, *Formstein*, the Court promulgated limitations to the scope of equivalents, which does not extend over an equivalent element that does not represent a patentable invention with respect to the prior art:

> The defence that the embodiment alleged to be an equivalent would not be patentable over the prior art is admissible.[715]

The defence does not challenge the validity of the patent at suit and as such is more challenging than its succinct definition suggests. The Formstein defence should not be confused with the revocation of the patents, as this is not its objective. It does not suffice to state that an element belongs to the prior art; it must be located exactly between the prior art and the inventive, novel, and non-obvious level of patentability. More precisely, it is “known from the prior art” and “obvious in view of the prior art,” but nonetheless non-patentable due to the missing inventive step.[716]

The *Formstein* objection can be raised if the claimed element is equivalent to its patented counterpart, that is, when it functionally resembles the patented device, but is not identical thereto. In *Formstein,* the Court held that:

---

[712] Gesthuysen, "Der „Formstein”-Einwand," 911; Reimer, "Äquivalenz, Erfindungsgegenstand," 393.
[713] *Schneidmesser I [Cutting Blade I]*; likewise in the UK order - *Catnic Components Ltd. v. Hill & Smith Ltd.*
[714] Gesthuysen, "Der „Formstein”-Einwand."; Reimer, "Äquivalenz, Erfindungsgegenstand," 392-93.
[715] *Formstein [Moulded Curbstone]*.
[716] ibid., 800; Kraßer, *Patentrecht*, 736; Pagenberg, "New Trends in Patent Claim Interpretation in Germany - Good-bye to the "General Inventive Idea"," 788.

> An equivalent use of an invention requires that the means of the solution of the alleged infringement are not identical with those protected by the patent at issue, but coincide in their technical function, i.e. reach substantially the same effect. (…) the alleged infringement in spite of the same problem, is not based on the patented solution principle.[717]

The reference point remains the evaluation of an average person skilled in the art, who determines whether the given embodiment falls within the scope of equivalence and whether an alleged infringement can be deemed as obvious from the prior art without any inventive efforts.[718] The defence works under two conditions: the embodiment does not literally correspond to the invention and represents an equivalent variation (*äquivalente Abwandlung*).[719]

The Formstein objection may partially question the validity of a patent if a person skilled in the art finds the missing inventiveness or novelty of the patented solution at suit[720]; however, the *Formstein* defence does not serve to revoke the patent, but rather, to determine whether the claimed element was anticipatable in light of the state of the art.[721] The intention of BGH was not to combine the infringement and nullity proceedings and, in consequence, to shift the competence of the patent court on patent re-examination to the civil court. The *Formstein* objection is exclusively concerned with the equivalency of the infringing element and deals with the re-definition of the protection scope, but not the accompanying validity standards.[722]

In *Schneidermesser*[723]*,* the Court specified the elements of the equivalency examination process. Equivalency is ruled if:

1) the deviating embodiment solves the problem underlying the invention by means which, although modified, objectively have the same effect;
2) a person skilled in the art is capable of finding the modified means as having the same effect;
3) a person skilled in the art recognises the deviating embodiment and the modified means as an equivalent solution in light of the technical teaching of the patent claims.[724]

---

[717] *Formstein [Moulded Curbstone]*, 798.

[718] "New Trends in Patent Claim Interpretation in Germany - Good-bye to the "General Inventive Idea"," 788.

[719] Kraßer, *Patentrecht*, 737; *Rollstuhlfahrrad*, LG Düsseldorf 21.12.1993 4 O 235/92, GRUR 1994, 509, 511; Grabinski, "„Schneidmesser" versus „Amgen"," 715-16.

[720] Kraßer, *Patentrecht*, 737; *Rollstuhlfahrrad*, 511; Grabinski, "„Schneidmesser" versus „Amgen"," 715-16; AIPPI, "Germany. Report Q175. The Role of Equivalents and Prosecution History in Defining the Scope of Patent Protection."

[721] *Kabeldurchfurhrung [Cable Duct]*, BGH 04.02.1997 - X ZR 74/94, IIC 1999, 558, 565-66.

[722] Eugen Popp, "Formstein-Einwand -reine Theorie?," *GRUR* (2009).

[723] *Schneidmesser I*, BGH 12. 3. 2002 - X ZR 168/00, GRUR 2002, 515.

[724] "Formstein-Einwand -reine Theorie?," 321-22; Christian von Drathen, "Patent Scope in English and German Law under the European Patent Convention 1973 and 2000," *IIC* (2008): 405.

Such considerations do not take place when determining the validity of the patent, which rests upon weighing the patented solution against the state of the art: its contribution, the level of departure from the existing knowledge, the quality of the problem-solution concept. In practical dimensions, the preparatory works and the delivered evidence might be much more similar between the two types of proceedings, and in certain aspects, they might be equal. Nonetheless, the argumentation lines depart from each other.[725]

4.6.2.2 The United Kingdom: Gillette Defence – The Prior Art Defence

In the UK doctrine, the scope of patent claims must remain *rigid*, i.e. the patentee cannot adjust them according to the strategy acquired in a certain case – the claims must be construed "before the defendant was borne"[726]. The doctrine does not accept the "full-blooded" doctrine of equivalents[727] known in the US system; however, it does not reject the concept of equivalents outright.

UK jurisprudence has developed a method of claim construction based on the patentee's intentions. In the landmark decision*, Catnic v. Hill&Smith,* the Court formulated the *purposive construction* (the *Catnic principle*), which indicates that the patentee is given the ambit of a full protection (monopoly) as specified by the person skilled in the art who construes the claims in a manner intended by the patentee.[728]

---

[725] Popp, "Formstein-Einwand -reine Theorie?."

[726] *Nobel's Explosives Co Ltd. v. Anderson* [1984], 11 R.P.C. 519, 523.

[727] Understood as a "full-blooded" doctrine of equivalents. Leonard Hubert Hoffmann, "Patent Construction," *GRUR* (2006): 722.

[728] Catnic Components Ltd. v. Hill & Smith Ltd., 242-43.
In *Improver v. Remington* the Court restructured the *Catnic principle* into three questions (steps), labelled later as "Improver"Questions, and re-named into "Protocol Questions":
"(1) Does the variant have a material effect upon the way the invention works? If yes, the variant is outside the claim. If no—
(2) Would this (i.e. that the variant had no material effect) have been obvious at the date of publication of the patent to a reader skilled in the art. If no, the variant is outside the claim. If yes—
(3) Would the reader skilled in the art nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention. If yes, the variant is outside the claim."
Improver Corporation v. Remington Consumer Products Ltd., [1990] F.S.R. 181, 189-90.
Known also as *Epilady* case, it illustrates well the equivalents analysis according to *Catnic principle.* The case concerned a depilatory device under the brand name *Epilady, which* comprised of an electric motor in a hand-held housing with attached helical steel spring. The in fringing device (known as "Smooth and Silky") replaced the metal spring with a rubber rod having the same effect of plucking hair out of the skin. The question was whether that rubber rod "was" a helical metal spring in light of language used in the patent claims at suit; whether the alleged infringement was covered by the language of the patent claims. The Court decided that the rubber rod id not infringed based on the following:
1) a rubber rod had no material effect on the way the invention worked – it worked the same ways the helical spring;

The Court formulated the *question-objective* method (*Lord Diplock's three questions*) with the aim of understanding whether the terms used by the patentee are meant literally or figuratively, which allows for the further inclusion (or non-inclusion) of certain variants.[729] First, the question arises of when the embodiments under investigation have any material effect on the way the invention works. Second, this should be cleared "in the light of then-existing knowledge," i.e. at the date of publication[730]. Afterwards, it must be considered whether the patentee intended to include (or exclude) minor variants in the meaning of the wording or phrase at issue. Figurative meaning significantly broadens the spectrum of potential forms, figures, and structures applied in the performance of an invention.[731]

Although the *Catnic principle* was introduced in the Patent Act of 1949, it was also included later without hesitation in the Act of 1977.[732] It also corresponds to Article 69 of EPC and Protocol, as it takes the same approach to construing patent claims.[733]

Equivalence analysis underwent a thorough examination in *Kirin-Amgen*[734]*,* which concerned a completely new technology field that the *Catnic* principle has not been examined against to date: the production of erythropoietin by recombinant DNA technology. As far as the adopted interpretation model worked impeccably with "numbers, measures, figures, angels" it faced difficulties with words (or phrases), the conventional or broader meaning of which could not be decided upon. The Court pointed to the existence of cases in which questions about the meaning were not asked. The term used in the patent claims was as follows: "an exogenous DNA sequence coding for EPO was confronted with an endogenous DNA sequence for EPO." The two terms – *exogenous* and *endogenous* – could obviously not be treated as variants of the conventional

---

2) it would have been obvious to an expert that the rubber rod would work in the same way;
3) the expert would have understood from the patent that the patentee meant to confine his claim to a "helical spring," in its primary meaning and not in a wide generic sense.

729 *Catnic Components Ltd. v. Hill & Smith Ltd.*, 243.

730 Ibid.
It is held that that the priority date should remain the reference point because: 1) an invention must already be novel and non-obvious at the time of the application; 2) a variant not having an effect upon the invention can be claimed obvious ("disclosed") if it is obvious to a person skilled in the art at the point of patent application.
Niels Holder, "Exogenous Equals Endogenous? Claim Construction After the Amgen Decision," *IIC* (2006): 667.

731 *Catnic Components Ltd. v. Hill & Smith Ltd.*, 243.

732 *Improver Corporation v. Remington Consumer Products Ltd.*, 190.
In 1994, the Court of Appeal rejected the *Catnic principle* and named it as perilous to the future patent certainty despite its wide recognition and application. This was followed by two decision bringing back *pro-Catnic approach.* See PLG v. Ardon, [1995] R.P.C. 287, 309; AssioDoman Multipack v. Mead, [1995] R.P.C. 321, 328-337; Beloit Technologies Inc. v. Valmet Paper Machinery Inc. (No.2) R.P.C. 705, 719-721, quoted in Terrell and Editors, *The Law of Patents*, 130-31.

733 *Improver Corporation v. Remington Consumer Products Ltd.*, 190.

734 *Karin-Amgen Inc. v. Hoechst Marin Roussel Ltd.*, [2005] R.P.C. 9.

meaning. In effect, a certain level of generality must have been required in order to cluster them under the same method of making EPO. The Court consequently stated that the variants could not be derived from the words themselves by means of "loosening" their meaning, but instead must be conveyed by a skilled person who would interpret the other possible variants, retaining the level of generality as assumed by the patentee.[735]

Against this complex background of claim interpretation and equivalent determination, the *Gillette* defence appears plain and simple (at least theoretically). The doctrine refers to a scenario in which the defendant proves that the act in question was known from prior art (and was therefore obvious) and prior publications. However, not only the validity of the patent, but also the equivalency of the infringing embodiment are at stake. The Gillette defence combines two aspects in one proceeding: first, it determines whether the embodiment falls within the scope of the protection, and second, if this is found to be true, whether the embodiment was easily conceivable in light of the prior art, which in turn may affect the validity of the patent itself.

The findings upon equivalency are decisive for further argumentations:

1) if the patent claims include the infringing embodiment, the *Gillette* defence may result in patent revocation and no infringement;
2) if the infringing act remains outside the scope of the patent claim, no further validity examination is required – the patent remains valid, but there is no infringement.

---

[735] ibid., 193-97; Holder, "Exogenous Equals Endogenous? Claim Construction After the Amgen Decision."
The amendments to the purposive approaches were later summarized in 11 points in *Technip France SA*, updated in *Halliburton v. Smith*. The list-summary facilitates the comprehension of the purposive approach and clarifies certain aspects:
1) Article 69 remains the "main governing provision";
2) The terms of the claims constitute the basis of determining the ambit of patent protection. They must be interpreted contextually, i.e. within the context of descriptions and drawings, which serve as the background knowledge (the contextualisation);
3-5) Description and drawings serve the proper understanding of the inventor's intention. In the case of ambiguity, they are looked upon as the source to clear all doubts. As the inventor may have many purposes, it is the general idea that counts;
6) The protocol is merely a guideline, the claim terms demarcate the patentee's territory;
7) Limitations introduced by the patentee cannot be ignored. The protocol guidelines are of particular value when the meaning of words conveyed out of the context must be compared within the context. E.g., the phrase *vertically* in the Catnic case did not mean "geometrically vertical," but "vertical enough to do the job";
8) Words and phrases must be construed within the given context;
9) There is no need for a general doctrine of equivalents: this is because that is the fair way of reading the claim in context;
10) Trivial and minor variants fall within the scope only when the claims are read in a fair way. It is not the effect of the doctrine of equivalents;
11) Pedantry and patents are incompatible.
Technip France SA's Patent, [2004] R.P.C. 46, 950-52; *Halliburton Energy Services Inc. v. Smith International (North Sea) Ltd.*, [2006] R.P.C. 2, 55-56.

The defence derives from an old judgement rendered in 1913 – *Gillette Safe Razor Co. v. Anglo-American Trading Co.* – in the case of which the defendant infringed on a safety razor patent, and claimed that the infringing item is almost identical to the one known from prior art. Gillette found itself in trouble and the Court enunciated a defence based on the conviction that:

> The defence that the alleged infringement was not novel at the date of the plaintiff's latters patent is a good defence in law, and it would sometimes obviate the great length and expense of patent cases if the defendant could and would put forth his case in this form, and thus spare himself the trouble of demonstration on which horn of the well-known dilemma the plaintiff had impaled himself, invalidity or non-infringement.[736]

The defence was construed on the constitutional patent law principle that no patent protection can be claimed once an idea was disclosed and in that manner become obvious and publicly available:

> It was still the law that any person was entitled to do that which was old, namely that which had been described in a prior published document, and be confident that he would not infringe the patent of another.[737]

The standard of proof is very high; the defence directly targets the validity of the patent. Its complexity results from the fact that it combines claim construction in light of equivalency and certain aspects of validity. Its peculiarity rests upon the fact that it may revoke the patent on the grounds of obviousness and anticipation.[738] The evidence must be flawless and unequivocal; otherwise, the efforts may be in vain and erroneous, like in the case of *Hickman v. Andrews:*

> There were inconsistencies in the defendants' evidence as to how the prototype of their product had come to be made. In addition, no contemporaneous corroborative material had been put forward by the defendants to support their evidence on this point. The balance of probabilities led to the conclusion that the defendants' product had originated from use having been made of knowledge of the plaintiffs' "Workmate". Since the standard of proof in a "Gillette" defence was strict, the defendants had accordingly failed to make good this defence.[739]

Like the *Formstein* defence, the *Gillette* defence demands scrupulous preparatory works and thorough analysis of strategies that would best support the objectives of the defendant.

---

[736] *Gillette Safty Razor Co. v. Anglo-American Trading Co.*, [1913] R.P.C. 465, 480.
[737] *Merrell Dow Pharmaceuticals Inc. v. HN Norton & Co., Ltd.*, [1994] R.P.C. 1, 13; *Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd.*, [1985] R.P.C. 59, 60.
[738] Terrell and Editors, *The Law of Patents*, 341.
[739] *Hickman v. Andrews*, [1983] R.P.C. 147, 148.

4.6.2.3 The United States: The Reverse Doctrine of Equivalents

The US jurisprudence formulated the doctrine of equivalents (DoE), which applies in scenarios in which an element "performs substantially the same function in substantially the same way to obtain the same results."[740]

DoE scrutinises three aspects of similarities – function, method, and results – to determine the degree of departure of the accused device from the patented one, i.e. whether differences between the two objects in question can be recognised as insubstantial. When "the insubstantiality" is confirmed, the infringing embodiment falls within the scope of equivalents. This further indicates that the device is infringing when it covers every element of the patent claim (the all-element test), which limits the application of the doctrine. The doctrine does not affect embodiments directly based on prior art or disclosed in a patent description, but not claimed (the doctrine of "dedication to the public domain"). The purpose of the DoE is to compensate in some fashion for the natural constraints of patent drafting, as well as the constraints of language, which cannot foresee new forms and technological changes. However, it is not intended to restore the scope of protection once the patentee excluded certain forms during patent prosecution (prosecution history estoppel). One of the key decisions upon scope interpretation was the *Markman* case[741], in which the Supreme Court recognised claim construction as a question of law that judges rule upon, and not a question of facts decided by the jury. In the aftermath of the decision, courts began to review infringement claims involving literal claim construction and the application of the doctrine of equivalents in summary judgements, in a *Markman* hearing (a pre-trial examination). [742]

As mentioned above, the doctrine has been usually asserted to the benefit of the patent owner.[743] Therefore, to maintain the balance of interests, and to limit, if necessary, the DoE, it was established that the doctrine could operate "in reverse".[744]

The reverse doctrine of equivalents (RDoE) absolves the infringement liability when the accused product appears to perform "the same function as the claimed invention" *(i.e.* represents a literal

---

[740] *Graver Tank & Mfg. Co. Inc. et al., v Linde Air Products Co.*, 339 U.S. 605, *607 (1950).

[741] *Markman v Westview Instruments, Inc.* , 517 U.S. 370(1996).

[742] John Allison and Mark Lemley, "The (Unnoticed) Demise of the Doctrine of Equivalents," *Stanford Law Review* 59, no. 4 (2007): 959-61, 77.

[743] The statistics prepared by Allison and Lemley clearly indicate that a small rate of cases on DoE was asserted in favour of the patentee, only 24% of studied cases. Authors indicate the Markman hearing as the cause of the decline.
See ibid.

[744] Mueller, *Patent Law*, 476.

infringement), but does it "in a modified and substantially different way."[745] In other words, based on the reading of patent claims, the accused device literally corresponds to the patented invention, but it has been modified to the extent that it appears to be a different invention altogether.

The notion of the reverse doctrine of equivalents was first pronounced in *Westinghouse v. Boyden*[746]. The patent at issue concerned an automatic air brake mechanism used in trains, which was allegedly infringed on by defendants who manufactured and sold fluid-pressure brakes that sere similar to the patented invention. The Court did not find infringement since, the means used "were quite different and not equivalent of one another, though the function performed was the same."[747] It asserted that mere correspondence with elements of the patent did not suffice to state infringement:

> The patentee may bring the defendant within the letter of his claims, but if the latter has so far changed the principle of the device that the claims of the patent, literally construed, have ceased to represent his actual invention, he is as little subject to be adjudged an infringer (…), when he has done nothing in conflict with its spirit and intent.[748]

RDoE finds its pronunciation in the words referring to Boyden's ingenuity as an independent inventor who improved on the plaintiff's patented solution by enriching it with elements that achieved the same functions, albeit in a more efficient and simple manner.[749]

In *Graver Tank v. Linder Air Products,* the Court affirmed the infringement based on the doctrine of equivalents: "the infringing device performed substantially the same function and in substantially the same way obtained the same results"; but at the same time made an important reference to RDoE:

> The wholesome realism of the doctrine is not always applied in favour of a patentee but is sometimes used against him. Thus, where a device is so far changed in principle from a patented article that it performs the same or a similar function in a substantially different way, but nevertheless falls within the literal words of the claim, the doctrine of equivalents may be used to [in reverse – author] restrict the claim and defeat the patentee's action for infringement.[750]

---

[745] Harmon, *Harmon on Patents*, 151; *Texas Instruments, Inc., v. United States*, 846 F.2d 1369, *1371 (1988). In light of the doctrine of equivalents, a device is deemed an equivalent "if it performs substantially the same function in substantially the same way to obtain the same result." See *Graver Tank & Mfg. Co. Inc. et al., v Linde Air Products Co., *608; Machine Co. v. Murphy, 97 U.S. 120, *125 (1878); Sanitary Refrigerator Co. v. Winters, 280 U.S. 30, *42 (1929).*

[746] *Westinghouse v. Boyden*, 170 U.S. 537(1898).

[747] Charles F. Pigott, "Equivalents in Reverse," *J. Pat. Off. Soc'y* 48, no. 5 (1966): 294.

[748] *Westinghouse v. Boyden*, *568.

[749] ibid., *573.

[750] *Graver Tank & Mfg. Co. Inc. et al., v Linde Air Products Co.*, *608-09.

In the aftermath of *Graver Tank*, the Congress enacted 35 U.S.C. §112, which imposed requirements for "written description, enablement, definiteness, and mean-plus-function claims that are co-extensive with the broadest possible reach of the RDoE."[751]

RDoE was also invoked in *Scripps v. Genentech,* which concerned an imitation of a complex protein. In reference to the RDoE, the defendant questioned scientific and evidential facts underlying the patent, but did not succeed in proving non-infringement. None of furnished evidence proved the infringing recombinant to be structurally and functionally different. In effect, the Court ruled infringement on the ground of the doctrine of equivalents. The Federal Circuit panel stressed, however, a *pro-patent* purpose behind RDoE in preventing the unwarranted extension of the claims beyond the fair scope of the patentee's invention.[752] Nonetheless, in *Tate v. Interface*, the Court clearly signalised that there was no single case where non-infringement was affirmed upon RDoE.[753]

Proving non-infringement by the means of RDoE is very challenging – it requires that claims be read outside of their literal meaning in order to narrow down their construction.[754] The RDoE can be invoked when claims appear more extensive then in the authorised disclosure. RDoE preserves the "validity of the claims in their original intended scope"[755] and moderates the patentee's power over the invention. Thus, RDoE represents an important (but rarely applied) tool which intended to ensure that the patent system is capable of serving its public purposes. When nascent technologies wash away the soil under traditional patent protection, the preservation of the patent claims in the appropriate borders is of special concern. Biotechnological patents that cover product-by-process claims, like in *Scripps v. Genentech*, may concern the same products achieved through different substances and different mechanisms. The same applies to inventions concerning living organisms that undergo rapid modifications.[756] The concept of RDoE could possibly be applied already during the patent prosecution stage. However, the patent office refrains from doing so and gives the broadest possible interpretation of the claim to avoid the rejection by anticipation or unsupported disclosure.[757] Theoretically, the probability of applying RDoE increases when the claims are written broadly and in an ambiguous way, like in pioneer inventions, and when the patentee fails to provide

[751] *Tate Access Floors, Inc. v. Interface Architectural Resources, Inc.* , 279 F.3d 1357, *1368 (2002).
[752] *Scripps Clinic v. Genentech*, 927 F.2d 1565(1991); *Texas Instruments, Inc., v. United States*.
[753] *Tate Access Floors, Inc. v. Interface Architectural Resources, Inc.* , *1368.
[754] Scenarios presented in Karl Bozicevic, "The Reverse Doctrine of Equivalents in the World of Reverse Transcriptase," *J. Pat. & Trademark Off. Soc'y* 71, no. 353 (1989): 354-58.
[755] *Texas Instruments, Inc., v. United States*, *1371.
[756] Harmon, *Harmon on Patents*, 151; Bozicevic, "The Reverse Doctrine of Equivalents in the World of Reverse Transcriptase," 367. E.g., (oncogene mouse) transgenic animal patent US 4,736,866.
[757] "The Reverse Doctrine of Equivalents in the World of Reverse Transcriptase," 354-55.

sufficient evidence explaining the intentions embedded in patent claims.[758] Practically, the application of RDoE does not guarantee that the Court finds non-infringement because the infringement might occur even if the RDoE narrows down the patent claims.

4.6.2.4 Japan: The Fourth Criterion of the Equivalence Test

The Japanese system does not provide any clear doctrine of non-equivalents. It had, however, developed a doctrine of equivalents comprising of five requirements, with the fourth criterion allowing for the defence of non-infringement. It works when the infringer proves that the claimed device does belong to the state of the art or can be easily anticipated therefrom (and contradicts the fourth requirement).

The patent claims are the point of departure and the main indicator for the patent scope – the Japanese system does not deviate in that regard from international standards. The claims are supported by the patent specification (an abstract, drawings, and a detailed explanation). According to Article 36(6)(i) of the Patent Act, an invention for which a patent is sought should be stated in the detailed explanation of the invention. The scope of patent claims shall not be broader than the specification itself. Otherwise, the protection would be granted to an invention that was insufficiently disclosed. The IP High Court identified this principle as *support requirement.*[759] Non-compliance with the requirement results in an objection to or the invalidation of a patent.

For a very long time, Japanese courts construed claims literally (and rarely departed from this approach): once no literal infringement was found, the infringement claim was rejected. Only when the fairness and clarity was in peril, the literal meaning was slightly stretched in order to cover the alleged infringement.[760]

In the mid-1990s, the Courts lessened that *rigid* trend in favour of the greater flexibility of "the doctrine of equivalents."

---

[758] ibid., 356.

[759] The *support requirement* formulated in *Polarizing Film* (IP High Court (Grand Panel), 11 Nov. 2005, 1911 Hanrei Jiho 48) stipulates that "the detailed explanation in the specification should be stated in a way that a person skilled in the art" could easily recognized how the claimed solution solves a certain technical problem. The compliance with the *support requirement* should be decided upon the comparison of the scope of claims with the detailed explanation – likewise in Examination Guidelines cited above. From Kazuyo Kadota, "Claims Support in Japanese Patent Law," *IIC* (2012): 333-37.

[760] Toshiko Takenaka, "The Doctrine of Equivalents in Japan," *CASRIP Symposium Publication Series: Rethinking International Intellectual Property*, no. 6 (2001): 125-26.

In 1996, the Osaka High Court rendered a judgement on the modified embodiment of a human tissue plasminogen activator (t-PA), in which it affirmed the application of the doctrine of equivalents within the general meaning of Article 70(1)[761]. The Court acknowledged that in certain cases the interpretation of patent claims cannot be limited to the literal wording, and that a certain level of flexibility must be introduced in order to safeguard appropriate patent protection.[762] Previously, Courts were reluctant to offer figurative interpretations due to the uncertainty of outcomes, but in the aforementioned case, the Court affirmed that "the establishment of equivalence also does not destroy the confidence of third parties in the scope of patent claims."[763]

However, it was not until the *Ball Spline* that the Supreme Court set forth conditions upon the applicability of the doctrine of equivalents.[764] The patent at issue concerned "ball spline bearings for infinite sliding." The alleged infringer made and sold bearings similar to those claimed in the invention. While Tokyo High Court found infringement, the Supreme Court dismissed it in the appeal and named the criteria under which an infringing device may fall within the scope of a patented invention. Equivalence can be affirmed if:

1. an element in the accused product that differs from the claimed element is not an essential part of the invention,
2. the allegedly infringing element achieves the same function and effect, and hence, the same objective as the claimed invention,
3. a person skilled in the art could have easily anticipated the replacement at the time of production,
4. the allegedly infringing device at the time of the patent application did not belong to the state of the art or could have been easily anticipated therefrom,
5. in the course of patent application proceedings, the scope of the patent claims was not meant to exclude the allegedly infringing device.[765]

The first criterion concerns the *non-essentiality test*: to what extent the non-similar part of the accused device represents a non-substantial part of the claimed invention.[766] In *Ball Spline*, the Court defined *an essential element* as a key technical feature of the claimed invention constituting a basis to solve a unique problem stipulated in the invention.[767] The distinction between essential

---

[761] The technical scope of a patented invention shall be determined based upon the statements in the scope of claims attached to the application.

[762] *T-PA 2*, Osaka High Court 29.03.1996 Heisei 6(ne) 3292, IIC 1997, 391.

[763] ibid., 394.

[764] *Ball Spline* remains the sole source of the doctrine of equivalence.

[765] Junichi Yamazaki, Yasunori Ohtsuka, and Sakata Yasuhiro, "Recent IP High Court Decision Involving Infringment under Doctrine of Equivalents," *Patents and Licensing* (June 2010): 33; *Ball Spline Bearing 3*, Supreme Court 24.02.1998 AB-1997-5, IIC 1999, 443, 444.

[766] "Recent IP High Court Decision," 36.

[767] ibid., 34.
"Essentiality refers to the key technical idea of the claimed invention which supports the solution of the invention." From Mohri, *Maintenance, Replacement and Recycling*, 103, footnote 454.

and non-essential elements provokes understandable reservations. As reported, 70% of cases on equivalent infringement were denied for non-compliance with this requirement.[768] The non-essentiality test may lead to divergent results when comparing various prior art references. Another shortcoming of this approach is bias (and surprising), or the favouring of minor inventions that gain a greater ambit of equivalents over pioneer inventions that have fewer equivalents, but which have a greater number of essential elements.[769]

The second criterion, *replaceability,* assumes that the differing element shall have no effect upon the objective of the patented invention: its purpose and results.

According to the third requirement, the element should be easily conceived by the expertise of a person skilled in the art at the time of production or exploitation. The time reference is crucial because the patent protection changes with time: it differs between the priority date and the date of manufacturing. The patent claims remain unchanged, but their construction evolves as technology and language develop – the patentee cannot predict all possible and future applications. Hence, when the Supreme Court introduced variability *at the time of production,* it stretched the scope of patent protection over forms that emerged after the patent application.[770]

The fourth requirement resembles the German *Formstein* defence and stipulates that the accused product cannot be obvious from the prior art at the time of filing the patent application. The infringing equivalent must meet the requirement of non-obviousness and fall within the ambit of the invention as a similarly innovative solution. The defendant must prove "in reverse" that the accused device was obvious and easily conceivable based on the prior art, and that it was not inventive. If this approach succeeds, the patented solution might be challenged on the grounds of the lack of novelty and non-obviousness.[771]

The fifth requirement excludes the doctrine of equivalents when an element has been intentionally removed from the scope of the patent during the patent prosecution, comprising the so-called *filed wrapped estoppel.*[772] This may occur when the applicant wanted to avoid rejection for insufficient novelty or inventive step by narrowing the claim and excluding certain prior art for the

[768] Yamazaki, Ohtsuka, and Yasuhiro, "Recent IP High Court Decision," 34-36.
[769] Takenaka, "The Doctrine of Equivalents in Japan," 131.
[770] AIPPI, "Japan. Report Q175. The Role of Equivalents and Prosecution History in Defining the Scope of Patent Protection," 4.
[771] Takenaka, "The Doctrine of Equivalents in Japan," 129; Yamazaki, Ohtsuka, and Yasuhiro, "Recent IP High Court Decision," 33-34.
[772] The Article 1(2) of the Civil Code and the Article 1 of the Code of Civil Procedure. AIPPI, "Japan. Report Q175," 2.

aforementioned purposes.[773] Japanese Courts seldom reject the claim for not complying with this requirement.[774]

As reported, in the 10-year-period after *Ball Spline* only in 17 decisions did the courts find infringement under the doctrine of equivalents.[775] Japanese courts have established a clever practice when dealing with equivalents: they start the analysis by determining the second and third requirements in order to constitute a merits-related grounding that is later applied to deal with the first requirement. When addressing the essentiality-test, they define elements that *are not essential*, and not the elements that are *non-essential*.[776]

The defendant must prove that the accused product does not comply with any of the five requirements – with the *Formstein*-like requirement being of special concern.[777]

[773] Takenaka, "The Doctrine of Equivalents in Japan," 128-30.
[774] ibid.
[775] Yamazaki, Ohtsuka, and Yasuhiro, "Recent IP High Court Decision," 33. Up until 2003, the doctrine of equivalents was affirmed in 10 out of 121 lower court cases. AIPPI, "Japan. Report Q175," 5.
[776] Yamazaki, Ohtsuka, and Yasuhiro, "Recent IP High Court Decision," 36.
[777] Katayama, *Japanese Patent Litigation*, 51.

4.7 Patent Exceptions Which Could Prove Beneficial for Makers

4.7.1 Patent Exceptions Incompatible with Making

A group of flexibilities does not correspond with the conditions of making, as they serve different purposes than making itself. The exception for preparation of a medicine, the exception concerning permissible conducts on vessels, and aircraft, as well as permissible conducts for agricultural purposes, do not find a place in the adopted *making* scenario – no maker would be able to make a use of them. The same concerns the exhaustion rule pursuant to Article 10 of the 98/44/EC Directive. The "extensions" of experimental use exception, such as *Bolar* exception and plant variety exception, are not helpful for regular makers, since they do not operate in those fields.

Admittedly, the expanding do-it-yourself bio (DIYbio) movement is opening a new era in making and patent exception use: in many biohackerspaces, various activities involve genetic engineering and reverse engineering on actual organisms. Nonetheless, exceptions applicable for biotechnological patents refer to activities that demand advanced facilities, resources, and time. While the latter is not an obstacle in regular hardware and software *making,* the first two are obstacles indeed.

The UPC Agreement introduces an exception for computer programs for the purposes of interoperability. Its current form does not resonate with the needs of free making, where tinkering with software and hardware represents a baseline for many projects (see Arduino). First, makers work with and on open source programs. Second, the scope of provisions remains narrow: it merely concerns the part of the source code which is inaccessible, albeit required in creating interfaces. The entitled subject is required to either be a licensee or another authorized person, and the information obtained should solely serve the purpose of interoperability in order to be disseminated. Launching any interoperability works in the first place requires obtaining a license, which may involve a very high cost. The communal character of making and its varied organizational structures represent another hurdle in this regard. The exception does not work in the context of a free software environment, since it was intended to control the process of creating interfaces which are inevitable in software-based industries and markets. Finally, yet importantly, the interoperability exception for patents only spell troubles.

The defence of non-equivalence does not assist makers in their daily routine, as it does not create a space which would be free from patents. As the name itself indicates, the concept of non-equivalents serves as a defensive measure against claims of patent infringement. For this reason, knowledge on and an understanding of the mechanism in determining the patent scope and

extension over equivalents might be helpful for makers who deal with patents in their workings and attempt to determine their meaning, like in the EFF program to keep the 3D printing free from patents.[778] To reiterate, regardless of the specific defence, whether Formstein, Gillette, or RDoE, makers still lack the *ex ante* freedom to operate, but are nonetheless supported in clarifying the borders of patent exclusivity in intensively *patent-rich* fields.

4.7.2 Patent Exceptions (Partially) Compatible with Making

4.7.2.1 Private and Non-commercial Use

The private and non-commercial use exception is an appealing option for makers when we consider the following scenario: (1) a maker starts making without any business motivation and (2) keeps working without revealing the idea to others (in the adverbial basement or garage). The requirements of the provision are complementary and cannot be considered individually. Thus, as long as *making* remains within the border of private and personal use and without any indication of commercial application, the exception is applicable.

Continuing the story: the instant the idea (e.g., how to improve a device or how to add to it a new functionality) is disseminated among friends and neighbours (now a group of makers), making loses its pure private and personal character and the exception cannot be invoked.

According to the letter of law, the use must literally stay behind "the walls" – patents are instruments of public use and intended to control the use of the patented solution in the public sphere. Even when the idea is shared and appreciated among other individuals, who themselves do not generate any profit from making, its sharing nonetheless represents an unauthorised public use over the patented idea and is forbidden by law (indirect infringement or inducement to infringe). Such public use may "grab" the power away from the patent holder by taking away a part of the market. For example, when a maker produces a high-tech gadget, the price of which solely covers the material expenses, not earning its creator even a penny, he or she still creates competition for the patent holder, who has had his or her privilege granted with a patent (to exclude third parties from using, manufacturing, offering to sell, or selling the solution) infringed. If the maker starts making a profit from the sale of the gadget, referring to the exception is out of the question – the

[778] Buth, *3D Printer: Patents and Innovations*; Electronic Frontier Foundation, "Join EFF's Efforts to Keep 3D Printing Open."

use is both public and commercial. As we know, making may result in commercialization (see Adafruit products), because hobby and commerce are not far from each other.[779]

The legal construction of the exception permits uses for private and individual purposes. Each situation in which the borders are blurred calls the exception into question, since the information might leak into the public sphere. In conclusion, a private and non-commercial use exception cannot actively protect makers who share their ideas (a fundamental concept of making) and are engaged in community workings.

4.7.2.2 Experimental Use

The space left by the private use exception is filled by the experimental use. Conceived to facilitate acts performed with the intention of gaining new information on and an understanding of the patented substance (product), it corresponds with the profile of *making* and, in addition, allows public activities.

The scope of the exception differs among jurisdictions. The US doctrine represents its conservative wing and accepts acts done "solely for amusement or to satisfy idle curiosity or for a strictly philosophical inquiry" – which is exactly what makers do. Activities with the slightest commercial implication do not fall within the scope of US experimental use. The German approach, along with its UK counterpart, is more liberal, since it recognizes the commercial motivation behind experimental conducts as long as experiments and tests serve the purpose of expanding knowledge. Although this generous interpretation has been articulated in decisions relating to pharmaceutical products, the experimental use exception as a general norm embraces all fields, e.g. hardware engineering, pharmaceuticals, or biotechnology, on a non-discriminatory basis. Nonetheless, it might be questioned whether the same approach would be manifested in non-pharma-related cases. Biotechnological and pharmaceutical sectors are, for obvious reasons, privileged. Even the US courts have accepted the commercial background of experiments in these fields. The *Bolar* case illustrates this matter very well. Though judged against a generic company invoking the experimental use exception, the case initiated many changes on a global scale and demonstrated that the objective of fluent drug supply and fair market relations could not be achieved without additional measures. The need for a wider interpretation of the experimental use exception in this particular scenario was evident and led to further legislative steps, namely the construction of the *Bolar* exception.

[779] Buth, *3D Printer: Patents and Innovations*, 24.

The classic experimental use exception permits reverse engineering, measuring, and experimenting *on* the patented substance, with the aim of measuring its feasibility and utility; but does not permit acts which move toward manufacturing. This means that any further works require a license. In terms of quantity, the exception allows operations on small samples and, inferring from the case law, conducted in one specific place (e.g. a laboratory). In terms of objectives, it serves two main goals: 1) the pursuit of scientific knowledge, and 2) determining the adequacy and validity of the patent information – exactly what is done in many makerspaces and biohackerspaces.

Making includes testing, measuring, and experimenting, but this is not its full spectrum – it also covers mixing, adding new elements, and changing a certain portion of elements. In the present form, the exception covers only a small portion of making activities and requires a careful and exact application that partially addresses the making scenario. Moreover, with *open sharing* of ideas projects (prototypes) are being tested and re-made globally in various maker community at the same time – this is much more than experimenting in one specific place.

In addition, the already strict US doctrine fortified the exception with the notion of a legitimate interest. What would the legitimate interest be in case of makers?

Based on the case law, a legitimate interest pertains to the business profile of a company or institution in question. For example, the legitimate interest of the US defence department is *defence*, and hence includes the testing of military helicopters. The interest of a university is education and attracting students to collect tuitions. In this light, the interest of maker communities is attracting more participants to work on projects that might (but do not have to) change into marketable products, educating a larger number of people, bringing joy, and making people happy. Makerspaces works like gyms in which you need a (paid) membership to use the equipment – the fee covers the operational expenses. Could the concept of a legitimate business (understood as commercial implications) go to such extremes as to cover making activities? The affirmative answer cannot be excluded.

The fact that the experimental use exception only partially complies with making activities corresponds with the declining quality of patents in terms of novelty and non-obviousness. This leads to the relative easiness of comprehension in regard to the patented technical teaching, which, consequently, is detrimental to the significance of the exception: its core idea and functionality. Substantially speaking, there is very little substance to experiment on when it comes to poor-quality patents.

4.7.2.3 Prior Use

As was posted on the RepRap forum: "Go check any DIY, makers website and I bet you find a patent for ANY item described there."[780] This ironic statement indicates two things: the novelty-destructive character of the makers' internet publications and posts, and the importance of prior user privilege once "a patent is found." In regard to the latter, prior use is compatible with making under specific circumstances which makes it inapplicable to the adopted model of making.

The prior use privilege protects the legitimate possession and its economic status against destruction by the subsequent application of a third party. It applies to commercial activities or serious preparatory works and serves the protection of investment; in principle, it protects trade secrecy. When translated into making, the privilege would support makers when their works are at an advanced stage (close to commercialisation) and then patented by a third party.

When it comes to court investigation of the prior use right, the stakes parties play for are high – the evidence they deliver must be unequivocal, impeccable, and flawless. Otherwise, the alleged prior user risks the accusation of patent infringement (by the preponderance of infringement-indications); and the patentee – of trade secrecy theft. But because makers' projects are well documented and supervised in principle, it is safe to assume that the evidence requirement can be met without much difficulty.

The preparations, i.e. conceptualization, testing, and prototyping, are often made within a community (see Makerbot established by Bre Pitts after leaving the RepRap community). A question arises of whether community collaboration could be recognised as serious preparations before establishing a start-up. Should this be the case, the next question pertains to the public circulation of an idea prior to the application of a patent, and the validity of the latter (though prior use as such does not invalidate prior art).

Secrecy does not constitute a distinguishing feature of making behaviour, which is based mainly around sharing and communal working. Secrecy is considered only if certain pieces of information are not disclosed. Let us assume the following scenario – an individual maker develops a solution that gains a marketable form, and wishes to commercialise it. To collect the necessary starting capital, the maker launches a project on one of the many crowdfunding platforms (like Kickstarter or Indigogo), where the project must be presented and promoted to gather the funding. Trade secrecy might be questionable, unless it concerns methods, or processes undisclosed in the

[780] RepRap Forum, smartfriendz, November 26, 2013 03:52PM.

promotional presentation. In the latter case, the prior use privilege can protect the commercial maker.

The prior user right addresses a very specific scenario which deviates substantially from classic making conduct – a successful individual innovator establishing a start-up while keeping technology-relevant information secret. The scenario runs against the communitarian ethics of makers. Furthermore, the objective of the prior use, i.e. the protection of investment and trade secrecy within a company, marginally corresponds with the needs of makers and maker communities. Once the privilege is asserted by a court, it applies solely to one particular enterprise (a party in the court proceeding), but the community is left "blocked" by a granted patent. In that regard, prior use represents a defensive measure, but not the ultimate goal, which is in such case the invalidation of a given patent with the aim of keeping the field free from any legal encumbrances.

4.7.2.4 Repair Doctrine

The repair doctrine could serve as protection for makers only under very specific conditions. The doctrine is vague, hard to comprehend, and requires single-case analysis. And while certain guidelines can be extracted from the case law, accurate examination demands a profound understanding of patent claims and the protection scope. Therefore, due to the high level of uncertainty, the doctrine remains a less appealing option to lean on.

Furthermore, the scope of lawful repair remains narrow. It allows for the replacement of a worn-out element that does not change the identity of an invention, but merely restores the normal utility of a device. That approach is common in all of the analysed systems. The US doctrine also permits conducts "akin to" repair, but this exemption pertains solely to the modification of unpatented elements.

Making, meanwhile, has become much more advanced and has left the safe harbour of permissible repair. Not only do makers replace broken parts, but also enhance and modify products. One additional aspect deserves consideration, namely the phenomenon of the home 3D printing of required parts – "a home-made indirect infringement." Desktop 3D printing builds competition for the suppliers of replaceable parts. Makers can manufacture parts at home (for themselves and for friends). As long as repairs remain within lawful borders, homemade parts are acceptable. If further enhancements and replacements remain unnoticed, they do not attract much trouble. However, makers like to share. Some solutions that gain attention and appreciation are further improved upon. As they become popular and successful, patent holders might target the makers. The repair

doctrine would not be much helpful in such situations (neither would it be feasible to squeeze such “viral” workings into the experimental use exception).

Certainly, the repair doctrine is inevitable in the system and everyone intuitively understands its significance. However, legal considerations make its usefulness more challenging. To apply the lawful dose of repair, it is necessary to become familiar with patent claims, as well as consider the essentiality of the replaced elements and their contributions to the technical teaching. Marking of a patented article by fixing the patent number onto the article or its package helps in increasing the awareness of embedded patents; however, reading patent claims to determine the scope of permissible changes represents a huge challenge in terms of the required legal knowledge. Finally, yet importantly, who would think of reading patent(s) before repairing a device?

Chapter 5. PATENT COMPULSORY LICENSING

This chapter focuses solely on patent-related aspects of compulsory licensing (CL), and does not investigate the anti-competitive factors that the misuse of patent exclusivity might involve. Not every refusal to license and not every aggressive negotiating position of a patent holder is anti-competitive in terms of competition law.

The following analysis of grounds for patCL in examined jurisdictions presents the diverse ways in which this mechanism is structured. Each subsection on a specific national compulsory licensing scheme follows the same pattern, and consists of a general presentation of norms, the applicable criteria, and the practice of granting CLs. Attention was given primarily to the substantive aspects of compulsory licensing, with additional short insights into procedural matters. Considering the economic significance and political impact of compulsory licensing, its practical dimension builds a crucial reference point when applying circumstances of patCL in the context of makers.

5.1 The TRIPS Agreement as the International Foundation for Compulsory Licensing

A patent compulsory license (patCL) is a countervailing instrument with a long historical record, adopted in almost all patent systems worldwide. Unlike a *classic voluntary* patent license, in which a patentee voluntarily enters into a license agreement, a compulsory license is concluded without the patentee's authorisation by the power of an administrative or judicial decision that restrains the exclusive right conferred with a patent.

In terms of international codification, compulsory licensing was introduced in Article 5.A.2 of the Paris Convention[781] as a measure against the insufficient working or a failure to work a patent. Currently, the TRIPS Agreement (in reference to the Paris Convention) construes a legal framework for granting compulsory licenses and lists other eligible circumstances. Notably, the term *compulsory licence* as such does not appear in any of the TRIPS provisions; but functionally it is conceived in Article 31, which lays down this measure along with the grounds and terms for its awarding[782]. Next to Article 30, Article 31 can be recognised as a patent flexibility and a supplement

[781] The Hague Revision, 1925.

[782] Michael Blakeney, *Trade Related Aspects of Intellectual Property Rights: A Concise Guide to the TRIPs Agreement* (London: Sweet & Maxwell, 1996), 89-90.

to limitations of patent rights.[783] It was not a novel mechanism, but a synthesis of circumstances and grounds upon which a compulsory license had traditionally been granted upon.

The primary goal of patCL is to re-establish the balance of interests when access to patented goods is hindered by the malpractice of the patent holder. While the idea itself is plain and simple, its implementation is complicated: a patCL is a forceful instrument which tempers patent monopoly, and for that reason it must be employed *wisely*, which in practice translates into *scarcely*. To this end, the CL mechanism has been fortified with a number of conditions, such as public interest, economic significance of a patented solution, to avoid the abuse of this instrument.

Some scholars classify CL as a trade-restricting regulation[784], which in the author's own opinion contradicts the primary goal of CL, i.e. enabling the use of a patented invention, safeguarding the access to the solution and, ultimately, safeguarding product variety on the market. In practical terms, owing to the stringent requirements for issuing a CL, the limitation of patent exclusivity resulting therefrom occurs in "special" cases, which mainly concern governmental uses. As a rule, private parties refrain from resorting to this measure.

The TRIPS Agreement delivers guidelines on the issuance of a patCL: there is no golden rule, each case must be determined individually, and countries (theoretically) enjoy full discretion in regard to defining the conditions and circumstances for compulsory licensing. Article 31 merely names the conditions, like anti-competitive practices, national emergencies or other circumstances of extreme urgency, public non-commercial uses, and cases of dependent invention, when patCL comes into question, and indicates that every request and procedure underlies judicial examination.[785]

Failure to work or the insufficient working of a patent is not covered explicitly in the TRIPS Agreement, but remains under the jurisdiction of the Paris Convention in Article 5.A.2. Moreover, during the TRIPS negotiations, countries recognised importation as a sufficient use of patents. To that end, the Agreement solves this issue by proclaiming in Article 27 "patents shall be available and patent rights enjoyable without discrimination (…) whether products are imported or locally produced." In addition, the TRIPS Agreement does not derogate the older regulations - Article 2states that Parts I to IV of the Agreement must comply with obligations Members have under the Paris, Berne and Rome conventions.
ibid., 40, 90-91; Sara M. Ford, "Compulsory Licensing Provisions under the TRIPs Agreement: Balancing Pills and Patents," *Am. U. Int'l L. Rev.* 941, no. 15 (1999-2000): 957-58.

783 Alesch Staehelin, *Das TRIPs-Abkommen. Immaterialguterrecht im Licht der globalisierten Handelspolitik* (Bern: Stampfli Verlag AG, 1999), 150.

784 Joost Pauwelyn, "The Role of Public International Law in the WTO: How Far Can We Go?," *The American Journal of International Law* 95, no. 3 (2001): 548.

785 The Article 8 of the TRIPS indicates other circumstances Article 31 also applies, e.g. the protection of public health and nutrition, promotion of the public interest in sectors of vital importance to their socio-economic and technological development, as well as prevention of IP-rights abuse, and resort of practices, which restrain the trade or impair the technology transfer. Blakeney, *Trade Related Aspects*, 90.

5.1.1 General Criteria of Article 31 TRIPS

1) Individual Merits – Section (a)

Each patCL request must concern a particular product and a specific patent holder, and underlie a thorough material and procedural judicial examination. This requirement hinders granting "blanket" patCL, approved e.g. for a whole technology field or for a group of patentees.[786] To reiterate, patent exclusivity is given special consideration, and therefore any endeavour to limit its scope is strictly scrutinized, especially when it takes the form of a compulsory license.

2) Patentee Protection – Sections (b, h, i-j)

All conditions on patCL prosecution safeguard the rightful assessment of circumstances underlying a CL-request to avoid an unlawful curtailment of patent rights. A patCL should be recognised as a measure of last resort to "enforce" a user right upon a *blocked* patented solution. To that end, a group of criteria serves the protection of the patent holder and regulates the indemnification of the "compulsory" loss in the patent exclusivity*:*

a) Unsuccessful Prior Negotiations – Section (b)

Unsuccessful prior license negotiations on reasonable commercial terms and within a reasonable time must predate every patCL application. In that regard, a license-seeker must prove to have undertaken credible attempts at acquiring a license: a single one-time attempt does not suffice to justify the request, as the right to refuse a license and to choose a licensee builds the core of patent exclusivity. Continuous refusals on the side of the patent owner reflect not only an unwillingness to conclude a license agreement, but also constitutes anti-competitive behaviour directed at the patentee.[787] What the term *reasonable* objectively means, remains uncertain and undefined; its factual meaning can be ascertained only based on case-by-case analysis.[788]

The requirement of prior negotiations might be waived in situations of national emergency or other circumstances of extreme urgency, as well as in situations of public non-commercial uses. The TRIPS Agreement, however, does not define those terms either; it devolves the competency in this matter to particular countries, which determine these notions at their own discretion.[789] In fact, the Doha Declaration indicates that a national emergency or urgency relate to public health crises like

[786] ibid., 91.
[787] Hiroko Yamane, *Interpreting TRIPS. Globalisation of Intellectual Property Rights and Access to Medicines* (Oxford, UK: Hart Publishing, 2011), 311.
[788] Cynthia M. Ho, "Patent Breaking or Balancing?: Spearating Strands of Facts form Fiction under TRIPS," *N.C.J. Int'l L. & Com. Reg.* 34, no. 371 (2008-2009): 400.
[789] ibid., 401.

HIV/AIDS, tuberculosis, malaria, and other epidemics[790]; however (and unfortunately), the list does not exhaust all possibilities. Some commentators suggest that in the future the waiver might also cover environmental issues.[791]

The waiver of prior negotiations applies in the field of semiconductors. Although, the TRIPS Agreement as a principle remains non-discriminatory towards technologies, integrated-circuit technology is the sole exception.[792] Accordingly, Article 31 of Section (c) names this technology and relinquishes the requirement of prior negotiations for non-commercial uses or in cases of anti-competitive practices.[793]

b) Adequate Remuneration – Section (h)

The rightsholder must obtain reasonable and adequate compensation, which should correlate with the ordinary license depending on various factors: the type of inventions, its quality, innovativeness, but also the market size. In case of anti-competitive practices, the level of remuneration might be lower than the normal market price.[794] Once again, the TRIPS Agreement leaves the vague term *adequacy* without any further clarification.[795]

c) Judicial Review – Sections (i-j)

All aspects of compulsory licensing, i.e. its scope, duration, remuneration, and validity, must pass judicial scrutiny by a court or another responsible authority. This safeguards the objective and factual assessment of the circumstances of a patCL request.

3) Scope and Duration – Sections (f - g)

In regard to the scope of patCL, Section (f) stipulates that a compulsory license applies solely to the purpose for which it was granted, e.g. to produce a given patented solution, and may concern only certain patent claims or a single patent application. In practical terms, the objective of patCL is to

---

[790] "Declaration on the TRIPS Agreement and Public Health. Adopted on 14 November 2001": 5(c).

[791] Blakeney, *Trade Related Aspects*, 91.

[792] Special treatment of IC: Articles 35-38 of the TRIPS Agreement.

[793] See Thomas Hoeren, "Chip Protection in Europe," *High Technology Law Journal (Comp. &High Techn. LJ)* 7, no. 19 (1991).

[794] Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis*, 3rd ed. (Yorkshire, UK: Thomson Reuters, 2008), 394.
The USA insisted on full compensation for governmental uses. Blakeney, *Trade Related Aspects*, 91.

[795] Ho, "Patent Breaking or Balancing?," 408.
Countries take different approaches in determining reasonable and adequate remuneration. In the case related to the drug cimetidine, the UK awarded CL royalties at the level of 45%, the Philippines – 2.5%, Japan – 3.5%. World Health Organisation, "Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies," in *Health Economics and Drugs* (WHO/TCM/2005.1), 19. The EU in the Resolution 816/2006, Recitals 15 of the Preamble, suggested the figure of 4% as a reference point when estimating the adequate remuneration in cases in which the Regulation applies.

ensure supply on the domestic market via either importation or production within the requesting country.[796]

This requirement (still) constitutes an enormous challenge for countries which lack sufficient manufacturing capacities, or do not have them to begin with. This corresponds with the situation of many developing countries, which are affected by diverse public health crises. In practice, this criterion has translated into blocking the export of generics to affected countries. Although exportation as such was not excluded from the list of permissible acts falling under a compulsory license, it was accepted only if the country with a CL to manufacture pharmaceuticals, invoked an equivalent CL to export the medicines.[797] Subsequent declarations and documents[798] narrowed this restriction down to facilitate the management of the public health crisis. Nonetheless, exportation as such is not the main function of a compulsory license.[799]

With regard to the duration (Section (g)), a compulsory license stays in force as long as the grounds for its granting exist, and ends when the objective can no longer be longer justified. A competent authority must review those circumstances (and the changes) and verify the legitimacy of the decision.

4) General Licensing Terms – Sections (c-e)

A patCL is non-exclusive and non-assignable (with the exception of the transfer of an enterprise and goodwill). Its non-discriminatory character is evidenced in awarding compulsory licensing only upon individual requests that concern a specific product and the patent owner. As mentioned before, in the case of semi-conductor technology, compulsory licensing is granted for public non-commercial use or as a remedy against anti-competitive practices.

5) Anti-competitive Practice – Section (k)

First and foremost, a patCL prevents the abuse of patent exclusivity, which might be pronounced as anti-competitive. In such circumstance, the requirements of "prior negotiations and supply of domestic market," do not apply. This, however, does not mean that Article 31(k) facilitates the granting of a patent compulsory license. On the contrary, it sets higher requirements than an anti-trust compulsory license: a competent authority must decide in the course of judicial or

[796] Gervais, *The TRIPS Agreement*, 392.
[797] Duncan Matthews, "WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?," *Journal of International Economic Law* 7, no. 1 (2004): 78.
[798] See the following part: *Access to medicine – Doha Declaration and Article 31bis.*
[799] Guy Tritton, Richard Davis, and et al., *Intellectual Property in Europe* (London: Sweet & Maxwell, 2008), 64; Gervais, *The TRIPS Agreement*, 390-91.

administrative proceedings whether the claimed practice is or is not anti-competitive[800], and whether it complies with the further conditions of Article 31.[801]

6) Dependent Patents – Section (l)

Obtaining a compulsory license for a dependent patent is possible only if the patent presents a significant technical improvement of considerable economic benefit.[802] As reciprocation, the first inventor must receive a cross-license to utilize the invention of the second patent.

5.1.2 Access to Medicine – Doha Declaration and Article 31 *bis*

Patent compulsory licensing became the central issue of a heated debate on the access to medicine in less developed countries that recognise a patCL as an effective measure to supply domestic markets with affordable generic pharmaceuticals inevitable in combating deadly epidemics.

In the opinion of many, by lifting the prices to unaffordable levels, patent protection constitutes an enormous impediment in distribution of pharmaceuticals in developing countries.[803] Civil groups and governments of developing countries launched intensive campaigns targeted first at loosening the grip on IP protection, which were then followed with a series of discussions and resolutions of the WHO.[804] In the aftermath of a controversial South African legislative challenge[805], the milestone

[800] Member States freely decide upon the nature of anti-competitive practice. Munoz Tellez, "Dispute Settlement under the TRIPS Agreement: the United States-Brazil (2000) and United States-Argentina (2002) Patent Disputes," 219.

[801] Henrik Meinberg, *Zwangslizenz im Patent- und Urheberrecht als Instrument der kartellrechtlichen Missbrauchsaufischt im deutschen und europäischen Recht* (Hamburg: Verlag Dr. Kovac, 2006), 63.

[802] Gervais, *The TRIPS Agreement*, 394.

[803] IP protection builds only a part of the total cost of medicines. Taxes, distribution costs (which are very high in DC), transfer prices, operation costs contribute as well. Moreover, the general market situation, insufficient infrastructure, a weak health insurance system, and the poverty of people who are unable to afford the needed medicines, complete that sad picture. In the situation of a failing public market, which otherwise would allow preferential prices in increasing demand, pharmaceutical companies resort to a "cherry picking" strategy, in which prices are determined according to the very narrow wealthy class, and are hence set on the same level as in the developed countries. See Yamane, *Interpreting TRIPS*, Part III 'Access to medicine" p. 264-342; A. Attaran and L. Gillespie-White, "Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment an Africa?," *JAMA* 286, no. 15 (2001); See also R. Beall and R. Kuhn, "Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis," *PLoS Med* 9, no. 1 (2012); Matthews, "WTO decision."

[804] Yamane, *Interpreting TRIPS*, 292-93.

[805] In 2001, South Africa enacted CL that allowed local manufacturers to produce drugs against AIDS and import them from neighbouring countries for affordable prices. The patent owners – European and US pharmaceutical companies – argued that the decision violated international patent law, as it was undertaken without prior negotiations, with no compensation promise, and without proving any patent abuse – the companies withdrew the suit eventually. Although South Africa commenced the international

Doha Declaration responded to growing concerns on the implications of the TRIPS Agreement for the access to medicine.[806] The Declaration granted countries wide discretion and flexibility in issuing CL, including the legal ground and the remuneration mechanisms. Paragraph 6 of the Declaration addressed the problem of the inapplicability of Article 31(f)[807] of TRIPS in countries with weak or no manufacturing capacities, compelled to import generic drugs. The Declaration obliged the Members "to find an expeditious solution to this problem and to report the General Council by the end of 2002."

That weakness of TRIPS was addressed later in Decision 2003[808], which led to the Amendment of Article 31 (in Article 31bis).[809] The Decision facilitates the management of public health crises in developing countries. It contains restrictions intended to prevent the misuse of rights, e.g. by non-eligible Members, via the obligation of notification. It allows the export of pharmaceutical products to the least-developed Member States, which made an appropriate notification about their intention to use the system. The importing country should name the products and the quantities needed, and confirm that it has insufficient or no-manufacturing capacities in the pharmaceutical sector. (However, should the importing Member State develop such capacities, the system no longer applies). The exporting country must name the products, as well as and their required quantities, the target countries, and the duration. Re-export is forbidden. Although the Decision

---

dispute, only recently has it undertaken measures to incorporate into its patent law a regulation on parallel import and compulsory licensing (according to the TRIPS standards).
Donald Harris, "TRIPs after Fifteen Years: Success or Failure, as Measured by Compulsory Licensing," *J. Intell. Prop. L.* 367, no. 18 (2010-2011): 384-86; Yamane, *Interpreting TRIPS*, 276; Ed Silverman, "South Africa embraces Compulsory Licensing over AIDS Crisis," http://www.pharmalive.com/south-africa-embraces-compulsory-licensing-dueto-aids-crisis, accessed 13.11.2013; Matthews, "WTO decision," 78-79.

806 Silverman, "South Africa embraces Compulsory Licensing over AIDS Crisis."; "As Pharma Eyes Patent Changes in South Africa, a Government Minister Cries 'Genocide'," http://www.forbes.com/sites/edsilverman/2014/01/18/as-pharma-eyes-patent-changes-in-south-africa-a-government-minister-cries-genocide/, accessed 31.01.2014.

807 Supply on the domestic market.

808 The 2003 Decision (WT/L/540) instructed the TRIPS Council to initiate by the end of 2003 workings on an amendment to the TRIPS Agreement, with a view to its adoption within 6 months. In December 2005, the General Council with Decision 2005 (WT/L/641) agreed to amend the TRIPS Agreement by "inserting Article 31 *bis* after Article 31 and by inserting the Annex to the TRIPS after Article 73". The amendment would enter into force after its ratification by 2/3 of the WTO Members. Upon ratification, the amendment becomes immediately effective in the ratifying countries. Originally, the deadline was set for December 1, 2007, but the General Council extended it to December 1, 2009, and later – to December 31, 2011. The waiver to the amendment will continue to apply until the remaining Members accept the amendment and takes it effect.
Yamane, *Interpreting TRIPS*, 318; "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. Decision of the General Council of 30 August 2003," WT/L/540 and Corr. 1, 1 September 2003.

809 Harris, "TRIPs after Fifteen Years," 386.

names certain permitting circumstances, such as HIV/AIDS, tuberculosis, malaria, and other epidemics, the list is not exhaustive.[810]

In 2005, WTO Members adopted an Amendment to Article 31 (Article 31bis), which enabled non-manufacturing countries to import generic drugs from other countries without the fear of infringing patent rights under a domestic compulsory license.[811] However, as long as the Amendment is not ratified, the provisions of the Decision 2003 apply.[812]

Among various international attempts to solve this delicate and utterly important issue, the EU undertook decisive steps toward the harmonisation of legal procedures in this particular context, and adopted Regulation 816/2006[813], which implements the conditions and requirements for releasing patCL for exportation, as stipulated in Decision 2003.[814] The EU Member States were given the competence to determine administrative aspects such as language regime, the application form, the identification of patents, and supplementary certificates.

5.1.3 Compulsory Licensing in Practice – the International Level

Despite a relatively wide discretion in granting patCL in times of crisis, reality does not affirm the willingness to practice compulsory licensing, nor interest in the idea, even in countries where this measure would be beneficial.[815] The perspective of repercussions and criticism from the counter-parties is enough to deter potential beneficiaries from requesting this remedy. Additionally, such a time-consuming procedure (long negotiations) does not incite prompt action – even in the case of governmental orders, an immediate response in face of urgent needs is impossible.[816]

A study by Beall and Kuhn on compulsory licenses granted between 1995-2011 shows that the Doha Declaration had a low impact on facilitating access to medicines. The issuance of patCL

---

[810] Gervais, *The TRIPS Agreement*, 398-400.

[811] Harris, "TRIPs after Fifteen Years," 386.

[812] Gervais, *The TRIPS Agreement*, 397.

[813] "REGULATION (EC) No 816/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems," Official Journal of the European Union, L 157/1, 9.6.2006.

[814] Kraßer, *Patentrecht*, 832; "Compulsory Licensing System for the Production and Export of Generic Medicinal Products to Developing Countries," http://europa.eu/legislation_summaries/development/sectoral_development_policies/l21172_en.htm, accessed 30.01.2014.

[815] Beall and Kuhn, "Trends in Compulsory Licensing."

[816] The Canada-Rwanda case, where the involved parties decided to invoke the waiver of Article 31bis, illustrated the arduousness of the procedures, despite the alleged simplifications of the procedure.

skyrocketed in the short period of 2003-2005, owing to a torrent of social campaigns against rigid IP protection, only to decline after that period.[817]

The analysis of CL cases demonstrates that their recognition depends to a large degree on the political and economic status of the requesting country.

In 2006 and 2007, Thailand introduced a compulsory license to produce antiretroviral drugs that included drugs delivered by Merck and Abbott. In 2010, the CL was prolonged until the expiration of patents on the required drugs. That decision was met with the prompt reaction of the involved companies: Abbott held the introduction of new drugs into Thailand. Moreover, the United States placed Thailand in the *Special 301 Report*[818] of countries that fail to provide an adequate level of IP protection or enforcement.[819]

In contrast, Brazil's requests for antiretroviral drugs were more successful. Initially, Brazil threatened to employ a CL to obtain a price reduction on Merck's Efavirenz, and their attempt ended with considerable success. However, Brazil ordered a CL regardless, as generic drugs were still much cheaper than their original counterparts. The same solution worked in regard to other companies, e.g. Gliead reduced their prices by 50%.[820] Brazil did not experience any burdensome consequences of its decision.

The above illustration demonstrates that the functionality of patCL depends on a large degree on the political climate. Indisputably, the negotiation power of Brazil outstrips Thailand's position. Due to its economic potential and resources (crucial for developed countries), Brazil can take care of its interests more victoriously than small Thailand, with its incomparably lower political and economic impact.

Another drawback of the patCL scheme is the so-called red tape, which runs counter to even the best intentions, as it was in the case of the Canda-Rwanda CL request based on the waiver of Article 31bis. The two countries intended to ship the generic medicine ApoTriAvir (AIDS drug), which was

---

[817] Beall and Kuhn, "Trends in Compulsory Licensing."

[818] The Special 301 Report is an annual review of global IP protection measures adopted by countries which adversely affect the US companies and economy. It is prepared pursuant to Section 182 of the Trade Act of 1974.
Harris, "TRIPs after Fifteen Years," 386-87; International Intellectual Property Alliance IIPA, "Special 301," http://www.iipa.com/special301.html, accessed 30.01.2014; U.S. Trade Representative, "USTR Releases Annual Special 301 Report on Intellectual Property Rights," accessed 30.01.2014.

[819] As of 2015, Thailand has already been on the *Special 301 Report* for nine consecutive years, following the issuance of three compulsory licenses on pharmaceuticals.
"US Keeps Thailand on Intellectual Rights Watch List," Bangkok Post, http://www.bangkokpost.com/news/general/548239/us-keeps-thailand-on-intellectual-rights-watch-list.html, accessed 07.05.2015.

[820] Harris, "TRIPs after Fifteen Years," 387-88.

to be delivered by Apotex Inc. Prior to this initiative, Canada implemented *Canada's Access to Medicine Regime* to facilitate the transfer of medicines to less-developed countries. In spite of such measures, the whole operation took 6 years: from 2002 (initiation by Apotex to produce a new drug combination) to 2008 (two shipments); and was fraught with immense bureaucracy.[821] Apotex was trapped in 2-year-long negotiations with patent holders: GlaxoSmithKline, Boehringer Ingelheim, and Shire BioChem Inc.. Eventually, the Canada Commissioner of Patents granted Apotex a license to use their patents to produce the drug. However, the Canadian government blamed Rwanda for the late notification to WTO about its desire to import the drug, since, once notified, it took Apotex 15 days to obtain the necessary CLs. In other words, the national regulation worked as intended, but international regulation hindered the process by requiring "various notifications, packaging, labelling, and website tracking requirements."[822] The Canada-Rwanda case was a test on the ease of applying Article 31bis waiver, one which received rather poor notes: the process was too cumbersome for both parties involved.

5.1.3.1 Recent Cases of Compulsory Licensing

Recently, India has provoked a storm around patCL and itself became the subject of fierce criticism after issuing its first patent compulsory license.

In March 2012, India granted a CL to Natco Pharma (an Indian generic company) on Bayer's liver and kidney cancer drug Nexavar for 3% of the patented drug's price in return for 6% royalties on sales to Bayer (which requested 15%). In effect, the price of the drug plunged from 280,000 (ca. $5,000) to 8,800 rupees (ca. $160).[823] Bayer appealed the decision, but India's Intellectual Property Appellate Board upheld it. The decision created widespread international resonance, with the USPTO criticising India over decreasing IP protection.[824]

The decision reignited debates on access to medicine via compulsory licensing. The proponents of the decision underlined that it provided India's generic section with much more security and legal

[821] ibid., 390-91; Apotex Inc., "Submission to the Standing Committee on Industry, Science and Technology Bill C-393; an Act to Amend the Patent Act (Drugs for International Humanitarian Purposes) and to Make a Consequential Amendment to Another Act," http://www.apotex.com/global/docs/submission_order_en.pdf, accessed 15.11.2013.

[822] "TRIPS Council: Debate over Effectiveness of System for Access to Medicine," *Bridges Weekly Trade News Digest* 14, no. 38 (2010).

[823] Patralekha Chatterjee, "India's First Compulsory Licence Upheld, but Legal Fights Likely to Continue," http://www.ip-watch.org/2013/03/04/indias-first-compulsory-licence-upheld-but-legal-fights-likely-to-continue/, accessed 18.09.2013.(accessed 18.09.2013)

[824] Michael Francisco, "Compulsory License Bandwagon Gains Momentum," *Nat Biotech* 30, no. 9 (2012): 814.

certainty. The organization *Medecins Sans Frontieres* expressed its utmost satisfaction and urged Bayer "to address the reality that their prices are too high and not to appeal this decision. It is not the use of a compulsory licence that should be challenged, but the continued pursuit of excessively high profits over public health needs."[825] In reply, Bayer argued that poor services, and infrastructure, and not the patents themselves limit access to medicine.[826]

In contrast, in 2013 India rejected two CL-requests: for Roche Trastuzumab (Herceptin; July) and for Bristol Meyer-Squibb's Dasatinib (October). In both cases, the refusal was based on the non-fulfilment of the formal criterion of prior negotiation. Some commented, however, that the decisions were the outcome of imposed international pressure.[827]

Additionally, India's government appointed a special panel to evaluate drugs for generic manufacturing against HIV, diabetes, and cancer. The Indian government strives to make medical treatment affordable and available to low-income citizens. The primary-drug companies like Merck & Co. and Bristol-Myers Squibb Co. still question Indian IP policy, pointing to its detrimental impact on the innovation sector.[828]

In 2013, the Republic of South Africa emerged again in the spectacle of compulsory licensing for lifesaving medicines. The government intended to implement rules facilitating the production of generics via compulsory licensing and parallel importation according to international agreements – a move made only a decade after its pioneering battle over AIDS drugs. The idea automatically sparked outrage among patent proprietors, who indicated that a weak IP system would deter the whole life science sector in the country (i.e. lower the investment rate), a development which might resonate in other countries. As a counter-measure, the companies: Merck, Alcon, Bayer, Boehringer-Ingelheim, Roche, and others, launched a lobbying campaign in favour of a strong IP

---

[825] Chatterjee, "India's first compulsory licence."

[826] According to sources, Bayer's import policy was as follows: in 2007, Bayer received approval to import and market the drug in India, which was not in use until 2009, when Bayer started importing small quantities of the drug – Natco applied for a CL. The Indian Patents Office argued that Bayer did not take the necessary steps to start the working of the invention. However, Bayer defended its actions, pointing to the marketing of a similar drug by the company Cipla, which it sued for infringement.
Intellecutal Property Watch, " Bayer will appeal India Compulsory Licence on Its Cancer Drug," http://www.ip-watch.org/2013/03/05/bayer-will-appeal-india-compulsory-licence-on-its-cancer-drug/ accessed 18.09.2013.

[827] Peter Leung, "India Rejects Another Compulsory Licence," *Managing Intellectual Property* http://www.managingip.com/Blog/3273950/India-rejects-another-compulsory-licence.html(2013).(accessed 6.11.2013)

[828] Ketaki Gokhale, "Merck to Bristol-Myers Face More Threats on India Patents," http://www.bloomberg.com/news/print/2014-01-21/merck-to-bristol-myers-face-more-threats-on-india-patents.html, accessed 31.01.2014.(accessed 31.01.2014)

system by delaying the finalization of the governmental program[829]. In 2014, almost 50,000 people worldwide signed a petition condemning the attempts of pharma companies to hinder the reform of South Africa's patent system (a campaign launched in 2012 under the slogan "Fix the Patent Law"). Apart from the CL mechanism, the said reform concerns establishing substantive patent examination and strengthening the patentability criteria with the objective of slowing down the issuance of evergreen patents for pharmaceuticals and boosting competition in the generics sector. The Department of Trade and Industry announced the implementation of the reform from April 2015. Further developments are to come.[830]

Countries applying CL for vital public interests, such as public health and access to medicines at affordable prices, not only become subjects of strong criticism, but also face the threats of lower foreign investment and a decrease of R&D operations. The proponents of a "strong IP system" argue that solely a system of firm IP rights can ensure and support technological development. Allegedly, compulsory licensing destroys the image of the issuing country and creates an atmosphere of mistrust toward the IP system and among market players.

In the author's opinion, such claims appear disproportionated and unsuitable. Patent compulsory licences are issued *extremely* rarely and if they are issued in the first place (like in 2012 in India), they do not and cannot directly affect comprehensive trade relations with the issuing country and the development of its patent system. It is therefore difficult to acknowledge that a single issuance of a patent compulsory license for a particular product can do so much harm to the national industry. Every compulsory license is granted after a diligent and meticulous procedure examining all circumstances of the given request. In the case of governmental uses, which constitute the majority of granted CL, it is no exaggeration to say that patCL are instruments intended for *drastic circumstances* and should only be issued when such circumstances arise.

Accusations against countries that apply the CL mechanism manifest the bad intentions of their authors, who repeat conventional statements of no technical progress without patents. If a certain

---

829 "Email from Michael Azrak, Merck (10 January 2014) Action Required: Agreement to Proceede with Stage 1 of IP campaign - due to Januar 15," http://keionline.org/sites/default/files/merck-email.pdf, accessed 30.01.2014.

830 Silverman, "As Pharma Eyes Patent Changes in South Africa, a Government Minister Cries 'Genocide'."; Lynne Taylor, "S Africa pledges Action on Compulsory Licenses, Parallel Imports," PharmaTimes Online, http://www.pharmatimes.com/article/13-11-07/S_Africa_pledges_action_on_compulsory_licenses_parallel_imports.aspx#ixzz2rzkKHxvA accessed 31.01.2014; Manyaradzi Makoni, "South Africa awaits Patent Reforms with Hope, Concern," Intellectual Property Watch, http://www.ip-watch.org/2015/02/27/south-africa-awaits-patent-reforms-with-hope-concern/, accessed 08.05.2015; "South Africa, Pharmaceutical Industry face off on Patent Reform," International Centre for Trade and Sustainable Development, Bridges Africa (3, No.1), http://www/ictsd.org/bridges-news/bridges-africa/news/south-africa-pharmaceutical-industry-face-off-on-patent-reform-0, accessed 08.05.2015.

measure was constituted to counteract specific situations under specific conditions, and only in such conditions is it implemented, why so much panic and so many exaggerated statements?

5.2 Germany

5.2.1 The Norm

Section 24 of the German Patent Act enumerates the conditions and requirements of granting a patCL. In 1998, the norm was adjusted to correspond with the TRIPS Agreement. Later in 2005, it adopted the *Biopatent* Directive[831] with its provision on dependent patents.

Initially, the Patent Act of 1911 did not envisage any similar measure. It introduced, however, an instrument with much more stringent repercussions, namely *patent revocation*. Obligatory licensing constituted a countermeasure to maintain the patent. The strict legal tool in question was not abandoned until in 1998.[832] The current patent act remains in accordance with the international standards: the TRIPS Agreement (Articles 27 and 31), the Paris Convention (Article 5A (2)), and the EU law.

The examination of CL requests rests within the competencies of the Federal Patent Court, which renders decisions based on the individual merits of each case. The law only provides grounds for justifying the use of a CL; the proper trade-off of interests follows the general rule of law and reason.[833]

The procedure for granting a CL follows the rules of the patent nullity procedure provided in Sections 81-85 of the Patent Act. The Patent Court renders a judgement as the first instance[834], which might be subsequently appealed to the Federal Court[835]. (Sections 81-85 of the Patent Act apply in the first instance procedures; Sections 110-121 – in the appellation[836].)

The parties are entitled to deliver evidence; however, the court may carry out its own investigation and, in principle, is not dependent on the parties' argumentations.[837] The application, i.e. the scope of a requested compulsory license, may change in the course of the proceedings (or in the appellation). The issuance of a patCL comes into force when the court decision becomes

[831] "DIRECTIVE 98/44/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 July 1998 on the legal protection of biotechnological inventions".
[832] Benkard and Editors, *Patentgesetz*, § 24 at 4; Kraßer, *Patentrecht*, 833.
[833] *Polyferon*, BGH 05.12.1995 - X ZR 26/92, GRUR 1996, 190, 192-93.
[834] The Nullity Senate – Section 66 (1)(2).
[835] Section 110 (1).
[836] Section 122.
[837] Section 87 (1).

final[838]; however, it is neither registered nor published. Under certain circumstances, such as special public concern, a patCL can already be ruled temporarily enforceable in the second instance.[839] Above that, German law includes an instrument of preliminary injunction in CL requests, but only under the condition of extreme urgency, i.e. when a patCL serves special public interest and all requirements of Section 24 are met.[840] The preliminary injunction becomes unenforceable if the main claim is withdrawn. In such case, the license-seeker must pay the patent owner an adequate remuneration for the use of invention.[841]

The Court decides upon the adequate remuneration for a compulsory license[842]; and as a rule, a patent owner cannot unilaterally terminate a CL for unpaid remuneration or another breach of obligations.[843]

5.2.2 Grounds for Awarding a Compulsory License

1) Prior Negotiations and the Public Interest

Section 24(1) lays down that each CL request shall be examined on a case-by-case basis. Each request must comply with two strict conditions, i.e. prior negotiations with the patent holder and being in the public interest.

The first condition pertains to unsuccessful negotiations to obtain a license within reasonable period of time and on reasonable licensing terms. A single request for a license is not sufficient; the negotiation process must be a sustainable and repeated.[844] *Reasonable* licensing terms denote an offer of an *adequate* compensation for the patentee: not only a certain amount of money, but also a guarantee to pay the sum.[845] The license fee stays between one and ten percent, and is calculated upon the abstract sale price and per license analogy. Technically, it resembles the calculation of an inventor's fee.[846]

The condition of public interest pertains to the key concept of compulsory licensing: safeguarding public access to the invention. It also elevates the threshold for CL requests to ensure that CL only addresses situations of high public concern. The requirement corresponds with Section 13(1) of the

[838] Section 84(1)(1).
[839] Section 85 (6).
[840] Section 85(1).
[841] Section 85 (5).
[842] Section 84(2).
[843] Benkard and Editors, *Patentgesetz*, Para. 24, Rn. 35-37; Kraßer, *Patentrecht*, 837-38.
[844] Meinberg, *Zwangslizenz*, 52.
[845] ibid.; *Polyferon*.
[846] *Zwangslizenz*, BPatG 07.06.1991 3 Li 1/90, GRUR 1994, 98, 103.

Patent Act, which concerns the interests of public welfare.[847] In *Polyferon* the Court ruled that patCL addresses situations of *unconventional* patent exploitation, which contradict normal and reasonable patent utilization, a state which needs to be eliminated with a countervailing measure.[848]

The term *public interest* is broad, and hence unclear. Defined by social, economic, and technical factors, it refers to diverse circumstances, such as public health, economic crises, environmental catastrophes, and social matters.[849] German Courts maintain a flexible construction of the term and avoid formulating a single general definition. Some commentators indicate that a single definition could support the predictability of judicial decisions, and could thus serve as guidepost. Others stress the fluctuation of the general socio-political circumstances, which would make the application of a general definition unfeasible.[850] For this reason, German courts conscientiously scrutinize the context of public interest in every case to avoid misjudging the interests of the involved parties.[851] The criterion of public interest is not met by providing an invention at lower cost. However, if the production costs of an invention are lowered, access to the invention might be recognized as serving the public interest.[852]

The requirement of public interest is only referred to by name in Section 24(1), which does not mean, however, that it is abandoned in subsequent provisions. The public interest is the main indicator for a CL request, because it is not the purpose of patCL to serve the private interests of the license seeker.

2) Dependent Patents

Section 24 (2) pertains to blocking (dependent) patents: when a given use of a new patent is hindered by an older patent under the reservation that the new invention represents a significant improvement with a relevant economic meaning (making it in the public interest).[853] The request must be predated with unsuccessful endeavours to obtain a license from the holder of an older patent under the usual trade condition (Section 24(1)). The owner of the older patent has the right to request a cross-license to utilize the younger invention (compulsory cross licensing).[854]

---

[847] Section 13(1) entitles the Federal Government to restrict the patent effect on the acts for the interest of the Federation (but not the third parties) in the course of an administrative state act. *Zwangslizenz*, 53.

[848] *Polyferon*, 192.

[849] Friedrich-Karl Beier, "Ausschließlichkeit, gesetzliche Lizenzen und Zwangslizenzen im Patent- und Musterrecht," *GRUR* (1998): 189-91; *Polyferon*, 192; *Zwangslizenz*, 100.

[850] Even more challenging would be craving out one general definition of public interest for the international forum. "Ausschließlichkeit," 189; *Zwangslizenz*, 100.

[851] Meinberg, *Zwangslizenz*, 54-55.

[852] Kraßer, *Patentrecht*, 836-37.

[853] ibid., 836.

[854] Benkard and Editors, *Patentgesetz*, §24 at 24.

In *Zwangslizenz,* the German jurisprudence acknowledged that small improvements may have significant contributions to welfare, and therefore, awarding a CL for such improvements is not excluded. Furthermore, it affirmed that such a possibility also exists in small markets with innovative and effective pharmaceutical products, e.g. cancer drugs. In terms of the general public interest, the court classified a disease of prevalence of 1-2M as a national disease.[855]

Section 24(3), appended in the course of the implementation of the *Biopatent* Directive[856], regulates the situation of dependent patents in regard to plant breeding: when a certain plant variety cannot be utilized without violating of an earlier patent. The prerequisites of Section 24(2) must be met to request a patCL in that subject-matter.[857]

3) Semiconductors

Section 24(4) stipulates a CL in the area of semiconductor technology to terminate the anti-competitive practice of the patent holder.[858]

4) Insufficient Working

Section 24(5) introduces a patCL for the insufficient working of a patent. Patent use is manifested through the manufacture of a patented device, the application of a patented process, or importation.[859] Compulsory licensing addresses the problem of product shortages on the domestic market, but only if greater supply is preferable with the public interest in mind, e.g. if insufficient working impairs a technology transfer. A patCL awarded under this provision does not allow for the use of a patent in another country – in such circumstance, the exhaustion principle does not apply. Furthermore, the provision does not cover the condition of unmet demand whenever anti-trust measures (including compulsory licensing) can be employed. Notably, not every underutilisation bears traits of patent misuse: working a patent in certain markets might be unprofitable due to various factors, such as insufficient infrastructure and inherently low demand, and the decision to refrain from patent exploitation under such circumstances rests within the ambit of patent exclusivity. Such aspects must be considered when examining a CL-request, otherwise, compulsory licensing practices would remain unreasonable and erroneous.[860]

---

855 *Zwangslizenz*, 101-03.

856 "DIRECTIVE 98/44/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 July 1998 on the legal protection of biotechnological inventions".

857 Meinberg, *Zwangslizenz*, 66.

858 ibid., 65; Kraßer, *Patentrecht*, 831.

859 Meinberg, *Zwangslizenz*, 65; Rudolf Busse, *Patentgesetz* (Berlin: de Gruyter, 2013), §24 at 66.

860 Meinberg, *Zwangslizenz*, 56; Beier, "Ausschließlichkeit," 190; *Polyferon*, 192.

More importantly, in light of intensive international trade, the import of a patented product is a response to the problem of market deficiency and, as commentators suggest, consequently undermines the relevance of this specific regulation.[861]

5) General Licensing Terms:

Section 24(6) specifies the general licensing terms of compulsory licensing. A patCL has a non-exclusive character and is granted solely for the period the grounds it rests on exist. It cannot be viewed as a contract.[862] The patent holder may request adequate remuneration estimated e.g. on the market value of the CL. A holder of a CL cannot transfer it as an ordinary license; however, it is permissible under Section 24(7) to transfer a CL with the transfer of an enterprise or of a dependent patent.

5.2.3 Practice

The statistics of the Federal Patent Court, established in 1961, indicate only 20 applications for a CL until 2004, with only one granted to *Polyferon* in the first instance, but then dismissed in the appellation[863]. German courts have never been too generous in awarding a patCL. In the case of the aforementioned *Polyferon*, the Federal Patent Court issued a CL for the production and sale of the medicine; however, the Federal Supreme Court turned down the decision due to the missing requirement of public interest.

The low rate of requests does not challenge the purpose of the norm. On the contrary, the spectre of compulsory licensing (with its arduous court proceedings) incentivises parties to hold regular licensing negotiations.[864]

5.3 The United Kingdom

5.3.1 The Norm

The Patents Act elaborately regulates the matter of compulsory licensing in Sections 48-58. It differentiates between conditions of granting a compulsory license according to:

1) the type of use: commercial (Section 48 – 54), and governmental uses (Sections 55-59);

---

[861] Meinberg, *Zwangslizenz*, 65.
[862] *Klinische Versuche*; Mes, *Patentgesetz*, § 24 at 32.
[863] *Polyferon*.
[864] Beier, "Ausschließlichkeit," 189-90; Benkard and Editors, *Patentgesetz*, §24 at 4.

2) the proprietor of rights: WTO-proprietors[865] – Section 48A, and non-WTO proprietors – Section 48B.

The provisions comply with international agreements: the TRIPS Agreement, the Paris Convention, and the EU Treaties.

Patent compulsory licensing in the UK system is an instrument with a long legal tradition. The first statutory provisions emerged in the Patent, Designs, and Trade Marks Act of 1883, which postulated awarding a CL due to the insufficient working of a patent, that is, when the patentee did not work the invention or the requirements of the public to use the invention were not satisfied. The Patent Act of 1949 introduced a separate provision for inventions regarding food, medicine, and surgical and curative devices – the legislator omitted this provision when adopting the Patent Act of 1977.[866] The EU compulsory licensing scheme for exporting pharmaceuticals after Regulation 816/2006[867] was incorporated into the Patents Act in Section 128A.[868]

The current law determines diverse grounds for a CL request but, with a single definite time point of 3 years from the date of patent issuance.[869] Section 48A(6) lays down the common licensing terms of a compulsory license:

1) it must be non-exclusive and non-assignable (except when in the course of assigning of an enterprise or part of the goodwill);
2) it should predominantly serve to supply the domestic market;
3) the patent owner shall obtain remuneration adequate to the circumstances of the case;
4) it has a specified scope and duration – it is limited to the purpose for which it was ordered.

Section 48(2) stipulates that a license seeker must make efforts to obtain a license and only if they are not successful within a reasonable period (determined on single-case merits), an order, or entry for a patCL might then be considered.

The procedural aspects are stipulated in Section 52, supplemented with the Rules 68-71 of the Patent Rules of 1995. The decision upon granting a CL rests in the hands of the Comptroller. The license seeker shall provide all facts and evidence in a statement delivered to the Comptroller, who

[865] Section 48(5) defines the term of "WTO Proprietor" as a person who (a) is a national of, or is domiciled in, a country that is a member of the World Trade Organisation; or (b) has a real and effective industrial or commercial establishment in such a country.

[866] Terrell and Editors, *The Law of Patents*, 433.

[867] "REGULATION (EC) No 816/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems".

[868] UK IPO, "Manual of Patent Practice": 128A.

[869] Section 48(1); Section 48B(2) extends this period if the time has been insufficient to make the invention working.

may dismiss them if the statement does not clarify the purpose of the CL to a satisfactory degree. Accepted applications are published in the Official Journal and announced to all parties involved. In reply, the patentee presents a notice of opposition verifying the evidence of the applicant - only then may the Comptroller decide. At the request of the Comptroller, the applicant may deliver a draft licence. If the case requires, an arbitrator may enter the procedure to clarify certain questions pertaining to the science or the documentation. The Comptroller's decision may be appealed to the Patents Court – the Attorney General may enter the proceedings at this stage. The parties are allowed to furnish additional evidence. Pursuant to Section 97 the parties may appeal from the Comptroller's decision to the Patents Court.[870]

5.3.2 Grounds for Awarding a Compulsory License

5.3.2.1 Commercial Compulsory Licensing

1) Unmet Demand

Sections 48A (1) (a), 48B (1) (b) stipulate the condition of unmet demand, i.e. a situation in which the demand for a certain product is not met on reasonable terms. Both manufacturing and importation may sufficiently fulfil this requirement.[871]

The *demand* must be real and actual, i.e. it must already exist and a potential licensee must be willing to satisfy it.[872] The notion of *reasonable terms*, which also emerges in other provisions, remains vague and is very flexible. The Manual of Patent Practice provides the following guidelines:

> What constitutes "reasonable terms" depends on a careful consideration of all the surrounding circumstances in each case, e.g. the nature of the invention, the terms of any license under the patent, the expenditure and liabilities of the patentee in respect of the patent, and the requirements of the purchasing public. The price charged by the patentee should be bona fide one and not one adopted to suppress or depress demand.
>
> [A reasonable royalty is] How much are manufacturers who are anxious to make and deal with the patented article on commercial lines ready and willing to pay? [873]

If the Court does not recognise the given pricing and supply terms as unreasonable and in regard to the market[874], no patent misconduct occurs. In other words, if the demand is met via either

---

[870] Terrell and Editors, *The Law of Patents*, 459-61.
[871] ibid., 452-53.
[872] UK IPO, "Manual of Patent Practice": 48A.02; also Cathro's Applications 51 R.P.C. 75.
[873] ibid., 48A.03; also Brownie Wireless Co Ltd's Applications 46 R.P.C. 457.

manufacturing or importation[875], pricing and supply terms are irrelevant. Thereby, a claim that demand would be higher by lower pricing scheme remains futile if the given supply covers the demand.[876] In *Swansea Imports Ltd v Carver Technology Ltd*, the Court refused to award a CL. Despite the fact that the high price for the remaining stock of a patented heater adversely affected the demand, the applicant (*Swansea Imports*) did not succeed in proving that this condition led to a failure to meet demand on reasonable terms.[877]

2) Refusal to License and Unfair Prejudice

Sections 48A (1) (b), 48B (1) (d)[878] lay down that if the patentee's conduct hinders or prevents the exploitation of a dependent patent that contributes *to* "an important technical advance of considerable economic significance," a license seeker may apply for a CL. The same pertains to license refusal that leads to unfair prejudice in establishing and developing commercial and industrial activities (including the use of the patented product or process, or the manufacture, use, and disposal of materials not protected with a patent).[879] The applicant must prove one of the two named situations. Non-WTO applicants must additionally prove that the domestic market (the UK market) is insufficiently supplied.

The oblique phrase *unfairly prejudiced practice* does not find a clear explanation in the case law. It is indicated that it might apply in specific circumstances under the phrase *unreasonable terms*. It rests within the discretion of a court to consider certain aspects within one or the other category. When approaching the matter of an unfair and a prejudice conduct, the court considers its overall market impact, as well as the investment the patentee intends to recoup, and refrains from evaluating the notion of individual unfairness, regardless of its substantiality.[880]

3) Insufficient Commercial Working

---

[874] Charles Lawson, "Public Interest Compulsory Licensing under the Patents Act 1990 (Cth): A Real Incentive or a Barrier to Working?," *Australian Intellectual Property Journal* 19, no. 3 (2003): 135-38.

[875] Terrell and Editors, *The Law of Patents*, 452-53.

[876] ibid., 442-43.

[877] Intellectual Property Office UK IPO, "Swansea Imports Ltd. v. Craver Technology Ltd, BL Number O/170/04," http://www.ipo.gov.uk/pro-types/pro-patent/pro-p-os/p-challenge-decision-results-bl?BL_Number=O/170/04, accessed 28.11.2013.

[878] Unfair prejudice is a precondition stipulated in Sections 48A (1) (c), 48B (1) (e), which refers to conditions imposed by the patent proprietor on the use, disposal of the patented product (or process) and the manufacture, disposal and use of material not protected with a patent. It also concerns misconduct hindering the establishment or development of commercial or industrial activities.

[879] The term *commercial activity* is construed broadly; the growth of business in size meets the criterion of *commercial development*. Terrell and Editors, *The Law of Patents*, 444; UK IPO, "Manual of Patent Practice": 48A.04, 48A.07; also Kamborian's Patent [1961] R.P.C. 403.

[880] Lawson, "Public Interest Compulsory Licensing," 134-35,40-41; UK IPO, "Manual of Patent Practice": 48A.08; Terrell and Editors, *The Law of Patents*, 445.

Pursuant to Section 48B (1)(a) compulsory licensing can remedy the insufficient commercial working of an invention, i.e. "working not to the fullest extent that is reasonably practicable."[881] The applicant bears the burden of proof: the scarcity of production and contribution of the invention to the total value of the production. The fullest extent to which an invention might be practiced is "the highest rate of the production which is practicable and necessary substantially to meet the demand."[882]

The concept of working a patent covers manufacturing a product, using a method or a process, or importing. Additionally, the working must be on a commercial basis. While determining whether a patent has been worked is relatively uncomplicated, determining the commercial basis raises certain difficulties and questions: how many machines, how many types must be produced, where should the product be utilized? For example, in *McKechnie Bros Ltd's Application*, the Court acknowledged research work and work in laboratories as sufficient for working a patent. The examiners affirmed the capability of a patented invention to be worked, even though it was produced on a small scale in the USA, due to the evidence on potential customers in the UK.[883]

4) Anti-competitive Practices

The Patents Act regulates two kinds of anti-competitive conducts: 1) following from mergers and market investigations (Section 50A), and 2) affecting the public interest (Section 51).

Section 50A allows for taking an action against mergers or market investigations to prevent or remedy competition that cannot be secured in other way under the Enterprise Act. The Competition Commission or the Secretary of State notifies the comptroller about conducts which result either from the refusal to license on reasonable terms or a restriction on the use of an invention (Section 50A(1) (c)).

Section 51 concerns operations against the public interest. Upon a report of the Competition Commission, the Minister may apply to the comptroller to undertake according measures. The acts against the public interest should involve licensing terms restricting the use of a patented product, or a refusal to grant a license on reasonable terms (Section 51(1) (c), 51(3)).

[881] UK IPO, "Manual of Patent Practice": 48B.04.
[882] ibid., 48B.04; also Kamborian's Patent [1961] R.P.C. 403.
[883] Lawson, "Public Interest Compulsory Licensing," 142-43.

5.3.2.2 Governmental Use – Sections 55-59

Section 55(1) provides that the government or any person acting on its behalf is authorised to use patented inventions without the patentee's consent "for the services of the Crown."[884] The government has a wide discretion in regard to the use of a patented product. It has the right to make, to use, to import, to keep a patented invention (products and/or processes), or to sell or to offer to sell it[885]. The government may also dispose of or offer to dispose of anything which was made, used, imported, or kept in the exercise of its powers.

The norms apply at all times and for the purposes as named in Section 56(2):

a) the supply of anything for foreign defence purposes,
b) the production or supply of specified drugs and medicines,
c) purposes relating to the production or use of atomic energy or research into matter connected therewith.[886]

The Crown is entitled to extend its power in relation to an invention in states of emergency, for a period declared by the Order in Council (Section 59(3)). According to Section 59(1), states of emergency concern situations affecting the life and well-being of the community, the efficient prosecution of a war, and assistance for countries gravely distressed by the course of a war. Besides political circumstances, the Act allows the extension of power in times of economic necessity, to foster productivity and the exchange of goods, or to ensure access to resources.

Pursuant to Section 57A, the Crown shall pay for the profit loss suffered by the patent owner. This is determined upon the profit, which would otherwise have been made under contractual conditions, and to the extent to which any manufacturing or capacity was under-used.[887] However, as provided in Section 55(3), if the government or the UK Atomic Energy Authority use an invention before its priority date, then such uses are free of any royalty to the proprietor, i.e. the Crown enjoys prior use with remuneration.

[884] The use of European patents regulated in Sections 77-78.
[885] Section 122 renders the Crown the right to dispose of or use articles forfeited under the customs and excise laws; the Crown is exempted from infringement for the sale or use of the sized goods.
[886] UK IPO, "Manual of Patent Practice": 55.05.
[887] ibid., 57A.

5.3.3 Practice

As reported by UK AIPPI Group, very few applications have been made for compulsory licensing (on average less than one application per year (!)), with even fewer being awarded. One could rightly assume that patent holders do not cause situations which force the Crown to resort to compulsory licensing; and if so, the issues are clarified during conventional license negotiations. In regard to governmental uses, no records are maintained in the UK IPO. The Office assumes that the Crown gravitates toward conventional negotiations to determine the conditions and compensations for the use of a patented invention.[888]

5.4 The United States

5.4.1 The Norm

> "Compulsory licensing is a rarity in our patent system."[889]

A patent compulsory license in the USA has a miniscule regulatory basis – the sole statutory provisions on compulsory licensing can be found in the Clean Air Act and the Atomic Energy Act. The US system disfavours applying a patCL, with the exceptions of conditions of anti-competitive conducts, such as:

1) the misuse of IP-rights, e.g. anti-competitive mergers, anti-competitive use of patents, activities outside IP-rights[890];
2) improper enforcement: patent procurement by fraud, lawsuits solely to interfere with business of competitors.[891]

---

[888] WIPO, "Survey on Compulsory Licenses Granted by WIPO Member States to Address Anti-Competitive Uses in Intellectual Properties Rights - CDIP/4/4 REV./STUDY/INF/5," (2011), 13; "Questionnaire on Exceptions and Limitations to Patent Rights. The United Kingdom," Section 9; AIPPI, "United Kingdom. Report Q187. Limitations on exclusive IP Rights by competition law," 4.

[889] *Dawson Chemical Co. v. Rohm & Haas Co.*, 448 U.S. 176, *215 (1980).

[890] E.g., 1) tying arrangement (requiring the purchase of unpatented goods in connection with the patented goods, conditioning a sale or license of patented goods on the agreement to sale or license other unpatented goods); 2) prohibiting purchasers or licensees of patented goods from making or selling goods that compete with the patented goods; and 3) conditioning the sale or licensing of the patent invention on the payment of royalties or other consideration after the expiration of the right. "United States of America. Report Q187. Limitations on exclusive IP Rights by competition law," 2.

[891] WIPO, "Survey on Compulsory Licenses Granted by WIPO Member States to Address Anti-Competitive Uses in Intellectual Properties Rights - CDIP/4/4 REV./STUDY/INF/5," 14; Joseph A. Yosick, "Compulsory Patent Licensing for Efficient Use of Inventions," *University of Illinois Law Review* (2001): 1276; Gianna Julian-Arnold, "International Compulsory Licensing: The Rationales and the Reality," *IDEA* 33, no. 349 (1992-1993): 354.

A strict patent compulsory license has been proposed many times, but strong opposition from the industry and patent practitioners effectively impeded its enacting.[892] The USA neither introduced any new limitation of patent exclusivity upon the adoption of the TRIPS Agreement, nor implemented Article 5A of the Paris Convention on the insufficient working of patents.[893]

The government enjoys a wide discretion in issuing CL for governmental uses: in cases of health emergencies[894] and for federal-funded projects as provided in the Bayh-Dole Act (35 U.S.C 203).[895]

5.4.1.1 The Atomic Energy Act (42 U.S.C. Chapter 23)

The statute regulates the terms of patent licensing in the field of production and utilization of special nuclear material or atomic energy for peaceful purposes.[896]

At the request of the license seeker, the Atomic Energy Commission reviews the following conditions for granting a compulsory license: 1) the purpose must be clear and the party must hold specific qualifications, 2) prior negotiation with the patent holder to obtain the license must be unsuccessful. The Act provides that the patent owner should receive reasonable remuneration determined by the Commission, which considers specific factors, such as the importance of the invention and the cost of its development or acquisition.[897] The decision is made in the form of an administrative act, and as such can be challenged according to the Administrative Procedure Act.[898]

---

[892] Proposals: 1) the Hart Bill in 1973 allowing CL in the fields of public health, safety, or protection of the environment, and for underutilized patents if not worked within 3 years after issuance (or 4 years form the application), and for blocking patents; 2) the Affordable Prescription Drugs envisaged a CL for unreasonable pricing. The opponents argued that there was no evidence for trade suppression and that CL could discourage inventiveness and disclosure; and that "compulsory licensing is not creeping socialism: it is socialism run rampant." See Yosick, "Compulsory Patent Licensing for Efficient Use of Inventions," 1278; *Dawson Chemical Co. v. Rohm & Haas Co.*, *215.

[893] AIPPI, "United States of America. Report Q187," 3.

[894] Public Health Emergency Medicines Act (H.R.3235), Affordable Prescription Drugs and Medical Inventions Act (H.R.1708), Affordable Prescription Drugs Act (H. R. 2927), Essential Pharmaceutical Act of 1994 (H. R. 4151), from Consumer Project on Technology, "Chapter IV: Misc Compulsory Licensing Programs," accessed 30.11.2013.

[895] "KEI RN 2007:2 Recent Examples of Compulsory Licensing of Patents," http://keionline.org/content/view/41/1, accessed 30.11.2013.

[896] 42 U.S.C. §2181(a) stipulates that no patent shall be granted on invention or discovery on atomic energy or nuclear material intended to be applied in atomic weapon.

[897] 42 U.S.C. §2183.

[898] AIPPI, "United States of America. Report Q187," 5.

5.4.1.2 The Clean Air Act (42 U.S.C. Chapter 85)

The Act introduces CL to safeguard access to inventions that control and limit air pollution. As environmental aspects pertain to diverse fields, CL serves the public interest in preserving nature and social welfare.

Certain requirements must be met to apply for a CL: 1) the invention must comply with the emission requirement; 2) no reasonable alternatives can be obtained; 3) restricted access to the invention would adversely affect competition.[899]

Upon the request to the Administrator of the Environmental Protection Agency, the Administrator may apply to the Attorney General of the United States, who in turn makes a certification to a district court that determines the reasonable terms and conditions of licensing. Such a procedure, however, has never been exercised thus far.[900]

5.4.1.3 March-In Rights – the Bayh-Dole Act (35 U.S.C. 203)

The provision gives federal agencies which fund research projects the right to require the contractor (inventor, assignee, exclusive licensee) to grant a license (non-exclusive, partially exclusive, or exclusive) in any field of use and on reasonable terms. If the respective person refuses to do so, the federal agency may grant the license itself by determining in advance that such action is necessary:

1) because no effective steps have been taken within reasonable time to achieve the practical application of the invention in question in the given field of use;
2) to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;
3) to meet the requirements for public use specified by federal regulations when such requirements are not reasonably satisfied by the contractor, assignee, or licensees;
4) because the agreement required by Section 204[901] has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to Section 204.

[899] 42 U.S.C. §7608.

[900] AIPPI, "United States of America. Report Q187," 5.

[901] Section 204 obliges patent holders to manufacture products embodying the subject invention substantially in the US. A federal agency which funded the respective research project may waive the requirement if the parties reasonably but unsuccessfully sought licensees to manufacture the invention in the US, or if domestic manufacturing is not feasible.

5.4.2 Practice

5.4.2.1 Within Anti-trust Law

The relationship between compulsory licensing on the grounds of patent law and antitrust law has no statutory manifestation, but has been recorded in numerous court decisions. Though the two systems might seem discrepant, in fact they are complementary to each other:

> The aims and objective of patent and antitrust laws may seem, at first glance, wholly at odds. However, the two bodies of law are actually complementary, as both are aimed at encouraging innovation, industry and competition.[902]

The patent exclusive right and the resulting competence to choose or exclude licensors, or even the right not to work the invention, do not contravene the principle of fair competition as long as they remain within the legitimate patent monopoly[903]:

> The commercial advantage gained by new technology and its statutory protection by patent do not convert the possessor thereof into a prohibited monopolist.[904]

In the discussion on the "healthy" borders of patent monopoly, two approaches evolved: the absolute and the balance theory.

The *absolute theory* provides the patentee with the maximum scope of freedom to exercise their will over the invention, including locking the patent to exclude the competitors:

> As to the suggestion that competitors were excluded from the use of the new patent, we answer that such exclusion may be said to have been of the very essence of the right conferred by the patent, as it is the privilege of any owner of property to use or not use it, without question of motive.[905]

The other approach, the *balance theory,* limits the scope of the patent monopoly to acts serving the main purpose of the patent system, i.e. "the promotion of the progress of science and useful arts."[906] In *Hoe v. Knap*, dating back to 1886, the Court ruled that a patentee is "bound to either use the patent himself or allow others to use it on reasonable or equitable terms."[907] This balanced understanding of the patent privilege derives from the concept of "a privilege conditioned by a

---

902 *Atari Games Corp. v. Nintendo of Am.*, 897 F.2d 1572, *1576 (1990).

903 *CSU, L.L.C. v. Xerox Corp. Independent Service Organizations Antitrust Litigation* 203 F.3d 1322, *1325 (2000).

904 *Abbott Lab. v. Brennan*, 952 F.2d 1346, *1354 (1991); *Image Technical Services v. Eastman Kodak Co.* , 125 F.3d 1195, *1216 (1997).

905 *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405, *426 (1908); *Fastener Co. v. Eureka Specialty Co.*, 77 F. 288, *295 (1896).

906 *Special Equipment Co. v. Coe*, 324 U.S. 370, *381-83 (1945); *Vitamin Technologist, Inc. v. Wisconsin Alumni Research Foundation*, 146 F.2d 941, *944 (1945).

907 *Special Equipment Co. v. Coe*, *381.

public purpose"[908], whereas the absolute theory subordinates the public purpose to the private interest and extends the private privilege within the public domain.[909] The proponents of the *balanced* view stress the anti-market repercussions of the maximal patent power: =

> The use of a new patent is suppressed so as to preclude experimentation which might result in further invention by competitors. A whole technology is blocked off. The result is a clog to our economic machine and a barrier to an economy of abundance.[910]

An example of compulsory licensing within anti-trust remedies can be found in *Foster v. American Machine*, where the Court denied the injunction, as the plaintiff could not prove damages, and ordered a compulsory license with reasonable royalties for the use of the invention. The Court stressed the fact that the plaintiff did not work the invention and did not license it. Therefore, the plaintiff did not suffer any pecuniary losses in the course of the infringement of the patent, defined as the difference between the situation after the infringement and a hypothetical situation in which the infringement did not occur. In the given case, that difference amounted to zero.[911] The Court held that an injunctive relief would be an inequitable remedy in the given circumstances – a business cessation would be an excessive mean when the patentee did not exploit the patent:

> Here the compulsory license is a benefit to the patentee who has been unable to prevail in his quest for injunctive relief. To grant him a compulsory royalty is to give him half a loaf. In the circumstance of his utter failure to exploit the patent on his own, that seems fair.[912]

5.4.2.2 Within the Bayh-Dole Act

In the long history of Amendment 203, a compulsory license has never been granted. The National Institute of Health (NIH) has received numerous petitions to exercise the March-In Rights, but never decided to do so.[913] Considering that compulsory licensing for pharmaceuticals is mainly associated with developing countries, the fact that the USA has its own internal records on CL in the medical sectors is at least surprising – several examples will be provided below.

---

908 *Mercoid Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661, *666 (1944).
909 *Special Equipment Co. v. Coe*, *383.
910 ibid.
911 *Foster v. American Machine & Foundry Co.* , 492 F.2d 1317, *1322 (1974).
912 ibid., *1324.
913 James Love, "Four NGOs ask NIH to Grant Open Licenses to Ritonavir Patents under Bayh-Dole March-In Provisions," Knowledge Ecology International, http://keionline.org/node/1573, accessed 3.12.2013; "Notes on the Bayh-Dole Act of 1980," Knowledge Ecology International, http://keionline.org/bayh-dole, accessed 2.12.2013.

In 1997, *CellPro*, a startup of the Fred Hutchinson Cancer Center in Seattle, entered into a patent dispute with Johns Hopkins University over a patent on an antibody test to isolate stem cells in cancer treatment – a Johns Hopkins' patent that CellPro allegedly infringed.

Commentators pointed that the case shed light on the hurdles arising in the academia, such as "research secrecy, broadly defined patents, and the lack of governmental supervision over commercialization of university inventions made of federal funds." In the case, Johns Hopkins did not disclose the licensing agreements, which was required under the Bayh-Dole-Act. In the course of time, Hopkins and the contracted companies filed a suit for patent infringement against CellPro. CellPro assumed that it did not require Johns Hopkins' patent and worked on the development and clinical testing of its own bone marrow reconstruction technique, which is applicable in breast cancer treatment (an antibody-based isolation technique). Johns Hopkins claimed, however, that CellPro infringed its patent on cancer treatment technology – the patent holder believed the patent covered any use of antibodies for cell isolation.

The case pronounced the issue of NIH responsibility in regard to the commercialization of federal founded projects, in which it can exercise the march-in right, but refrains from doing so. As a result, CellPro lost the patent battle, had to withdraw its device (despite its clinical advantages and no alternatives), and went insolvent – an example of a squandered technology.[914]

In 2004, Essential Inventions (EI) requested a March-In right for Norvir of Abbott Laboratories (AIDS drug) and Pfizer's Xalatan (a glaucoma drug), which NIH eventually refused for both medicines. The petitioners argued that the two companies charged unreasonable prices and thereby violated the law on federally funded inventions – Abbott priced the drug four times, and Pfizer – two to five times higher in the USA than in other high-income countries. In opposition to the request, Abbott Laboratories claimed that the federal grant constituted only a fraction of the total investment: 3.5 million v. 300 million provided by Abbott itself (1:100)[915], and covered only preclinical research. In rejecting the petition, the NIH argued that March-In rights were not an appropriate mean of price control. In effect, Abbott reduced the price on drugs due to government-funded programs, but retained a high price for private-sector purchases. The petition regarding Pfizer drug was rejected without any concessions.[916]

---

[914] Dennis Meredith, "Patent Policy Flaws Complicate Commercialization of Federally Funded University Discoveries. New Case Study of Cellpro Calls for Changes in the Bayh-Dole Act," http://www.eurekalert.org/pub_releases/2002-12/du-ppf120602.php, accessed 30.11.2013.

[915] Jeffrey M. Leiden, "Abbott Laboratories Comments at NIH Public Meeting Regarding Norvir® and Bayh-Dole March-in Provisions," http://www.natap.org/2004/HIV/060104_04b.htm, accessed 12.02.2014.

[916] "KEI RN 2007:2 Recent Examples of Compulsory Licensing of Patents." "KEI RN 2007:2 Recent Examples of Compulsory Licensing of Patents."; "15 Frequently Asked Questions about the 2012-2013 Ritonavir March-In Petition," Knowledge Ecology International, http://keionline.org/node/1815, accessed 13.02.2014; "Ritonavir (Norvir)," http://www.essentialinventions.org/drug/ritonavir.html, accessed 30.11.2013;

In 2007, Essential Inventions requested from Robert Portman, Director of the Office of Management and Budget (OMB), to take steps to develop and accept alternative competitive sources of supply for federal procurement of two HIV-AIDS medicines: stavudine/d4T and Ritonavir.[917] Along with other companies, EI intended to manufacture generic versions of the two drugs, and therefore called for changes in administering the government-funded research programs to make medical technologies more available for patients. In regard to Ritonavir, EI stressed the detrimental price policy of Abbott Laboratories. During the meeting with OMB officials, EI extended the proposal to include the AIDS drug Emtricitabine (Emtriva).[918] Later in 2012, four NGOs – the American Medical Students Association (AMSA), Knowledge Ecology International (KEI), U.S. Public Interest Research Group (PIRG), and Universities Allied for Essential Medicines (UAEM) – requested that the NIH grant open licenses for patents owned by Abbott Laboratories for manufacturing Ritonavir.[919] They claimed (again) that the drug pricing was unreasonably high, which adversely affected US citizens, and that Abbott refused to license Ritonavir for co-formulated antiretroviral drug combinations. In March 2013, the NIH held a conference call with the NGOs. In November 2013, it refused to exercise the March-In right, explaining that the remedy is not a mean of price control, which should be left to the Congress to address in an appropriate legislative measures.[920]

In light of the presented facts, the March-In right appears to be a legal phantom; rather unsurprisingly, as compulsory licensing is a rare phenomenon also in the US system.

"Latanoprost (Xalatan)," http://www.essentialinventions.org/drug/latanoprost.html, accessed 30.11.2013; "Xalatan/Norvir - DHHS Secretary Thompson Asked to Grant Generic Manufacturers Licenses to Patents on Government Funded Inventions for Treatment of Glaucoma and Aids," http://www.essentialinventions.org/media/pr-29jan04.html, accessed 12.02.2014.

917 Due to public funding for the development of both drugs, the US government has a royalty free, nonexclusive, worldwide statutory license to the patents for each product – 35 U.S.C. §§ 202(c)(4) and 209(d)(l).

918 "The Request of Essential Inventions, Inc to Robert Portman, dated 5 January 2007 ", http://www.essentialinventions.org/eii2omb-5jan07.pdf, accessed 13.02.2014.

919 Ritonavir is a drug used in HIV/AIDS treatment as a “booster” of the efficacy of other drugs used in combination drug treatment. "15 Frequently Asked Questions about the 2012-2013 Ritonavir March-In Petition." "15 Frequently Asked Questions about the 2012-2013 Ritonavir March-In Petition."

920 ibid., Q11; Love, "Four NGOs ask NIH to Grant Open Licenses to Ritonavir Patents under Bayh-Dole March-In Provisions."; Krista Cox, "Notes from the March 18, 2013 NIH Call on the Ritonavir March-In Request," Knowledge Ecology International, http://keionline.org/node/1685, accessed 13.02.2014; Kevin Noonan, "Nih Declines to Exercise March-In Rights over Abbott Laboratories' Norvir[r]," Patent Docs, http://www.patentdocs.org/2013/11/nih-declines-to-excercise-march-in-rights-ver-abbott-laboratories-norvir.html, accessed 08.05.2015.

5.5 Japan

5.5.1 The Norm

The term *compulsory license* does not emerge in the Japanese Patent Act; however, the law stipulates a similar measure under the institution of *a non-exclusive license* for:

1) insufficient working of a patent in Article 83,
2) a dependent invention in Article 92,
3) public interest in Article 93.

The remedy was introduced into the system with the Patent Act of 1921.[921] It is a market-regulating tool intended to remedy a malpractice of the patent rights.[922] Unsuccessful prior negotiations with the patent owner (or the exclusive licensee) constitute the main prerequisite for a CL request to be made to the competent authority: either the Commissioner of the Patent Office or the Minister of Economy, Trade and Industry.

5.5.2 Grounds for Awarding a Compulsory License

1) Insufficient Working

Article 83 specifies that if the invention is not sufficiently and continuously worked for 3 years or longer in Japan, the intended user may request the patentee (or the exclusive licensee) to hold consultations upon granting a non-exclusive license after four years lapsed from the filling of the patent application. If the parties do not reach any agreement, the intended user may address the Commission of the Patent Office to award a CL. The import of goods meets the criterion of working the patent. Moreover, if the insufficient working can be justified by certain economic reasons, compulsory licensing does not come into question.[923]

2) Dependent Patent

Article 92 broadly address the procedural aspects of dependent patents. In material terms, it pertains to Article 72, which covers the scenario of an older patent being blocked by a younger patent:

1) the basis patent was filed prior to the date of the filing patent application for the subsequent invention;

[921] AIPPI, "Japan. Report Q187. Limitation on exclusive IP Rights by competition law," 4.
[922] "Japan. Report Q202," 5-7.
[923] ibid., 5.

2) the younger patent is in conflict with the older patent.

In the above cases, the patentee or exclusive licensee of the dependent patent may request consultation on licensing the dominant patent. Article 92 indicates that the consultation should concern the extent to which the two patents correlate with each other and the extent to which the license seeker intends to work upon the patent. If the agreement is unfeasible, upon the request of the patentee of a dependent patent the Commissioner of the Patent Office may decide to order a CL. If the license appears to be unreasonably prejudicial to the other party, the Commissioner of the Patent Office shall refrain from granting a license.[924]

The provision facilitates the access to pioneering technologies for innovators, which complies with the Japanese policy of *technology sharing*.[925]

3) Public Interest

Article 93 stipulates that license consultations may be requested if a patent at issue is particularly essential to the public interest. If the consultations are unsuccessful, the person intending to work the invention may request the Minister of Economy, Trade and Industry to render a decision.

Instruction of the System of Awarding Non-exclusive Licenses, issued by the Industrial Council, names the circumstances in which the working of the invention is of *particular* concern for the public interest:

a) areas relating directly to the lives of citizens, such as public health, asset protection and construction of public facilities;
b) situations in which the sound development of a relevant industry may deteriorate.[926]

---

[924] ibid., 5-6.

[925] Nancy J. Linck and John E. McGarry, "Patent Procurement and Enforcement in Japan - A Trade Barrier," *Geo. Wash. J. Int'l L. & Econ.* 27, no. 411 (1993-1994): 419-22; Teruo Doi, *The Intellectual Property Law of Japan* (The Netherlands: Sijthoff&Noordhoff, 1980), 38.

[926] As published in a report of the Foreign Investment Council's Expert Committee in 1968:
A non-exclusive license under Section 93 of the Patent Law may be allowed when the patent is regarded as being important for areas relating directly to the lives of citizens, such as the areas of public health, protection of assets and construction of public facilities. It may also be allowed when substantial adverse effects on the national economy are likely to occur due to the following events arising as a result of the monopolization of an important patented invention that is necessary for the production of certain products or is related to the implementation of certain industrial processes: (i) It is feared that a huge number of people will be made unemployed due to bankruptcy or other disruptions occurring for a corporation that is expected to use the patented invention; (ii) it is feared that, through bankruptcy or other disruptions occurring for corporations in a certain industry that are expected to use the patented invention, a huge amount of existing facilities in the industry, which would be utilized if the industry could use the patented invention, is likely to be destroyed; and (iii) when bankruptcy or other disruptions occur for corporations in a key industry, important export industry or hi–tech industry that is expected to use

The use of the term *particular* narrows down the ambit to situations in which no alternative to the patented invention is possible, regardless of the costs. The second criterion unequivocally suggests that CL applies in cases where the economy and the consumers are at stake, e.g. in the course of anti-competitive behaviour, and therefore, the Minister of Economy, Trade and Industry remains the decision-making body in the matter.[927]

5.5.3 Practice

No compulsory licenses have been granted in Japan in recent years.[928] The last case of a CL request on dependent patents was recorded more than 40 years ago.[929] No license was ever granted for insufficient working. However, it is estimated that at least 23 cases were settled privately, either unilaterally or via cross licensing, with most cases involving pharmaceutical companies. The mere existence of the provision sufficiently stimulates the working of inventions and the licensing behaviour.[930] Of particular interest is the fact that the protection of IP in Japan was strengthened by its 1994 agreement with the USA, in which Japan committed itself to refrain from awarding a CL for blocking patents (Article 92), with the exception of anti-competitive practices.[931]

5.6 Compulsory Licensing at Work – a Summary

Patent compulsory licensing, though rarely employed, represents an important legal instrument in regulating access to patented solutions, which is of particular concern in the field of pharmaceuticals and international drug supply.

Regardless of the differences in administrative procedures and material aspects of the patCL schemes between the analysed jurisdictions, which are the result of diverse legal traditions and established practice, the substantial framework (provided in the TRIPS Agreement) remains the

---

the patented invention, the sound economic or technological development of the industry is likely to be substantially hindered. AIPPI, "Japan. Report Q202," 6.

927 ibid., 6-7; Doi, *The Intellectual Property Law of Japan*, 41.

928 AIPPI, "Japan. Report Q187. Limitation on exclusive IP Rights by competition law," 5.

929 Julian-Arnold, "International Compulsory Licensing: The Rationales and the Reality," 351.

930 Sadao Nagaoka, "Determinants of High-Royalty Contracts and the Impact of Stronger Protection of Intellectual Property Rights in Japan," *Journal of the Japanese and International Economies* 19, no. 2 (2005): 236; Doi, *The Intellectual Property Law of Japan*, 41.

931 The USA and Japan decided upon three measures: Japan changed the pre-grant to post-grant opposition and unified the opposition system (1), pledged not to apply compulsory licenses in cases of blocking patents (2), reformed the early examination systems to enable the foreigners to enjoy the fast track status (3). Nagaoka, "Determinants of high-royalty contracts," 234-35; Klaus Hinkelmann, *Gewerblicher Rechtsschutz in Japan*, vol. 2. (Köln, München: Carl Heymanns Verlag, 2008), 196.

same, as do the objectives. PatCL ensures access to publicly significant patented solutions in cases when such access has been blocked by the patentee. As a forceful countervailing measure, it was not designed to support the individual interests of the patentee's competitors, but to protect the public benefit coming from the patented solution, and vocalised in the strict criteria.

Compulsory licensing serves to protect vital (inter)national interests, such as public welfare, technological development, and technology transfer. To combine all of the aforementioned issues into a single statement – compulsory licensing fosters competition and protects business and consumers. Even the criterion of the public interest, which is a dominant prerequisite of CL requests (like in Germany) and sharpens general conditions, pertains to market-related objectives, such as price reduction (to make a certain good affordable for citizens) and greater product diversity.

A low number of compulsory licenses may paradoxically prove the functionality of the law in stimulating voluntary licensing (a pushing effect[932]). According to the study by Beall and Kuhn, only 24 unique cases of CL were recorded between 1 January 1995 and 6 June 2011 – all concerned pharmaceutical products and were issued by national authorities.[933] In Germany, for instance, patCL has been granted only once (and revoked by the higher instance).[934] No CLs have been granted in the UK in the last ten years, with statistics showing a declining number of applications.[935] The same goes for Japan: several applications have been filled, but in the end, no compulsory licenses have been granted. After the 1994 Agreement with the US, it has become impossible to obtain a CL for a patented dependent invention. The USA does not permit any patent compulsory licensing whatsoever.

Certainly, compulsory licensing is not a remedy for low medical care, poor living standards, and malnutrition. To a much larger degree, it performs the role of a short-term solution in a state of emergency. Certainly, it is an abuse to claim that a justified issuance of CL increases the mistrust in the patent system or that it indicates a weak patent system. The mere fact of applying a legal instrument according to its purposes, objectives and requirements cannot be the cause of the malfunction of the patent system. Critical opinions expressed by IP holders in such cases constitute self-defence to protect own interest and to punish lawful, though undesired, patent practice.

---

[932] Esther Van Zimmeren and Geertrui Van Overwalle, "A Paper Tiger? Compulsory License Regimes for Public Health in Europe," *IIC* (2011): 23.

[933] Beall and Kuhn, "Trends in Compulsory Licensing."

[934] *Polyferon*, BPatG 7.6.1991 E 32; Kraßer, *Patentrecht*, 834.

[935] *Patentrecht*, 834; WIPO, "Survey on Compulsory Licenses Granted by WIPO Member States to Address Anti-Competitive Uses in Intellectual Properties Rights - CDIP/4/4 REV./STUDY/INF/5," 13; UK IPO, "Swansea Imports Ltd. v. Craver Technology Ltd, BL Number O/170/04."

5.7 Applying Compulsory Licensing in the Maker Scenario

At this point, one thing should be clear: the probability of a compulsory license requested either by a maker or for a maker's product is incredibly low:

a) makers do not require patents to work their inventions (they rarely patent their ideas);
b) a lot of their designing is done around patents;
c) neither would they seek a CL nor would grant it to anyone (makers, after all, freely share their ideas).

If tinkering on a product represents a substantial improvement, this fact might become a ground for licensing in the context of dependent inventions, assuming a maker will be the first to request patent protection.

In view of the infinitesimal ratio of compulsory licensing taking place, as well as its high requirements, this solution remains a rather theoretical remedy for makers. Nonetheless, it inspires further research and merits careful consideration.

5.7.1 Refusal to License

This criterion assumes lasting attempts to obtain a license. However, in order to satisfy this criterion, two preconditions must be met: having the awareness of relevant patents (or rather, an awareness of the patentees) and resources necessary to carry out license negotiations.

Studies show that entrepreneurship among makers has an "accidental character"[936], i.e. it is not calculated in the activity itself, which is why makers in principle do not conduct patent due diligence before launching a project – they simply *make*. This, however, should not imply that they are unaware of patents or patent-related issues as such – quite the opposite. Crowdsourcing in the field of 3D printing is a perfect example of open collaboration in detecting prior art with the aim of preventing "creative" patent drafting and keeping the field open.[937] Still, making does not start from the research in patent databases.

In regard to resources, assuming that makers found a patentee(s), they must offer "reasonable licensing terms." The phrase *reasonable terms* does not have any fixed definition and varies

[936] Shah and Tripsas, "The accidental entrepreneur."
[937] The initiative of Electronic Frontier Foundation: Electronic Frontier Foundation, "Join EFF's Efforts to Keep 3D Printing Open."

according to the circumstances of a given CL request; it concerns, however, predominantly financial commitments, i.e. an adequate remuneration for the use of a patent. Regardless of the ultimate financial contributions, licensing negotiations always constitute a significant investment in terms of time and money. They can be even more costly when the market launch of a given product is postponed. For an individual investor, license bargaining represents a reasonable option only in view of secure investment recoup. Otherwise, the outlay is too high and cumbersome.

In terms of making, it is unlikely that a maker would initiate licensing negotiations with a patent holder. The maker movement is immense, but single makers, even if clustered, do not achieve high purchasing power and the resources they have are intended for project developments and not licensing fees (particularly, in the case of non-commercial projects). It is more accurate to assume the opposite scenario: patentees (e.g. companies) are interested in specific maker solutions and initiate bargaining. In the worst-case scenario, licensing negotiations are part of a patent infringement settlement, when makers allegedly infringe patented solutions.

In conclusion, it is unlikely for makers to (attempt to) meet this requirement.

5.7.2. Anti-competitive Practices

The analysis of anti-competitive behaviours is a complex task which falls outside the scope of this research project. For this reason, a general overview of the subject in the context of makers is provided below.

Anti-competitive patent practices[938] can disturb workings at any stage of the development process. As indicated in the questionnaire, makers encounter diverse obstacles such as market entry barriers and limited access to resources and markets, which may be the results of the strong position of certain market players. Strong market position, however, does not immediately denote an abusive or anti-competitive behaviour (in terms of competition law), even if a given conduct impedes making. As studies show, makers prevail in small-scale sectors with unstable demand conditions, ambiguity, and great variety.[939] In that sense, almost every bigger company enjoys a strong and dominant position. However, this understanding does not correspond with the legal and economic comprehension of anti-competitive conducts. The maker movement is immense, but single makers,

[938] E.g. tying agreements (one patented good with other non-patented), licensing agreements extending the fee payment beyond the patent term, or including an obligation to pay a percentage from sale of goods not related to a patent.

[939] Shah and Tripsas, "The accidental entrepreneur," 126; Shah, "Sources and patterns of innovation."; Harhoff, Henkel, and von Hippel, "Profiting from Voluntary Information Spillovers."; Joshua Gans and Scott Stern, "The Economics of User-Based Innovation," *Working Paper* (1998).

even if clustered; do not achieve significant market power to push through their rights and ideas in conflict with big companies. As a disclaimer, the diversity of making, both in terms of scope and content, restrains the apprehension of the anti-competitive criterion. Last but not least, the dynamic of *making* unequivocally indicates that makers successfully bypass many market and legal barriers.

5.7.3 Public Interest

Most patent systems do not directly define the notion of public interest. However, it is expedient to encompass public health, social welfare, and other sectors of national importance. In fact, most of the cases involving compulsory licensing concern the pharmaceutical sector.

Two aspects make this ground inapplicable for the adopted model of making:

1) makers rarely look for patent protection to monetize the investment[940] – it is discouraged in the community: As stated in the code of conduct for makers, making is *open*[941];
2) makers would not be affected by compulsory licensing, since their solutions, as suggested above, are kept accessible without any additional restrictions.

At this point, it would be unjustified to say that the substance of the public interest does not apply to makers because makers only provide lifestyle solutions (or gadgets). They contribute socially valuable solutions, such as solutions in the field of medical equipment: the non-invasive anaemia diagnosis tool "ToucHb," or the urine analysis tool "uCheck" via smartphone applications[942], or the*Little Devices@MIT*[943] – just to name a few.

5.7.4 Dependent Patents

Literally understood, this circumstance would not apply to the model of making. As mentioned above, makers rarely patent their inventions (patenting is neither appealing nor reasonable in terms of time and investment recoup).[944] In a wider spectrum, the situation of dependent patents

[940] Harhoff, Henkel, and von Hippel, "Profiting from Voluntary Information Spillovers."
[941] Hatch, *The Maker Movement Manifesto. Rules for Innvoation in the New World of Crafters, Hackers, and Tinkerers*.
[942] Kate Torgovnick May, "Urinalysis: There's Now An App For That," http://blog.ted.com/2013/05/15/urinalysis-theres-now-an-app-for-that/, accessed 03.11.2013. See also http://www.biosense.in/products.html (accessed 03.11.2013)
[943] "LITTLE DEVICES @ MIT Affordable Health | Medical Technology | DIY Innovation," http://littledevices.org/, accessed 04.04.2014.
[944] Shah, "Sources and patterns of innovation," 15-16.

reflects the common making approach: makers tinker on existing products, and succeed in either creating improvements or new adaptations. There is a certain level of dependency between the patented solution and the maker's improvement, but it does not correspond with the situation of two related patents subjected to compulsory licensing. However, a license authorising conducts on an older patent which constitutes a dependent solution would correspond with some circumstances of making. The administrative aspects of CL are not convincing in terms of a suitable instrument facilitating makers' activities.

The context of dependent patents is inspirational for seeking a solution that would be milder than compulsory licensing and cover a wider range of activities than allowed under experimental use – hence the novel proposition of the *green light license*.

Chapter 6. *GREENLIGHT* – A NEW LEGAL FRAMEWORK FOR MAKERS

The proposal of a *green light* license – a green light from the patent owner to makers, which allows conducts associated with making – addresses the issue of communitarian testing and improving upon patented solutions on a non-commercial basis by makers.

The objective of this study was the examination of patent exceptions, i.e. legal instruments "de-capsulating" patent exclusivity for unauthorised uses on patented solutions from the perspective of the scale of the safeguarded *freedom to operate*. In that regard, the project measures the flexibility in the patent system, and its adaptability to modern technological occurrences, such as the maker movement. Its underlying hypothesis assumes the insufficiency of patent limitations in ensuring the balance of interests of the participating parties, with the stress on the end users.

In times of progressing *patentisation* and pressure toward a "strong IP system," recognised as the sole source of technological development and public welfare, the interests of end users are neglected for the sake of the *sacred* patent exclusivity.

The approved exceptions sanction well-established practices, such as agricultural uses and private and non-commercial uses, the ambit of which represents only a miniscule curtailment of patent rights. The proposals of new exceptions follow the same pattern and suggest only a minor derogation of patent exclusivity.[945] Admittedly, exceptions underlie dynamic legal interpretation that modifies their scopes according to the changing reality, as illustrated by the experimental use exception, which had been extended over testing medicines for regulatory approvals. However, such changes constitute a delicate adjustment within the established rigid framework of patent exceptions – they do not introduce any novel form, which would enable the system to smoothly interact with ongoing technological transformations. The sole direction of the present expansion of the patent system is the *inclusion* of patentable subject-matters and strengthening the enforcement of rights.[946]

The maker movement challenges the patent-related innovation pattern; it is comparable to the open source (copyleft) movement, which positions itself against the copyright regime. However, transposing a pure *copyleft* idea onto the patent field as a *patent-left* approach may eventually prove to be unsuccessful due to the inherent structural and procedural differences between the

[945] Naomi Hawkins, "An Exception to Infringement for Genetic Testing – Addressing Patient Access and Divergence Between Law and Practice," *IIC* (2012).
[946] See Llewelyn, "Schrodinger's Cat: An Observation on Modern Patent Law."

two systems: diverse types of protected works, diverse requirements and application fields, and, last but not least, complex and costly patent prosecution.

Nonetheless, *open source* projects for patents are emerging (and will continue to emerge) to hinder the blocking effects of patents by ensuring access to patented solutions (with no or fewer limitations). Sectors in which *patentisation* has reached the level of basic research (discoveries), as in biotechnology, are affected by proprietary claims on "enabling technologies that burden research with transaction costs and uncertainty."[947] Thus, interested parties are launching initiatives aimed at keeping knowledge open and communal, inspired by the philosophy of *open source software*, which, on principle, prohibits proprietary claims resulting in locking down information. Although the latter does not pertain so much to patents, which grant protection and exclusivity in return for disclosure; the main patent-driven obstacle is the *blocked* use of the patented solution. Projects (and models) such as Biological Innovation for Open Society (BiOS)[948], or the international HapMap Project[949], address this matter. The first one concerns public access to patented research tools in the field of agricultural biotechnology. It prohibits patenting improvements of research tools, but permits seeking protection on the results obtained therefrom. HapMap is a government-funded project that ensures access to information on the haplotype map of human genetic variations. Like BiOS, it does not prohibit patenting itself, but obliges the participant to license access to proprietary information on terms which will allow the other participants to continue their works.[950] Like in the case of classic open source, patent-opening projects apply licensing as the legal mean of sanctioning the use of information: a promise not to assert IP rights against the other parties participating in the project.

Patent *opening* projects concern mainly the biotechnological field, in which an increasing number of patents covers knowledge in the early stage of development, implementable in a broad spectrum of further developments.[951] Such projects ensure open access to patented information created or placed within a consortium for a specified field of technology, e.g. the RNAi Consortium, or the Single Nucleotide Polymorphisms Consortium. They are based on discrete membership, which obligates participants to certain conducts, like in BiOS, to share improvements on core technologies, not to enforce rights against other BiOS licensees, and to share all information about

[947] Sara Boettinger and Dan L. Burk, "Open Source Patenting," *JIBL* 1(2004).

[948] "Cambia Enabling Innovation. FAQs - BiOS Agreements," http://www/cambia.org/daisy/cambia/69.html, accessed 12.11.2014.

[949] "International HapMap Project," http://hapmap.ncbi.nlm.nih.gov/, accessed 21.11.2014.

[950] "Open Source Patenting."; Minna Allarakhia and Walsh Steven, "Managing Knowledge Assets under Conditions of Radical Changes: The Case of the Pharamceutical Industry," *Technovation* 31(2011).

[951] MIT established Registry of Standard Biological Parts that discloses non-patentable parts to hinder patenting of trivial solutions. "Registry of Standard Biological Parts," http://parts.igem.org/Main_Page?title=Main_Page, accessed 12.11.2014.

biosafety with the public.[952] They involve the cooperation of various entities (companies, universities, and research institutions) with the common objective of making the patented information accessible, on the one hand, and, on the other hand, attracting the funding by allowing a certain margin of patenting on the obtained results. The latter indicates that non-proprietary concepts may decrease R&D incentives and interest in a given project, if they block channels of investment recoup, such as patenting.

One could suggest the establishment of a patent opening project with the aim of creating a catalogue of patents available for makers. Such an initiative would definitely be helpful, though it would require many Elon Musks refraining from enforcing patent rights in cooperation with makers. If widespread, such an initiative could change the culture within and around the patent system. The main challenge of the maker movement, being its strength at the same time, is its size. In terms of the number of participants, an open patent project for makers would require a new infrastructure to maintain and supervise a consortium or a database with thousands of patent rights from various fields and interested users.

The concept of a *patentleft* regime in which, once an idea is made *patentleft,* it "infects" further ideas-solutions resulting therefrom with the *patentleft* effect, is worth considering and implementing in future endeavours. To some extent, the HapMap Project embodies the *patentleft* idea, because it imposes an obligation on users to refrain from patenting solutions based on information from HapMap, and, if they do manage to obtain patents, they are obliged to share the information on terms which will allow others to continue their work. HapMap is grounded in the principles of non-exclusive licensing and reciprocity. From another perspective, initiatives like HapMap or BiOS resemble classic patent pooling with cross-licensing, which is a behaviour common in many industries.[953] A similar initiative for makers would be formed in the same way: a pool of patents placed under specific conditions.

To reiterate, a *patentleft* idea is an engrossing concept which deserves further attention and elaboration. As the object of the study was the scope of patent exceptions, the study proposes a novel solution within the framework of patent limitations to address free tinkering and the public dissemination of information. Its objective is plain and simple: to free makers from infringing patent rights, from being involved in patent puzzles and from decoding abstruse patent claims. An instrument for makers should fulfil certain prerequisites – it should be:

1) self-evident like private and non-commercial use, assumed almost intuitively;

[952] "Cambia Enabling Innovation. FAQs - BiOS Agreements." "Cambia Enabling Innovation. FAQs - BiOS Agreements."

[953] Boettinger and Burk, "Open Source Patenting," 229-30.

2) non-discriminatory in terms of the technology field;
3) enabling communal working;
4) covering non-commercial uses.

The concept of the green light license (the greenlight) responds to these expectations. However, a number of questions arise at this point:

1) WHO: who should be given the license: the whole community or a single maker?
2) WHAT: Which uses should it cover?
3) HOW: What kind of license should it be? Should it be negotiated at all or be a blanket solution?
4) WHY: This is a broad concept in terms of permissible uses and the target group.

In regard to the first question, every maker should enjoy the freedom to make, and should be granted a green light license. To reiterate, a maker is a technology enthusiast who tinkers, develops, and improves solutions for one's own needs and/or to share with others for the mere act of sharing and enriching the maker community. The greenlight would exempt only makers who perform on a non-commercial basis; it would be a promise not to assert patent rights against public and non-commercial conducts.

Regarding the question of what, the greenlight would go further than the experimental use exception, since making is more than reverse engineering for the better understanding of the patented technical teaching – making denotes learning and improving one's own skills. Tinkering *on* a patented device (or a patented component) would be the main indication for the greenlight, akin to experimental use. However, the scope of tinkering is almost limitless; it is also more than improving or repairing – playfulness is a part of *making*.

As a conventional compulsory license covers the right to use, manufacture, and sell a patented invention, its milder derivative, the greenlight, would address all and only non-commercial uses, i.e. the development, adaptation, prototyping, and private-scale manufacturing (e.g. 3D printing) for the purposes of *making.* The greenlight would cover posting online information on a given improvement in the form of instructions, and would secure the makers themselves from the accusation of indirect infringement or inducement of infringement.

The red light would turn on when *making* would cross the border of commercial applications, e.g. the sale of a new product. This also concerns the use of the results of making as tools for commercial purposes or in pursuing professional activities.

However, as long as makers do not usurp the patentee's right to financial profits, *a green light license* should be upheld and should remain unpaid – otherwise, standard licensing (and royalties) should come into play. The main intention of the greenlight is to keep non-commercial *making* free from patent restrictions.

Regarding the question of how, the term "license" does not pertain to a conventional contractual obligation negotiated with a patent holder, or to an administrative decision like a compulsory license. To a larger degree, the proposal resembles "an implied license" for making activities that would come into force the moment an idea is disclosed to the general public: in the case of open sharing and collective working (e.g. testing, prototyping), where the private and non-commercial use exception terminates, and the experimental use exception cannot fully support makers. In other circumstances, private and non-commercial use applies. The greenlight is an implied allowance from the patent holder – a tolerance of making behaviour (on a royalty-free basis!) and a promise not to sue under the conditions of *making*.

The greenlight is a blanket solution, because open sharing cannot be supervised. In effect, as indicated in the first question, the greenlight should apply to all makers. Public use and the free dissemination of ideas represent the main obstacles in free *making* in light of the existing patent exceptions. The *green light license* should make collective (public and non-commercial) working lawful and remain non-discriminatory in regard to the technology field.

The proposal of the greenlight envisages also establishing a database, in which makers could publish projects eligible for the green light license. This would centralise the makers' ideas, which are now spread out among various communities and user forums.

When justifying the greenlight, one can reply that law sufficiently safeguards the freedom to work on patents if such work serves the better understanding of their technical teaching. However, making goes much further: it goes beyond pure experimenting; it mixes the patented idea with individual creations (one's own *making*).

"Makers are champions of change."[954] The maker movement is a movement with a mission and a vision: a mission to educate and excite people about science, and a vision to make the world better and people happier through self-expression in making. It is worth recalling that the White House appreciated the contribution of makers to the welfare of Americans and proclaimed 18 June a

[954] Howard, "The Maker Movement's Potential for Education, Jobs and Innovation is Growing."

National Day of Making.[955] This is one of the many reasons why the maker movement should be finally given the deserved attention in the legal science. To reiterate, *making* is more than life-style gadgets – it educates (*learning by doing)*, creates new jobs, and spreads the flare of innovation throughout society – which is exactly what patents intend to do. Moreover, it has a tremendous democratising impact: people participate, get involved, share, and feel responsible for themselves and their communities.[956] That alone should be a sufficient enough justification for an appropriate legal tool to keep the space open for makers. There is not much theorising in the Maker movement – it takes place, it brings more benefit than one would expect, and thus it should be protected.

The proposal of the greenlight aspires to establish a new statutory exception. However, at this initial phase, it intends to introduce a new model of a patent doctrine exempting the makers' non-commercial activities to be adopted via judicial precedence. This *modus operandi* would facilitate the reception of the greenlight in the system.

However, in light of the three-step test and its current construction, the green light license would hardly pass the first criterion of *limited exception,* i.e. a small diminution of patent rights, since it would exempt various uses upon patented products with the sole limitation to their non-commercial character. The scope of non-commercial making activities is wide, e.g. taking a device apart, adding new components, switching some elements, mixing them with others, manufacturing certain parts (for the purpose of making), or even building a patented device – all can be recognised as making and using a patented solution. The greenlight is designed to derogate patent exclusivity from public and non-commercial uses; the greenlight would not curb the patentee's exclusive right to make, use, offer to sell, and sell the invention on a commercial basis.

In that regard, it would be nonetheless unrealistic to assume that meticulous legal minds and proponents of a *strong patent system* would acknowledge such a generous exception in favour of makers as a *limited exception*.

Following the practice of the WTO Panel, once the first criterion has been excluded, the two other criteria – normal exploitation and legitimate interest – do not warrant further consideration. For the purpose of this analysis, it must be said that the greenlight may not be recognised as complying with the given construction of the other two criteria due to the possible curtailment of the economic interests of the patent holder, e.g. via home 3D printing of spare parts and instructions on enhancing patented solutions, as well as making similar solutions. When weighed against the

[955] "You're sort of the anti-Washington message, in that you guys just hang out and do great stuff," said U.S. CTO Aneesh Chopra when introducing [Dale] Dougherty. Ibid.

[956] ibid.

rights of third parties, i.e. society itself, the greenlight proves more valuable due to the contribution of *making* to the overall welfare. As demonstrated in the analysis of the patent tree-step tests for patents delivered by the WTO Panel, the interests of third parties get the least degree of attention, though the patent system serves vital public interests and is not intended to solely protect individual and private interests of patent holders.

When justifying the necessity for the greenlight, it must be accentuated that the proposal responds to the expectations arising from the deteriorated patent quality (to point it out again). How, otherwise, could one explain that individuals who do not possess advanced facilities and infrastructure to pursue their hobbies face the peril of being accused of patent infringement. Indeed, leading makers deliver great and often patent-worthy solutions, but not the whole community, not every single maker – the situation in the densely patented 3D printing field reflects such concerns perfectly.

From this perspective, the greenlight could contribute as a pressure tool in ensuring the high quality of patents. The mere possibility of invoking the greenlight could discourage patent-seeking entities from requesting patent protection for weak, non-inventive solutions, just to limit or deter third parties from studying them thoroughly. Patent applicants, especially in the fields of electronics, robotics, and 3D printing, should bear in mind that the downstream maker movement tweaks with solutions in all possible ways. From that perspective, making can be regarded as an unofficial form of post-grant examination: the faster a given patent is *re-made,* the lower its value. As mentioned before, a supportive element of the greenlight would be a freely accessible database (the greenbase) with results delivered by makers who apply the greenlight. This would be also to the advantage of patent authorities, which would gain another valuable resource in their search for prior art.

Paradoxically, a low degree of innovation is beneficial to the greenlight: the more people are capable of understanding (and remaking) patented subject-matter, the more people would require its protection. High patent quality gravitates towards a high degree of innovativeness – which is difficult to hack. The experimental use exception would be a supportive tool in understanding the technical teaching embedded in a patented solution.

On the other hand, the recognition of the greenlight might result in the further convolution of the system with protection instruments in the name strengthening the patent system to impede the use of the greenlight. In such a situation, the acceptance of the greenlight would be artificial and fraudulent. The dominant pro-patent mindset articulates that no progress could be possible

without strong IP (patent) rights. In fact, the progress would not be possible without the dissemination of knowledge; the patent system assists with patent disclosure. The greenlight promotes the same idea; all the more that the access is guaranteed only via information sharing. A disclosure of information, i.e. public making, already constitutes a precondition of the greenlight. Posting outcomes of makers' investigations in the greenbase would further ensure its application.

The greenlight proposal provokes us to reconsider the structure, values, and behaviours sanctioned in the present patent system. It does not exhort to abolish the system. Rather, it creates another window in the patent fortress. However, without a thorough re-evaluation and reform of the system, every pro-maker tool or any other novel “opening” concept will be just a phantom.

Chapter 7. FINDINGS AND CONCLUDING THOUGHTS

The underlying hypothesis challenged the functionality and effectiveness of existing patent limitations within the making scenario. The prior research assumed that certain limitations, such as private and non-commercial use, experimental use, the prior use right, and the repair doctrine, might protect making from patent liability, albeit in a narrow extent. The comparative analysis, partially assisted by the empirical study, proved the narrow application of exceptions and their inadequacy in supporting the activities of makers (public and non-commercial making).

Patent limitations as such do not enjoy much attention in the legal discourse.[957] Reports enlisting patent exceptions, such as those prepared by WIPO[958], do not investigate their effectiveness and functionality, and conclude analysis with the conventional explanation "for the balance of interests." Only experimental use and the *Bolar* exception have become the subjects of deep analyses and discussions owing to their economic significance, and in light of the objectives of the patent system.

Exceptions are necessary in the system: it is acknowledged that without such measures, patent exclusivity would be too powerful and detrimental to the public interest in terms of further R&D operations and access to inventions. The exceptions limit the expansion of patents and ensure the free use of patented solutions in fields that patents were not designed to interfere with, such as the private sphere, international relations, and the sovereignty of third countries, as in the exception on permissible uses of patented subject-matters on vehicles and vessels.

The dominant proprietary mindset, howerver, disregards patent exceptions. In the three-step test for patents, they are placed in the last criterion, which indicates the low position of third parties, including users, in the hierarchy of interests. This is also manifested by the ongoing criticism of imposing compulsory licensing schemes that apparently ruin the trust and stability of the patent system of the applying country, even if it serves crucial public purposes.

This situation is driven by the unshakable conviction of the rightfulness of patent protection, despite the lack of unequivocal empirical evidence to support it, apart from sectoral analyses. Based on the latter, it can be inferred that the diversification of the protection measures can

[957] See Lionel Bently and Brad Sherman, "Limiting Patents," in *Compulsory Licensing. Practical Experiences and Ways Forward*, ed. Reto M. Hilty and Kung-Chung Liu (Berlin Heidelberg: Springer, 2014).

[958] WIPO, "Questionnaire on Exceptions and Limitations to Patent Rights," http://www.wipo.int/scp/en/exceptions/, accessed 17.07.2013.

provide a more efficient and just rewarding system. Moreover, it is worth mentioning here that studies exploring the purposes behind patenting expose pure business and strategic objectives.

The current state of affairs in the patent field reinforces the opinion on the necessity to balance the disproportion that affects end users. As presented in the survey analysis, makers indeed face difficulties such as limited access to resources and legal barriers (i.e. the legal protection of ideas), and might be targeted by patent holders when they disclose their ideas publicly. Protection against such scenarios is the objective of the greenlight. It stretches the ambit of patent limitation over making activities, which as such do not deviate to a large degree from traditional exceptions, such as private and experimental use. The green light license embraces the variety of making operations and eliminates the restrictions placed on the quantity and quality of uses in the public sphere and solely within non-commercial applications. It secures the immunity of uses once the concepts are posted in the greenbase, which enhances cooperation between patent offices and makers, becoming a source of information in patent prosecution.

Not only do makers oppose the established paradigms of innovations, but also expose the flaws of the current patent system, with the main one being low patent quality. This issue, upheld by many practitioners, initiates a false chain-reaction resulting in the abundance of weak (trivial) patents that fuel the secondary market and portfolios of patent assertion entities. Low patent quality, pronounced in the obviousness of patented solutions, is often the cause of non-willful patent infringement due to the mistaken conviction that a certain solution is unpatentable.

It is assumed that higher patent quality within the maker scenario would bear two implications:

1) a greater scope of free state of the art due to higher thresholds of the non-obviousness and novelty of patented subjects;

2) the lack of need for a special pro-maker legal tool, as makers would operate within the free state of the art, and would refer to the existing patent exceptions, e.g. experimental use.

In regard to the latter, it was also considered whether the experimental use exception, as the most appropriate for making, should be construed in a broader way. The aforesaid manoeuvre could possibly lead to an excessive extension and a misinterpretation of the scope of the experimental use that could cover “unintended” uses. Furthermore, it would require a redefinition of what an experimental use is, as well as the types of operations it would cover. In that respect, it was found more suitable to propose a tool designed solely for makers, which would address the different aspects of making.

The importance of this study is manifested first and foremost in the introduction of the maker movement to the legal science and, secondly, in the preparation of a guide for makers, which

explains the scope of permissible use of patented solutions – as there are many misconceptions in this field.

In terms of branding, *user innovation* pertains to the same phenomenon, but remains an academic term (used mainly in the management field). The people it describes do not recognise themselves as user innovators but as makers. This remark does not solely concern the wording (as is common in legal discussions). Unlike the term *user innovation*, the concept of the maker movement describes not only individual innovators who work together, enjoy the work, and deliver interesting solutions, but much more. The maker movement introduces social changes, enhances democratic values, and, without exaggeration, saves young people from helplessness in destabilised regions – see makerspaces in Iraq[959]. Above that, making and makers exist in the political life – it is sufficient to recall that 18 June is the National Day of Making in the USA.

This research is not alone in pointing out the pitfalls of the system and by calling for modifications to its paradigms and working. The patent community should work on enhancing patent requirements and the ethical standards of patent practice. As various critical opinions pertain to the implementation of patent law (e.g. patent enforcement and the determination of license fees), we should reconsider the justification of the patent system that recently has been strongly exploited for business purposes.

[959] "Global Enterpreneurship and Maker Space Initative," www.gemsi.org, accessed 01.07.2014; Glen Dalakian II, "Iraq to be Reborn as Art & Science Hub through Baghdad Hackerspace," http://www.wamda.com/2012/09/iraq-reborn-art-science-hub-through-baghdad-hackerspace, accessed 01.07.2014.

ZUSAMMENFASSUNG

Kapitel 1. Einleitung und Forschungsfragen

Diese Dissertation untersucht die Fragestellung, in wie weit Maker von speziellen Ausnahmeregelungen im Patentwesen (Patentbeschränkungen) profitieren können und deshalb im Rahmen Ihrer Aktivitäten von einem „freedom to operate“ ausgehen können.

Es wird hinterfragt, inwieweit die Monopolstellung eines Patentinhabers beschränkt werden darf, und ob damit die Interessen der Verbraucher berührt werden.

Einige Rechtsinstrumente beschneiden die Patent-Exklusivität ab initio aus bestimmen Handlungen heraus, was im weitesten Sinne dem Ausbalancieren von Interessen zwischen den Patentinhabern und Benutzern in einem spezifischen Handlungsumfeld diesen soll.

Die Fragestellungen dieser Dissertation sind nicht von abstrakter Natur und bezwecken nicht eine rein theoretische Behandlung des Themas. Die Ergebnisse der Analyse sind stark praxisbezogen. Es ist zu untersuchen unter welchen Voraussetzungen die Wirkung von Patenten eingeschränkt sind und welche Auswirkungen solche Ausnahmeregelungen auf die Maker-Szene haben, um damit die kreativen Arbeiten der altruistisch motivierten Technikenthusiasten (Maker) unserer Zeit zu fördern.

In diesem Zusammenhang führt diese Dissertation das Konzept des Maker Movements in den patentrechtlichen Diskurs ein, und verwendet dieses Konzept als Basis für die vorgenomme Analyse.

Das Maker Movement bezeichnet ein Phänomen bzw. eine Massenbewegung von individuellen Entwickler – Maker - die in Technologiefeldern, wie Robotik, Elektronik und Elektrotechnik, hobbymäßig aktiv sind. Ihr technischer Hintergrund ist oft stark mit ihrem beruflichen Leben verknüpft und erlaubt es den Makern auch komplexe technische Probleme zu lösen und neue technische Ideen (Erfindungen) einzuführen. Diese Szene hat einen gewissen Verhaltenskodex etabliert. Zu dessen wichtigsten Eigenschaften (Standards) gehört die altruistische Verbreitung des Wissens und Know-Hows. Die Maker teilen ihre Erkenntnisse und ihr Wissen mit anderen; die Bewegung basiert auf einem intensiven Informationsaustausch.

Der Austausch an sich ist auf den ersten Blick nicht problematisch. Wenn man sich jedoch den spezifischen Inhalt mancher Entwicklungen ansieht, können Zweifel entstehen. Die verbreiteten Informationen betreffen meist die Art und Weise wie man eine Verbesserung einer bereits bestehenden Technologie erreichen kann. Dies kann insoweit kritisch werden, weil dies als Aufruf

zur Patentverletzung verstanden werden kann, auch wenn dies im privaten Umfeld, z.B. im Hobbyraum des Makers, auf nicht-kommerzieller Basis geschieht.

Die technische Affinität sowie die hohen technischen Fähigkeiten vieler Maker und die Qualität ihrer Projekte rücken die Maker ins juristische Umfeld des gewerblichen Rechtsschutzes. Zum einen sind deren Lösungen oft auch patentfähig, zum anderen kann deren Handeln in den Schutzbereich bestehender Rechte Dritter eingreifen.

Die Maker beschäftigen sich mit neuen Lösungen und Verbesserungen von bereits existierenden Produkten, die sie im täglichen Leben benutzen. Eine besondere patentrechtliche Gefahr entsteht wenn die Maker Ideen verbreiten welche entweder auf einer patentierten technischen Lehre beruhen oder ein patentiertes Bestandteil betreffen und dies verbessern.

Diese Dissertation betrachtet die Aktivitäten der Maker welche zum ersten ausschließlich einen nicht-kommerziellen Hintergrund haben und darüber hinaus in öffentlichen Maker-Foren vorgestellt/diskutiert werden.

Seit Jahren wird, oft auch scharf diskutiert, ob das Patentsystem seine Ziele zur Technologie- und Innovationförderung, wie ursprünglich proklamiert, immer noch erfüllt. Wenn man die gegenwärtige Patentlandschaft betrachtet, kann man den Eindruck gewinnen, dass das System vom damalig beschnitten Weg abgekommen ist. Patente werden heute nämlich oft nur noch als Business-Tool angesehen oder als Waffe gegen Mitbewerber eingesetzt.

Anders das Maker Movement welches eine alternative Trajektorie der technischen Entwicklung anstrebt, die auf den Prinzipien von „Open Sharing“ und Kooperation basiert.

Die ersten empirischen Untersuchungen zu diesem Thema, durch Prof. Eric von Hippel, deuteten darauf hin, dass in diesem Bereich ein großes wirtschaftliches und technisches Potenzial steckt, welches später auch große Firmen erkannt haben. Projekte wie LEGO Mindstorm oder der Einkauf von dem von Makern (RepRap Community) generierten 3D-Drucker "Makerbot" durch Stratasys beweisen, dass es sehr lohnend sein kann, in die Ergebnisse eines Maker-Projekts zu investieren. Gegenwärtig etablieren bereits große Firmen, wie Lenovo oder Huawei „Makerspaces“ (Werkstätten für Maker), um das Potenzial derer Ergebnisse früher erkennen zu können. Dennoch wird die Mehrheit makerischer Lösungen ohne Unterstützung von externen Unternehmen entwickelt.

In Anbetracht dessen konzentriert sich diese Arbeit auf die Frage, inwieweit die Maker-Szene erteilte Patent zu respektieren hat oder unter welchen Voraussetzungen sich diese im privilegierten, patentschutzfreien Raum bewegt.

Die unterliegende Hypothese setzt voraus, dass die Grundeigenschaften des Makings, d.h. die Gruppenarbeit und das Open Sharing, was hier freie und unbeschränkte Verbreitung von technischen Ideen bedeutet, tatsächlich gelebt wird und damit der Stand der Technik patentfrei weiterentwickelt wird. Die bestehenden Ausnahmeregelungen zum Patentschutz (Patentschranken, Patentbeschränkungen) können dieses Handeln aber aktuell nicht vollständig freistellen. Die Hypothese verlangte die grundlegende Analyse und das Würdigen der Ist-Situation, um dann im Anschluss die sich öffnenden Spielräume und Freiheitsgrade, insbesondere auch im internationalen Umfeld, beschreiben zu können.

Der Zweck der Patentbeschränkungen bleibt klar: Sie manifestieren einerseits wichtige Grenzen wo anderenfalls andere Rechtsgebiete oder Rechte Dritter unangemessen beeinträchtigt würden. Anderseits schützen sie ein relevantes öffentliches Interesse, wie dieses z.B. im Fall der experimentellen Benutzung einer Erfindung besteht.

Das Ziel dieser Dissertation ist somit nicht nur die rein rechtliche Analyse des Maker-Umfelds, sondern auch, falls notwendig, eine neue angepasste Form für eine Ausnahmeregelung, welche dem Geist des Maker Movement entgegenkommt, vorzuschlagen.

Als methodischer Ansatz wurde die Vergleichungsanalyse von Patentbeschränkungen gewählt und für vier Patentsysteme durchgeführt. Der Vergleich betrifft die Patentsysteme von Deutschland, Japan, Großbritannien und den Vereinigten Staaten von Amerika, die auf Grund ihrer patentrechtlichen aber auch wirtschaftlichen Relevanz, ausgewählt wurden.

Die vorgenommene Analyse bezieht sich größten Teils auf die materiellen Aspekte der untersuchten Rechtsinstrumente, wobei bewusst weniger Aufmerksamkeit auf die prozedurale Materie gelegt wurde. Als grundlegendes Muster für die Analyse dient der Katalog von Patentbeschränkungen nach dem Artikel 27 der Einheitspatentgericht-Vereinbarung. Die Analyse umfasst daneben auch das Vorbenutzungsrecht und den Zwangslizenz-Mechanismus, welche ebenfalls zu Einschränkungen von Patentrechten führen. Das deutsche Patentsystem dient als Referenz-System für rechtliche Doktrinen.

Ein Teil dieser Studie basiert auf einer empirischen Untersuchung in Form einer elektronischen Umfrage, die die Erfahrungen der Maker mit dem Patentrecht ermitteln soll. Die Umfrage zielte

explizit auf patentbezogene Hindernisse für Maker ab. Die Ergebnisse dieser Studie stellen die Basis sowie auch die empirische Begründung für das Projekt dar.

Kapitel 2. Einleitung und Beschreibung des Phänomens "Maker Movement"

Der Begriff das „Maker Movement“ ist relativ neu und aus der Zeitschrift „Make“, einer Maker-orientierten, populärwissenschaftlichen Zeitschrift entnommen, die im Jahr 2005 von Dale Dougherty gegründet wurde Der Beginn der Maker-Massenbewegung reicht jedoch bis in die 70-er Jahre des vorigen Jahrhunderts zurück.

Professor Eric von Hippel vom MIT hat die Entstehung der „neuen Innovationen-Quelle“ als Demokratisierung bezeichnet. Damit hat er die immer häufiger anzutreffende Technologieschaffung durch innovative Endverbraucher gemeint und als User Innovation bezeichnet. Im Rahmen seiner Untersuchungen beschreibt er die Aktivitäten der sich entfaltenden Maker-Bewegung als open-sharing (free-revealing) und kooperativ.

Seine Beobachtungen entstanden gerade zu der Zeit, als die Gesellschaft neu erarbeitetes Know-How als weiteren zentralen Punkt der Wertschöpfung anerkannt hat. Damals vollzogen die Gesellschaft und die Wirtschaft eine 180 Grad Drehung und „human capital“ bzw. „knowledge“ wurde ab dann als wesentliche Voraussetzung für eine Wertschöpfung erkannt. Dies führte auch zu Veränderungen im Verhältnis zwischen Hersteller und Verbraucher – Konzepte wie „co-creation“, „co-production“ haben sich erfolgreich am Markt etabliert, wobei Verbraucher als „Wertschöpfer“ und als „Ideen-Generator“ eingebunden werden.

Darüber hinaus führten enorme Fortschritte bei den IuK-Technologien dazu, dass der Informationsfluss immer weiter beschleunigt wurde. Der dadurch ermöglichte, intensive Informationsaustausch förderte die Entwicklung unserer Wissensgesellschaft und die Einbindung der Endverbraucher. Sogar die Punk-Kultur brachte erfinderische und kreative Menschen hervor und führte zu einer „do it yourself“-Kultur. Alvin Toffler, ein amerikanischer Schriftsteller und Futurist, hat dafür einen Hybride-Begriff, „Prosumer“, d.h. „a producer“ und „a consumer“ in einem, entwickelt.

Aus patentrechtlicher Sicht sind zwei Hauptaspekte für Maker besonders relevant: der Informationsaustausch (Open Sharing) und Zusammenarbeit. Darauf basiert die Kultur der Maker.

Organisatorisch gesehen arbeiten die Maker in unterschiedlichen kooperativen Formen: strukturierte Gruppen mit klaren und strikten Teilnahme-Bedingungen, aber auch lose

Zusammenschlüsse von erfinderischen Hobbyisten, die sowohl online als auch offline tätig sind. Die Informationen fließen zwischen den Gruppen und einzelnen Maker frei hin und her und bleiben offen für weitere Anregungen und Peer-Reviewing.

Hobbymäßige Beschäftigung kann sich aber auch in eine Einnahmen generierende Tätigkeit umwandeln. Maker sind, laut Studien und beobachteter Praxis, „accidental enterpreneurs“ („zufällige/ungeplannte Unternehmensgründer“). Grundsätzlich werden die Projekte nicht wegen einer Gewinnerwartung gestartet. Diese entsteht erst im Laufe eines Vorhabens, wenn sich die Aussichten auf eine mögliche kommerzielle Verwertung immer mehr abzeichnen. Die in den letzten Jahren verstärkt auftretenden Crowdfunding-Plattformen erleichtern dabei wesentlich den Zugang zu finanziellen Mitteln, welche für die Grundfinanzierung eines Maker Startups essentiell sind.

Erfolgreichen Maker-Projekte werden dann aber auch stärker mit patentrechtlichen Fragen konfrontiert. Ein Maker Projekt ist dann erfolgreich, wenn dieses zu einer populären, also viel diskutierten Lösung geführt hat oder mittels einer Crowdfunding-Kampagne finanziert werden konnte. Hierbei können erhebliche Summen eingesammelt werden, wie z.B. im Fall von FormLab, wo 1 Mio. US Dollar für einen Desktop 3D Drucker („From1“) eingeworben wurde.

Dieser Fall hat in den Medien viel Aufmerksamkeit gefunden, nachdem nicht nur FormLab, sondern auch die Crowdfunding-Plattform „Kickstarter“ von der Firma 3D Systems, wegen Patentverletzung, verklagt wurden. Die Auseinandersetzung wurde dann aber im Rahmen einer außergerichtlichen Einigung beendet.

Momentan beobachtet die Maker-Szene, mit angehaltenem Atem, die Entwicklung eines patentrechtlichen Streits zwischen Stratasys, einem großen 3D Drucker-Hersteller, und Afinia, einem mittelständischen Unternehmen, welches ebenfalls Desktop 3D Drucker anbietet. Die Maker sind dabei zweifach betroffen: 1) Stratasys hat eine aus der Maker-Community abstammende Firma (Projekt RepRap), MakerBot, gekauft und 2) Afinia wurde wegen der Benutzung einer weit verbreiteten Technologie verklagt, welche in der Community als freier Stand der Technik angesehen wird und deshalb von vielen Maker benutzt wird.

Kapitel 3. Maker im Umfeld des Patentsystems

Das 3. Kapitel setzt sich mit den Grundsätzen des Patentschutzes auseinander und thematisiert die Probleme der Maker im Rahmen des aktuellen Patentsystems.

Bewegen sie Maker auf einem mit Patenten geschütztem Gebiet, ergeben sich schnell viele Fragen zur Rechtsmäßigkeit ihres Handelns.

Die Tatsache, dass einige von Makern geführte Projekte die Aufmerksamkeit von Patentinhabern auf sich gezogen haben, reicht sicher nicht aus, um letztlich eine belastbare Grundlage für die Behauptung der fehlerhaften Funktionalität von Patentsystemen darzustellen. Schließlich ist es auch Zweck des Patentschutzes, im Fall einer Patentverletzung, dem Patentinhaber eine verlässliche Basis für die Durchsetzung seiner Rechte, zu bieten.

Die Ausweitung des Patentschutzes auf neue Gebiete wie Software und Biotechnologie wirft jedoch Schatten auf die Ziele des Patentsystems. So hat sich gezeigt, dass dies Einfluss auf die Qualität, d.h. den erfinderischen Abstand einer Neuentwicklung vom Stand der Technik, als auch die Patentierbarkeit von Lösungen insgesamt, nach sich gezogen hat.

Das Patentsystem wird von einigen als Patent-Industrie bezeichnet, die per analogiam Patente herstellt um diese dann, durch Lizenzierung oder Verkauf zu verwerten. Eine Antwort auf die Frage, ob man damit den technischen Fortschritt oder nur eine quantitative Steigerung von Patenten, z.B. für die Abwehr von Wettbewerbern, erreicht, ist nicht in allen Fällen leicht. Häufig gewinnt man aber doch den Eindruck, dass nur auf die Quantität und nicht auf die Qualität geachtet wird.

Für Maker ist das dreifach wichtig:

1) Es wird immer mehr patentiert und veröffentlicht. Es ist für eine Person fast unmöglich den gesamten Stand der Technik in einem Bereich zu recherchieren;
2) Bedingt durch immer enger werdende Schutzbereiche nähern sich die Patente dem Stand der Technik immer weiter an, und grenzen damit den patentfreien Spielraum für die Maker immer weiter ein;
3) Eine Auseinandersetzung mit dem Patentinhaber ist für eine Privatperson (Maker) aus finanziellen Gründen, trotz einiger „Erleichterungen“ wie inter partes-Review vor dem USPTO, fast unmöglich. De facto bleibt oft nur ein „working around“ übrig.

Spannungen zwischen den Makern und dem Patentsystem sind unvermeidbar: Während die Maker-Szene immer mehr Zulauf bekommt und immer komplexere Lösungen anbietet, bewirkt die steigende Patentdichte, zusätzlich verschärft durch ein immer breiteres Spektrum von Spezialformen technischer Schutzrechte, dass die Freiheitsgrade für makerisches Handeln, immer stärker eingeschränkt werden.

Die Kritik an den gegenwärtigen Bedingungen und den bestehenden Patentsystem bleibt unvollständig und möglicherweise dadurch fehlerhaft, wenn im Rahmen dieser Arbeit bewiesen

würde, dass die Patentbeschränkungen aktiv das Ungleichgewicht zwischen Patentinhabern und Makern reduziert, und damit Betätigungsfeld in ausreichendem Maß freigehalten wird.

Kapitel 4. Vergleichende Analyse von Patentbeschränkungen

Die Analyse folgt dem Katalog der Patentbeschränkungen gemäß Artikel 27 des Übereinkommens über ein Einheitliches Patentgericht. Darüber hinaus werden in dieser Arbeit die öffnenden Wirkungen des Vorbenutzungsrechts, des Patenterschöpfungsgrundsatzes, und der daraus resultierenden Doktrinen von „Reparatur und Neuherstellung“, sowie die Doktrinen von Nicht-äquivalenten Lösungen, als Verteidigungsmechanismen (Defence tools) gegen Verletzungsvorwürfe diskutiert.

Die Schlussfolgerungen zeigen, dass die heute existierenden "Öffnungsklauseln" im gewerblichen Rechtsschutz bezüglich den Ziele und Aktivitäten der Maker-Szene inkompatibel oder unzureichend sind. Die Ausnahmeregelungen haben sehr enge Anwendungsfelder, die lediglich einen kleinen Teil des Spektrums der Making Aktivitäten (Open Sharing, Veröffentlichung von patent-relevanten Informationen) decken bzw. zulassen.

So gilt es z.B. Freistellung, welche für Maker völlig irrelevant sind, wie z.B. die Benutzung von patentierten Gegenständen an Bord von Schiffen und für die Bedürfnisse des Schiffes, sowie für den Betrieb von Luft- und Landfahrzeugen. Gleiches gilt für Einzelzubereitung von Arzneimitteln, oder den Landwirtschaftsprivileg.

Als irrelevant wurden die Einschränkungen bezeichnet, die zwar Anwendungsgebiete betreffen, welche für Maker zwar zugänglich sind, diese aber nicht bearbeiten, wie z.B. im Fall von Interoperabilität-Vorschriften oder beim Bolar-Prinzip.

Die Mechanismen der Nicht-äquivalenz sind in der täglichen Making-Routine nicht hilfreich, weil sie erst im Patentverletzungsverfahren zur Anwendung kommen. Jedoch erst das Wissen über solche Rechtsinstrumente, erlaubt es den Makern sich mit Patenten intensiv zu beschäftigen und dem Aspekt der Äquivalenz angemessene Aufmerksamkeit zu schenken.

Vier Arten von Freistellungen begünstigen die Maker, wenn auch nur in einem begrenzten Rahmen. Dies vor allem deshalb, weil sie nur teilweise die Bedingungen, unter denen Maker arbeiten, berücksichtigen.

Die private und nicht-kommerzielle Benutzung setzt zwei eindeutigen Konditionen voraus, und zwar, dass die Benutzung nur für persönlichen Gebrauch erfolgt und daraus keine finanziellen

Vorteile resultieren. Streng genommen bedeutet das, dass die Maker anderen Maker die entwickelte Projekte nicht präsentieren dürfen. Da die Veröffentlichung einer von einem Maker generierten Idee auf einer Maker Plattform keine reine persönliche und private Benutzung darstellt, und damit eine Voraussetzung für eine Beschränkungen nicht vorliegt, auch wenn die Benutzung weiter nicht-kommerziell bleibt.

Da aber das Austauschen von Informationen über technische Aspekte, sowie die Veröffentlichungen möglicher weiterer Anwendungen einer Technologie essentielle Basis der Maker-Kultur ist, kann diese "Freistellung" ins Leere laufen.

Die Benutzung von patentierten Erfindungen für experimentelle Zwecke bietet einen größeren, wenn nicht den größten, Spielraum für die Maker. Versuche zur Eignungsprüfungen einer Erfindung oder zu deren Weiterentwicklung, dürfen Dritte, also auch Maker, ohne Erlaubnis des Rechtsinhabers durchführen.

Dabei ist wesentlich, dass diese Art der Freistellung (experimentelles Prinzip) nicht unter allen Rechtsordnungen identisch ist. So ist die amerikanische Doktrin sehr konservativ und streng: Sie erlaubt nur Handlungen, die der Befriedigung der wissenschaftlichen Neugier und/oder der Untersuchung der Erfindung dienen. Selbst Versuche mit minimal kommerziellem Charakter sind von der freistellenden Wirkung der experimentellen Benutzung ausgeschlossen. Die deutschen sowie die britischen Doktrinen erscheinen liberaler und „großzügiger“, da sie eine finanzielle Motivation hinter den Versuchen dulden können, solange die Versuche der Gewinnung von Erkenntnissen, bezüglich der Weiterentwicklung der Erfindung, dienen.

Die experimentelle Benutzung umfasst Messungen, das Reverse-Egineering und das Testen des patentierten Gegenstands. Die Herstellung an sich bleibt aber von der Freistellung ausgeschlossen.

In Bezug auf Maker klingt die experimentelle Benutzung plausibel und Maker-freundlich. Jedoch benötigt das Making an sich ein viel breiteres Spektrum an Aktivitäten, als die erlaubte experimentelle Benutzung. Making setzt das Mischen von Elementen, Ändern oder Ergänzen mit neuen Teilen voraus. Durch das Open Sharing können Änderungen in Folge der Veröffentlichung künftig weltweit durchgeführt werden.

Das Vorbenutzungsrecht wird selten herangezogen – das Risiko einer gerichtlichen Auseinandersetzung sowie die hohen Hürden bezüglich der Beweisführung, machen dieses Instrument eher unbeliebt.

Das Privileg der Vorbenutzung dient dem Schutz von gewerblichem und wirtschaftlichem Besitzstand, und verhindert die unbillige Vernichtung der vor der "gegnerischen" Patentanmeldung geschaffenen Werte und Gegenstände. Die vor dem Anmeldetag dieser Patentanmeldung erfolgten Arbeiten sollten sich dabei in einem fortgeschrittenen Vorbereitungsstadium befinden und auf die kommerzielle Verwertung abzielen.

In Bezug auf das Making, verhindern die folgenden Anforderungen des Vorbenutzungsrechts die wirksame Durchsetzung des Privilegs:

1) geheime Vorbereitungen zur Kommerzialisierung – das Making ist oft ein gemeinsames, öffentlich präsentiertes Vorhaben (entsprechend dem offiziellen Maker Manifest);
2) das Privileg wird national geregelt und erstreckt sich nur auf ein bestimmtes Unternehmen und Territorium, während Maker-Gruppen weltweit tätig sind. In Hinsicht darauf schränkt das Vorbenutzungsrecht die Patentexklusivität für die Maker Szene nicht ausreichend ein, um deren Aktivitäten zu unterstützen;
3) der kommerzielle Ansatz steht im krassen Widerspruch zur Philosophie der Maker-Szene.

Nach dem Reparaturprinzip werden solche Handlungen freigestellt, die das Ersetzen von abgenutzten bzw. gebrochenen Bestandteilen bezwecken, um die übliche Funktionalität des patentierten Objekts wieder herzustellen. Die Umsetzung dieser Definition gehört mit zu den größten Herausforderungen des Patentrechts: Es ist enorm wichtig die Grenze zwischen erlaubter Reparatur und rechtswidriger Wiederherstellung zu erkennen und zu respektieren. Die aktuelle Rechtsprechung lässt zwar gewisse Prinzipien erkennen. Dennoch verlangt deren Anwendung das detaillierte Analysieren des Handlungskontexts im Lichte der betroffenen Patente.

Gerade die wachsende Verfügbarkeit von Desktop 3D Druckern für Privatpersonen zwingt zu gründlicher Betrachtung vom sachlichen Umfang des Reparatur-Prinzips, insbesondere wenn gewisse Bestandteile bereits zu Hause hergestellt werden können.

Die Notwendigkeit des Prinzips im Patentsystem ist unbestritten; jedoch öffnet es in seiner jetzigen Form nur eine kleine Hintertür im Bollwerk des Patentschutzes. Um dieses Instrument rechtmäßig umsetzen zu können, bedarf es einer qualifizierten Analyse zum Schutzbereich, also was rechtlich geschützt ist, welche Teile zur technischen Lehre gehören und den Kern der patentierten Erfindung darstellen. Dies sind Fragen, die für Personen die mit dem Patentwesen nicht vertraut sind, nicht zu beantworten sind.

Kapitel 5. Die Zwangslizenz

Die Zwangslizenz (ZL) stellt ein weiteres Instrument zur Öffnung der Patentexklusivität dar und kann im Einzelfall von enormer Signifikanz sein. Diese Dissertation diskutiert die Mechanismen der ZL im Lichte des Making-Umfelds.

Das Instrument der Patentzwangslizenz (im Unterscheid zur kartellrechtlichen Zwangslizenz) gehört zu den dramatisten Rechtsinstrumenten, die das Patentsystem kennt. Es bezweckt die Einschränkung der Rechte eines Patentinhabers im Wege einer administrativen bzw. gerichtlichen Entscheidung (d.h. ohne Zustimmung des Patentinhabers). Dieser Eingriff erfolgt meist dann, wenn ein Missbrauch vorliegt oder wenn die vitalen Interessen der Öffentlichkeit beeinträchtigt werden. Eine ZL gesteht die Benutzung auch gegen den Willen eines Patentinhabers zu.

Das Instrument hat sich im Patentumfeld seit langem etabliert. Es wurde in der PVÜ, im Artikel 5.A.2 als eine Ausnahmeregelung zur Nicht-ausübung eines gewährten Patents, international eingerichtet. Die spätere Fortentwicklung der internationalen (und nationalen) Patentrechtsgrundlagen hat weitere Bedingungen und Umstände für die Zwangslizenz harmonisiert, z.B. erfolgloses Bemühen des Lizenzsuchers oder wettbewerbswidrige Handlungen des Rechtsinhabers.

Das TRIPS Übereinkommen legt die Hauptvoraussetzungen der Zwangslizenz fest. Durch die globale Harmonisierung der Zwangslizenz haben deren Gestaltung und Umsetzung weltweit ähnliche Formen angenommen. Unabhängig von den administrativen Unterschieden zwischen den Rechtsordnungen, die materiellen Hauptaspekte bleiben gleich, wie diese im dem TRIPS-Übereinkommen festgelegt wurden. Lediglich die USA erkennen die Patentzwangslizenz nicht an; es werden aber naheliegende Rechtsinstrumente für bestimmte Anwendungsbereiche konzipiert, wie z.B. die Zwangslizenz nach dem Luftverschmutzungsgesetz (Clean Air Act, 42 U.S.C. Chapter 85).

In der Praxis scheint die ZL nur auf internationaler Ebene von Bedeutung zu sein. Die Erteilung von nationalen Zwangslizenzen findet nämlich kaum statt: das umständliche Verfahren, die hohen Anforderungen bezüglich der Beweislast zur Gewährung eine ZL und der imense Aufwand den der Prozess selbst in Anspruch nimmt, führen dazu, dass die ZL ein „ungeliebtes“ Rechtsinstrument ist.

Auffallend ist dabei, dass die Zwangslizenzen meist die Herstellung bzw. den Vertrieb von Arzneimitteln in Entwicklungsländer betreffen.

Überdies wird jede Erteilung einer ZL sehr kontrovers und kritisch gesehen, auch wenn diese rechtmäßig und begründet ist, wie z.B. die ZL auf Bayer’s Nexavar für Natco Pharma im Jahr 2012.

Das Ergebnis der Analyse zeigt, dass die Zwangslizenz für die Maker von keinerlei praktischer Bedeutung ist.

Erstens, Maker gehören nicht zu den freiwilligen Lizenzsuchern, die an die Tür eines Patentinhabers klopfen würden. Auch sind die finanziellen Ressourcen der Maker sehr eingeschränkt, was eine Lizenznahme meist ausschließt. Es wird in dieser Dissertation zwar von einer Massenbewegung gesprochen, letztendlich aber arbeitet jede(r) Maker im eigenen Namen, auch wenn dies in Kooperation mit anderen Maker erfolgt. Maker benötigen für die Zwecke des Projekts auch häufig gemeinsame Ressourcen, aber grundsätzlich keine gemeinsame Lizenz, welche Lizenzgebühren mit sich bringen würde. Ein Projekt wird eher aufgegeben, als aufwändige Verhandlungen mit Patentinhabern (bzw. mit Lizenzinhabern) zu führen.

Diejenigen, die sich um eine ZL bemühen, haben geschäftliche und finanzielle Interessen im Rahmen einer gewerblichen Tätigkeit. Anderenfalls wäre das Bemühen um eine ZL unvernünftig und riskant. Zwar gibt es Maker, die erfolgreich eigene Ideen kommerzialisieren. Diese sind aber nicht Gegenstand dieser Dissertation, welche sich ausschließlich auf öffentliche (public) und nicht-kommerzielle Aktivitäten beschränkt.

Grundsätzlich ist jede Standardbedingung für eine Zwangslizenz in Bezug auf das Making abwegig. Die Hauptbedingungen für eine ZL, d.h. erfolgloses Bemühen eine Lizenz zu erhalten, kartellrechtliche Hintergründe oder öffentliches Interesse, sind im Umfeld der Maker Szene nicht einschlägig. Auch patentieren Maker selten ihre eigenen Ideen (entweder aus Kostengründen oder aus reiner Antipatent-Ideologie). Schon allein die Maker Grandphilosophie eliminiert den Aspekt des gefährdeten öffentlichen Interesses für die Einräumung einer Zwangslizenz, weil die "makerische" Ideen der Gesellschaft frei zu Verfügung gestellt werden.

Man darf auch nicht aus dem Blick verlieren, dass ZL selbst im wirtschaftlichen Umfeld nur sehr selten beantragt werden. Für Maker spielt dieses Instrument dann gar keine Rolle mehr.

Kaptiel 6. Greenlight für Maker

Der Vorschlag zur Etablierung eines Greenlights (GL) für Maker zielt auf die Freistellung von patentgeschützten Lösungen für die von öffentliche (public) und nicht-kommerzielle Benutzung ab. Es umfasst sowohl das Benutzen von geschützten Gegenständen (Prototyping, Making, Mixing), als auch das Open Sharing von Informationen und Anweisungen.

Es wurde gezeigt, dass die jeweiligen Ausnahmeregelungen an sehr stringente Bedingungen geknüpft sind und damit das Making nur teilweise unterstützen. Die gesetzmäßige Umsetzung verlangt umfassende Kenntnisse im Patentwesen, um sich im Making im gesetzlichen Rahmen bewegen zu können. Das kommt jedoch dem Geist der Maker Szene nicht entgegen und bietet darüberhinaus keine für Maker praktikable Lösung.

Als neuer rechtlicher Rahmen wird vorgeschlagen, dass genug freier Raum geschafft wird, ohne die kommerziellen Interessen der Patentinhaber zu beeinträchtigen.

Das GL-Konzept würde diese Forderungen erfüllen und hat die folgenden Eigenschaften:

1) Es ist intuitiv begreifbar, wie private und nicht-kommerzielle Benutzung (trotz vieler auch hier herrschender Missverständnisse);
2) Es ist nicht diskriminierend in Bezug auf ein Technologiefeld;
3) Es erlaubt Gemeinschaftsprojekte, welche zu den wichtigsten Aspekten beim Making gehören;
4) Es adressiert ausschließlich nicht-kommerzielle Benutzungen.

Nur Privatpersonen, d.h. Maker, die neue Lösungen entwickeln und dabei bereits patentierte Lösungen verbessern unterliegen dem Schutz des GL.

Das GL gilt wie eine Duldung des Patentinhabers Making-Aktivitäten durchzuführen. Es ist weder eine Lizenz in klassischem Sinne, noch eine administrative Entscheidung, die bestimmte Patente betrifft. Das GL funktioniert eher als „implied license“ und tritt im Moment der Offenbarung einer Idee, z.B. online als ein Forum-Post und gilt solange die Entwicklung und Benutzung keinen kommerziellen Charakter hat.

Das GL ergänzt den Wirkungsbereich der erlaubten privaten und nicht-kommerziellen, sowie auch der experimentellen Benutzung, welche zur Zeit fürs Making nicht ausreichend ist.

Der Vorschlag besteht aus zwei Teilen: dem rechtlichen Konzept und einer Datenbank für Maker Ideen.

Die GL-Datenbank (Greenbase) fasst die "makerischen" Ideen, die auf verschieden Maker Plattformen verstreut sind, zusammen. Die Veröffentlichung in der Datenbank wäre eine Voraussetzung, vor allem in der GL-Einführungsphase, um die Maker Lösungen unter dem Dach von GL freizustellen. Die Datenbank würde makerische Lösungen dokumentieren – unter Umständen auch eine Referenz für Patentprüfungsrecherchen darstellen – und damit auch einen durch Maker generierten Stand der Technik schaffen, um die Patentierung von nicht-erfinderischen und/oder nicht-neuen Lösungen zu verhindern.

Projektziel wäre es also auch diese Datenbank, als eine wichtige Quelle für Recherchen zum Stand der Technik, zu etablieren, welche dann auch eine wichtige Rolle im Rahmen der Patentprüfung durch die Patentämter spielen könnte.

Der Autorin ist es bewusst, dass der GL-Vorschlag sehr ambitioniert ist, und als unzulässig gesehen werden kann, da damit „erhebliche“ Einschränkung der Patentexklusivität verbunden wäre. Dies vor allem bei der gegenwärtigen Tendenz, den Kreis patentierbarer Technologie eher zu erweitern und die Rechte aus dem Patent zu verstärken. Es wird auch viel berichtet (beobachtet), dass sich die Patente sich nicht nur "horizontal" ausbreiten und so mehr Technologiefelder abdecken, sondern auch „vertikal“ und damit der erfinderische Abstand neuer Patente zum Stand der Technik immer kleiner wird, also der Grad des Erfindungsbeitrags absinkt.

In Hinblick darauf ist es zu beachten, dass das Patentsystem auch einen gewissen Freiraum für die Benutzung von patentierten Lösungen gewährleisten muss und sollte dies auch aktiv und nicht nur auf dem Papier tun, um seine Ziele in Hinblick auf die Förderung der Fortentwicklung des Stands der Technik erreichen zu können. Das Maker Movement ist ein gesellschaftlich und wirtschaftlich signifikantes Phänomen, das patentrechtliche Aufmerksamkeit verdient. Um dieses zu fördern, muss das Patentsystem in seiner jetzigen Gestalt, auch gegen den Willen des Patentinhabers, für Maker geöffnet werden.

Betonung verdient die Tatsache, dass die besprochene Notwendigkeit zur Öffnung der Patentexklusivität auch durch die niedrigere Patentqualität verursacht wird.

„Makers are champions of change“. Maker sind mehr als ein Verein von individuellen Erfindern, die sich mit Technologien hobby-mäßig beschäftigen. Das Making fördert die Leidenschaft an Wissen und Wissenschaften, kreiert langfristig neue Arbeitsplätze und unterstützt die Menschen dabei eigene Entwicklungswege zu beschreiten und die gefundenen Lösungen zu realisieren. Es entstehen Makerspaces in Kriegs- und Krisengebiete, wie in Gaza oder dem Nahen Osten. Die Bewegung hat starke pro-demokratische Auswirkungen: die Menschen werden ermutigt sich zu engagieren und fühlen sich verantwortlich für ihre Projekte und die Arbeitsgruppen. Der 18. Juni wurde in den USA als Nationaltag fürs Making proklamiert.

Kapitel 7. Schlussfolgerungen

Diese Dissertation hatte zweierlei Aufgaben:
1) Die Maker Bewegung in den patentrechtlichen Diskurs einzuführen und

2) Die Anwendbarkeit der bereits existierenden Patentbeschränkungen in Bezug auf die Maker Bewegung zu bewerten.

Besonders die Regelungen zur Beschneidung des Patentschutzes werden in der aktuellen Diskussion vernachlässigt und lediglich mit einer oberflächlichen Erklärung zum „Ausgleich der Interessen“ abgetan.

Selbst der Drei-Stufen-Test (Artikel 30, TRIPS) berücksichtigt die Interessen Dritter erst im letzten Schritt, was auf die Stellung in der Bedeutungshierarchie hinweist. Der Ruf nach Erteilung einer Zwangslizenz führt meist zu enormer Empörung.

Stets begegnet man der fantastischen, fast religiös anmutenden Behauptung, dass das bestehende Patentsystem die technische Entwicklung fördert und bereits leichte Einschränkung des Patentschutzes die ganze Industrie unzulässig bremsen würde.

Das was Maker leisten zeigt offensichtlich, dass eine technische Entwicklung auch ohne Patente und ohne finanzielle Belohnung und Marktexklusivität möglich ist. Die Bewegung beanstandet die klassischen Paradigmen der Innovationen und zeigt einen Weg, wie man Interessen anderer Menschen berücksichtigen kann, und sich dabei ethisch einwandfrei ihnen gegenüber verhält.

Das Making lenkt auch immer das Augenmerk auf die die Patentqualität, die momentan zum Haupt-Patentthema avisiert, und dabei viele weitere Makel des Patentsystems an die Oberfläche spült.

Die trivialen und schwachen Patente, die gleichen Schutz wie wesentliche Erfindungen gewähren, bremsen oft Entwicklungen Dritter, und fördern den sekundären Patentmarkt, wo Patente wie Güter gehandelt werden.

Es ist zu überlegen, ob durch eine höhere Patentqualität dieses Problem komplett eliminiert werden würde, weil es automatisch mehr nicht-erfinderischen Raum zur Verfügung stellen würde, in welchem sich Maker (und andere Benutzer) frei bewegen könnten.

Kritische Meinungen zum heutigen Patentsystem betreffen vor allem die Umsetzung, bzw. den Missbrauch in der Umsetzung, von gegebenen Instrumenten, die von vielen geduldet bzw. akzeptiert werden. Es wird vorgeschlagen das Patentsystem mit einer "Patentleft“-Option auszustatten, wie dies vergleichbar beim Urheberrecht geschehen ist. Ein "Patentleft"-Konzept bietet das Greenlight für die Maker Szene an.

Appendix

A. Survey on Makers and Patent Law

1. Introduction

The technological sophistication of makers, together with the prosperous growth of their projects, results in their exposure to patents. The results of this exposure can be twofold: makers may decide to patent their idea or, worse, receive a notification of alleged patent infringement. The latter may occur because making comprises of tinkering with and improving on existing patent-enclosing products, sharing information and/or instructing other makers how to achieve a presented solution.

The following questions underlie this survey: Do makers patent their solutions? Do they reach the point where a patent holder challenges their work, alleging patent infringement? These are the questions which are derived from the hypothesis of this project.

In regard to the second question, the media record only big cases, such as Stratasys v Afinia, leaving small-scale ones unnoticed. In effect, the need arises of investigating this matter directly by makers themselves via a survey posted in the makers' online communities. In terms of patenting, it was of interest to understand whether there is a desire to pursue patent protection, as patent office databases do not contain such information.

2. Method

a) General

The survey was posted on March 23, 2014, and was accessible until June 30, 2014. The invitations were posted in the following online communities: the RepRap Forum and the RepRap Forum Google+, Make Forum Google+, Make Hangar Google+, Makers, hackers, artists & engineers Google+, Arduino: Forum Google+, Raspberry Pi Google+, Makers – Electronics, Robotics, 3D Printing & More Google+. Reminders were sent out every 3 weeks.

The general population of the survey can be estimated at the level of more than 300.000 members (by adding up the numbers of members registered in the named communities). However, it cannot be excluded that a person can belong to more than one community (like the author herself).

In light of the above, the answer ratio of 94 participants (who completed the survey) looks rather modest; nonetheless, it allows for indicating certain tendencies and provides the required evidence in support of the hypothesis.

b) Selection of Communities

The selection of communities represented a real challenge. Google+, which is the main source of makers' communities, provides an infinite number of groups, with new groups emerging constantly. Therefore, the focus rests on classic examples of makers' groups, like RepRap and MAKE magazine, Arduino, Raspberry Pi, and Adafruit Industries. One community, "Makers-Electronics, Robotics, 3D printing & More", was selected since it directly pertains to makers.

The target groups for the survey were selected according to the following criteria:

a) the community should have a voluntary/discretionary and open character,

b) it should not be supported by any company (e.g. Mindstorms by Lego), unless created around a company established by a maker (e.g. Adafruit)

c) it should be technology-related.

c) The Questionnaire

The questionnaire comprised of four parts, each beginning with an explanatory introduction.

In the first part, respondents were asked about the way they innovate: whether in a community or individually, and if so, whether they share their ideas with others. The second part concerned their experience in commercializing their solutions: whether the process is conducted in cooperation with a manufacturer or individually; and which features determined the attractiveness of the innovation for the market.

The third part constituted the core of the questionnaire. It first asked about the obstacles that the respondents are faced with in the course of innovating; it also measured their experience in patenting and asked about their reasons for filling a patent application or refraining to do so. This part queried in detail whether the respondents have been notified of alleged patent infringement, what was the cause of the claim, its outcome, and the country the situation took place in.

The fourth part referred to the technological background of the respondents' activities as makers: the industry sector, the type of innovation, country, and years of experience.

The questionnaire was anonymous. It consisted of binary questions and was designed to measure the frequencies of asked occurrences.

d) Preparation

The launch of the survey in March 2014 was the second attempt at holding a survey that was prepared in 2012. The first launch of the survey took place in November 2012 and lasted until May 2013, when it was discontinued due to a low answer rate (55 completed/110 opened). For that reason, the first attempt was considered as a test run and the collected answers were not taken into account in the current study.

Three groups were identified as target groups – the RepRap Community, the readers of MAKE magazine and the alumni of JugendForscht[960].

The questionnaire was distributed via invitations posted on community forums, Facebook profiles, and Google+ groups (after the kind recommendation of the MAKE magazine). Initially, the reminders were sent out after the first two weeks; and later – at approximately one-month intervals.

The preliminary analysis was posted on the websites of the inquired communities. The obtained results and the overall progress of the project stimulated and motivated the re-launch of the survey, which was later appended with questions measuring the makers' experience in patenting.

Prior to the first launch, the questionnaire was pre-tested and distributed among:

1) the colleagues in the Fraunhofer-Gesellschaft,
2) invitations posted on RepRap and the MAKE magazine forum.

Respondents were asked to provide feedback on the comprehensibility of the questionnaire. Consequently, several changes were included to improve the clarity of questions.

The preparation and the conduct of this survey illustrates the maker approach of *learning by doing*.

[960] "Stiftung Jugend Forscht e. V.," http://www.jugend-forscht.de, accessed 16.10.2014.

3. Results Analysis

The questionnaire was opened 162 times and completed in 94 cases; however, in 10 cases, some answers in the last fourth part (technological background) were omitted. This situation happened despite the existence of a function which disallowed leaving the question unanswered. In such cases, the questionnaire was dropped, while the answers were nonetheless included in the analysis. Below is the quantitative description of the results:

Part 1 – How Do You Make?

This part pertained to the way the respondents were engaged in making activities.

Table 1. Classification of making activities, n=94 (100%)

How do you innovate?	
in a community	63 (67%)
Individually	31 (33%)

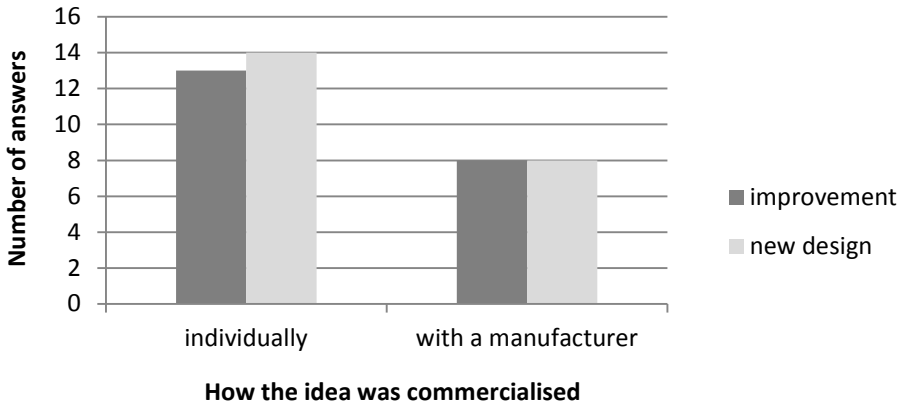
In the community group, active contributors, i.e. community innovators, dominated over helpers who assisted in the communities' workings (42 to 21 answers). Among individual makers, only eight respondents declared to work individually and to maintain their solutions for personal use only. The majority (25 respondents) shared their idea with friends or other enthusiasts with whom they continue to develop the idea or to whom they deliver the results (a finished product).

Part 2 – Have You Ever Commercialized?

The survey revealed that 26 respondents (27.7%; n=94, 100%) had experience in the commercialization of their developments; more new designs (19 answers) then improvements (15 answers) became marketable products.

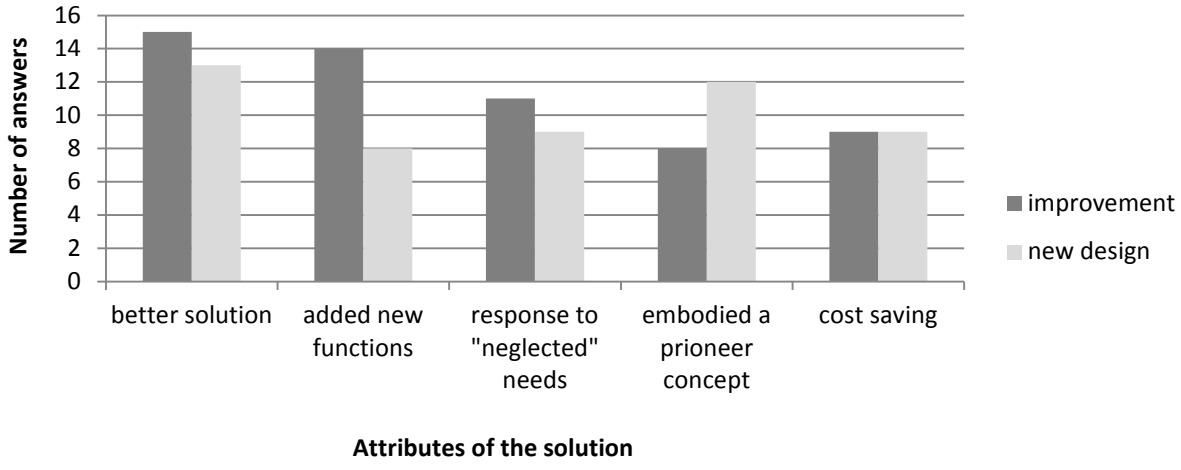
The prevalence of the respondents carried out the process individually, with no support from manufacturers (Chart 1).

Chart 1. Descriptive characteristics of how the solution was commercialized, n=26, multiple choice



In terms of features that spoke in favour of the marketization, the survey recorded strong differences between the two types of solutions in two variables: 1) a pioneer solution, 2) additional new functions – exactly as it was assumed. However, in other variables, the distinction between the two types was not so pronounced (Chart 2).

Chart 2. Classification of the attributes of marketed solutions, n=26, multiple choice



Part 3 – Experience With Patent Law

In terms of patenting, only twelve respondents (12.8%; n=94, 100%) claimed to have applied for a patent, with the following outcomes: the patent was granted (3 answers), the application is still pending (5 answers), and the application was rejected (4 answers). The reasons underlying their decisions are ranked as follows (Table 2).

Table 2. Reasons for patenting the solution, n=12, multiple choice

Why have you decided to apply for a patent?	
I wanted to monetize my investment and license my invention	6
I decided to start a company and wanted to protect my invention	2
The manufacturer I work with insisted on patent protection	2
Other: As proof that I had contributed Protect from competition	2

There is a strong correlation between commercialization pursuits and patenting: eight respondents who considered applying for patent protection also marketed their solutions.[961]

The prevalence of participants, 82 respondents (87.8%; n=94, 100%), did not apply for a patent, indicating the following reasons (Table 3).

Table 3. Reasons for not patenting, n=82, multiple choice

Why have you refrained from patenting?	
High patenting costs	39
It was not necessary	31
The invention would not meet the patentability criteria	20
Other:	26

[961] p =.0056, McNemar's test, p =.002 Fischer's exact test.

The option "other" allowed the respondents to provide a different reason for non-patenting, with the majority using this possibility to manifest their opinions on the patent system.

The given answers can be clustered in the following way:

1) disregard for the patent system and the support of (involvement in) open source projects (20 answers), including the following examples:
   - *Because part of why we are doing it is for it to be FREE and open for everyone*
   - *I am an open source advocate*
   - *I believe the patent and copyright rules have expanded to a ludicrous degree and do more to stifle innovation than they ever have done to promote it. I find the whole system reprehensible and actively avoid participating in it.*
   - *I/we do not like the idea of not sharing*
   - *My ideas should be open for all*
   - *Patenting is the antithesis of my world view*

2) diverse, ranging from state regulations and support to patenting the idea by a third party (6 answers):
   - *complicated patenting process*
   - *I live in Iraq. The amount of support that you get here is zer*
   - *my projects are at too early stage for consider patenting, but I'll think to do it later*
   - *No funds to defend the patent. Considerable efforts required to apply for a paten.*
   - *To generate prior art*
   - *When I researched my idea, someone had already patented something similar*

In terms of legal support, the low ratio of patents might be possibly explained by the low degree of legal assistance obtained by respondents (Table 4).

Table 4. Legal assistance, n=94 (100%)

Do you receive any legal assistance?	
Yes	20 (21.3%)
No	74 (78.7%)

The next variable pertained to obstacles the respondents meet in their making activities. Fifty two respondents (55.3%; n=94, 100%) admitted to experiencing various challenges, whereas 42 (44.7%; n=94, 100%) declared that they do not face any difficulties in making.

Those who confirmed facing difficulties were further asked to name the obstacles that impede their workings. The answers are ranked as follows (Table 5).

Table 5. Classification of obstacles, n=52, multiple choice

Could you name those obstacles?	
Limited access to resources and markets	35
Legal barriers, like patents, copyright restrictions	28
Organisational barriers	18
Dominant standards and high switching costs	15
Increasing technological complexity	13
Other:	15

Under the option "other," the respondents provided various interesting answers, which summarized as follows:

- *lack of time to develop ideas and funds to implement them*
- *isolation, i.e. no friends with similar interests, hence participation in an online community*
- *unfair treatment of open source: companies market and sell open-source innovations from other people without providing credit, and ultimately out-compete the original developers*
- *overall social inertia - aggressive marketing that deeply conditions consumers*
- *inability to access businesses to be heard*
- *red tape and state barriers; lack of information (lack of white papers or wiring diagrams)*
- *legal intimidation by companies that makers feel might be detrimental to their bottom line (rightly or not)*
- *trade secrecy*
- *the way the market is shaped and how it works*
- *the company owns all ideas*

The questions which formed the core of the survey referred to the makers' experience with allegations of patent infringement. The assumption was that due to the advanced character of making, some makers were perhaps targeted by patent holders assuming patent infringement based on public use or commercialization. Only six respondents (6.5%; n=94, 100%) confirmed being involved in such situations; however, four claimed that it happened more than once (mean = 7.75, median=4, n=4). Table 6 presents detailed characteristics of the cases.

Table 6. Descriptive characteristics of patent infringement claims, n=6, multiple choice

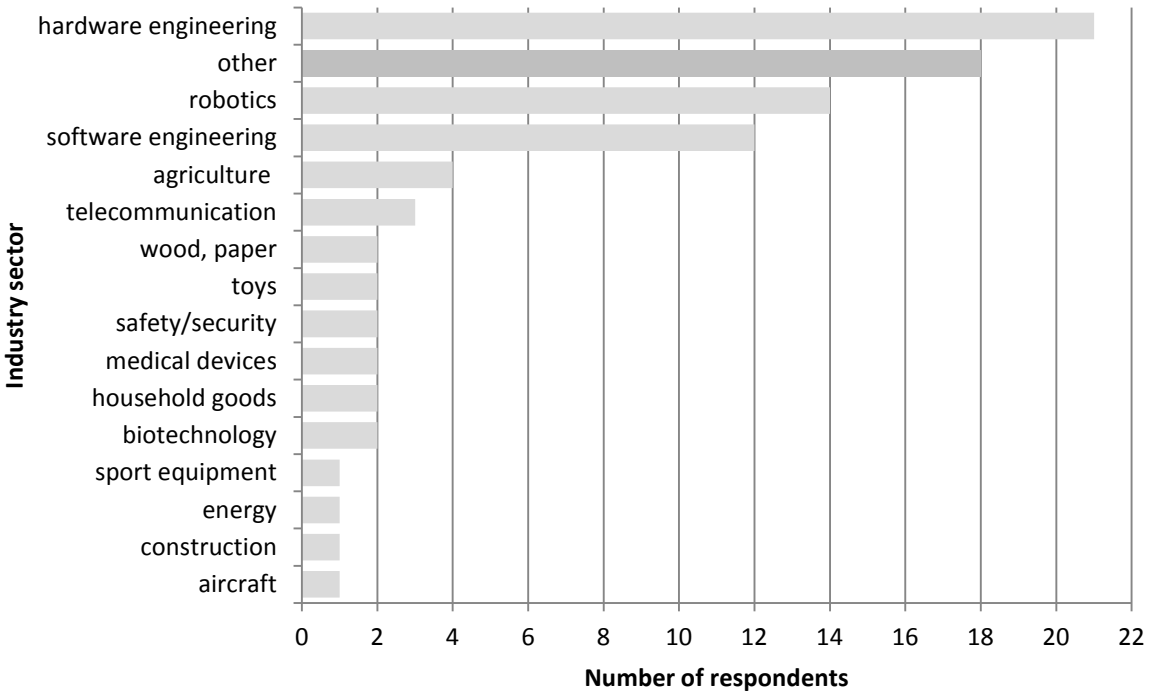
Variable	Number of answers
What type of innovation was involved?	
improvement	3
new design	5
What triggered the reaction of the patent holder?	
breach of the license agreement	0
sharing the innovation with others	3
market entry, commercialization	2
patent infringement	2
other	2
▪ *in one case, requesting information*	
▪ *patent trolling everyone in the industry*	
What was the outcome?	
settlement	1
license agreement	1
court proceeding	1
launch of a cooperation	0
other	3
▪ *re-design to avoid conflict*	
▪ *no pursued legal action (i.e. no legal grounds)*	
▪ *work stopped*	
Who was the rightsholder?	
A big company	4
A medium-sized company	0
A small company	1
An individual inventor	1

The patent holders signalized about the infringement either informally (3 answers) or via a formal letter (written notification) (4 answers). All of the recorded cases took place in the USA, with one answer also referring to Japan.

Part 4 – Technological Background

The respondents were active in various fields, predominantly hardware engineering (Chart 3).

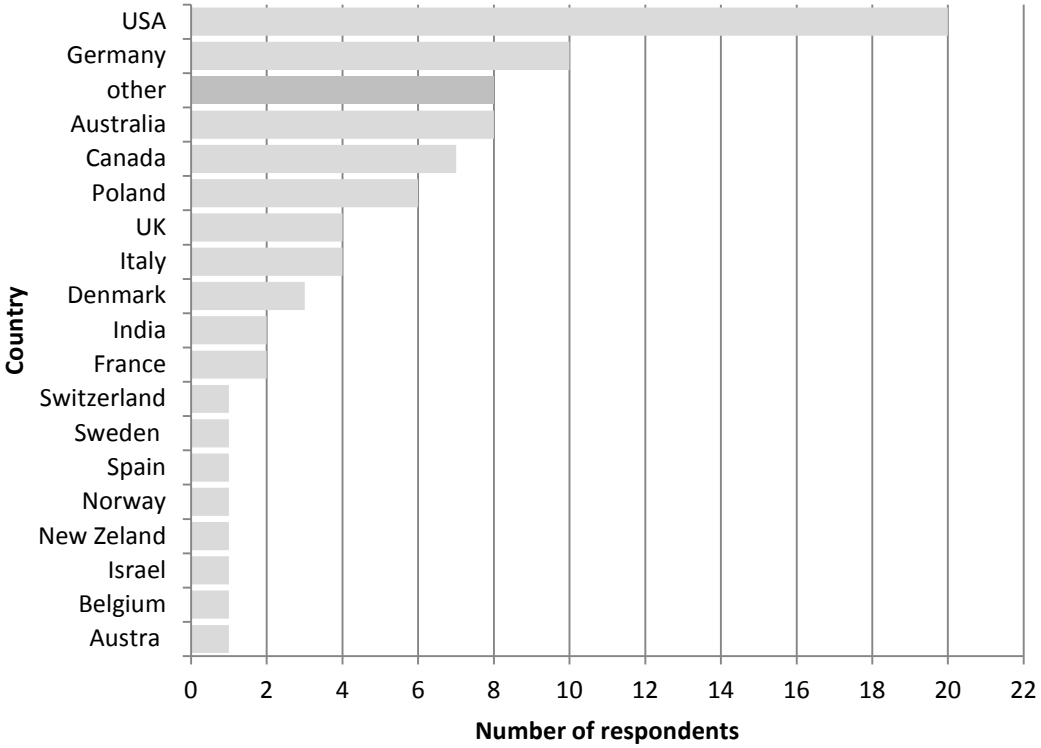
Chart 3. Technology sector, n=88 (100%)



Under the category "other," respondents named mainly 3D printing and a combination of software and hardware, including robotics. Further entries included Arduino, defense, but also “Education, Practical approach & methodology of team play in the US vs Europe in the sport of soccer.” The provided answers pointed to the intersectional character of workings, which could not be clearly assigned to a single sector.

The respondents represented various countries, with a prevalence of American makers (Chart 4.).

Chart 4. Country of *making*, n=84 (100%)



other	
Argentina	*1*
Iraq	*1*
EU	*1*
Online	*1*
Pakistan	*1*
Saudi Arabia	*1*
the milky way	*1*
US and EU	*1*

The respondent group was very diverse in regard to years of experience in making: starting from very young makers (one year in the movement) to very experienced makers with 40 years in the movement.

Last but not least, the respondents were asked about the project they worked on. The answers demonstrated the richness of ideas and the high level of skills dedicated to the projects. In fact, the question did not reveal anything new about makers and their skills – rather, it confirmed the previous assumptions about their remarkable contributions and proved that the questionnaire reached actual makers.

Below are some of the hard-to-narrow-down examples (with their original spelling):

- *3D Printer, Machine tool, CNC Robotics*
- *graffiti honeypot – spatial RF sensor – handheld document processing*
- *Motion controller for handicaped and able bodied*
- *Simple microcontroller based toys and gadgets*
- *Power on arduino système thrue housse electric network*
- *high power devices driver*
- *Simple devices or robots for households*
- *instrument to measure coffee cherry fermentation in Africa, automation for domestic chicken keeping*
- *Accelerometer-based free-form persistence of vision gadget*
- *Aircraft Design*
- *Needle driver, IV port, and a wound dressing*
- *navigation system, stroller, 3D printer, scientific instrument to measure*
- *Artificial muscle*
- *drills vs open competition structured practices as age approaches adolescence and vs. no practice all games and pick up games every games has outside referee sorce (US) vs. all games are self refereed (EU)*
- *Micro controller monitored chicken coop and greenhouse.*
- *Sentry gun 'rail guns autonomous flyng veachels*
- *Micro CHP system, Net zero greenhouse design, Ionic precipitator for biomass systems*
- *Personal flight instrument. Household control. Electronic educational toys.*
- *Hexapod*
- *Microprocessor based speaker protection, based on waveform analysis.*
- *some entstop-triggers for 3dPrinting a device that keeps headphone cords from tangling*
- *Biofeedback devices*

4. Discussion

The survey found and proved that makers can be targeted by patent holders. All respondents who declared to have received an infringement warning were active and innovating members of maker communities. This confirmed the assumption that public sharing within a group might expose a maker to the peril of infringement allegations.

Furthermore, the survey indicated that patenting, though not much common, takes place when the worked solution gains a marketable form and becomes commercialized.

It also revealed a negative attitude toward the patent system according to the credo of making: *you make, you share*. Though at the same time, it showed that what deterred respondents from filing a patent application to a large degree were high patenting costs. There is nothing wrong in patenting inventions; patents offer a good opportunity to recoup the investment and to earn a living. Some makers who patent their solutions, like William Steele, openly declare that they license their solutions in order to license them to commercial companies, while keeping the data (source code

and designs) open for hacking and making.[962] Such conduct blends together two approaches: an idealistic approach of making and sharing and a pragmatic approach of monetisation.

At this point, it must be stressed that the survey does not claim to reveal the prevailing opinions among makers. As the maker community is enormous and the answer ratio of this survey modest, the survey discloses indications of certain occurrences. It suggests that the investigated matters are not indifferent to makers.

The significance of the questions on the technological background of makers diminished with the growing overall comprehension of the maker movement and the progress of the research. The underlying questions and the hypothesis of the project were based on the notion of user innovation. At the time of the preparation of the questionnaire, the studied literature did not indicate that the projects of end users were characterized by high technological input[963] with the exception of communities set up by companies, but these were not the target group of this project. For that reason, technological questions were added to the survey to prove the assumed high technical affinity of makers (originally user innovators). As mentioned above, currently, due to increased media presence and various public events, the technological characteristics of the maker movement do not require any further research or a deeper presentation. Likewise, the section of the survey on commercialization set out to prove that makers deliver commercially successful solutions.

In conclusion, the survey was intended to gather information on the makers' experience with patents and to collect opinions on the protection system. The relaunch of the study was aimed at generating a higher answer ratio, which nonetheless remains modest when compared with the general population of makers (which is constantly growing). In other words, the results are not representative for the whole community. Nevertheless, the assumptions that makers have reached the level of patentable solutions and that they have attracted the interest of patent holders cannot be rejected, which provides the empirical groundwork for this project.

A great added value of the survey was the opportunity to enter maker and hacker communities, to learn their opinions on patents, their projects, and their aspirations; with the project culminating in a presentation during the Chaos Communication Congress in 2014.

---

962 "Ultra-Bot 3D Printer by William Steele. Questions about Open Source and our Patent Application." "Ultra-Bot 3D Printer by William Steele. Questions about Open Source and our Patent Application."

963 The open source communities, like Linux or Apache, without undermining the skills of programmers and hackers, were not the desired examples of user innovations, since the object of their works pertained to copyright protection. The sought communities and users were to be involved into high-tech tangibles: (self-) hand-made and -changed products.

B. Abbreviations

3D printing	Three-dimensional printing
AIA	America Invents Act
CJEU	Court of Justice for the European Union
CL	Compulsory license/compulsory licensing
DIY	Do-it-yourself
DoE	Doctrine of Equivalents
ECJ	European Court of Justice
EPC	European Patent Convention
EPO	European Patent Office
EU	European Union
IC	Integrated circuits
JPA	Japan Patent Act
JPO	Japan Patent Office
NPE	Non-practicing entity
PAE	Patent assertion entity
patCL	Patent compulsory license/patent compulsory licensing
R&D	Research and development
RDoE	Reverse doctrine of equivalents
TEC	Treaty establishing the European Community
TFEU	Treaty of functioning of the European Union
TRIPS	Agreement on the Trade-related Aspects of Intellectual Property Rights
UK IPO	United Kingdom Intellectual Property Office
UPC Agreement	Agreement on a Unified Patent Court
UPC	Unified Patent Court
U.S.C.	United States Code
USPTO	United States Patent and Trademark Office
WIPO	World Intellectual Property Organisation
FDM	Fused deposition modelling
i.e.	*Id es* (that is)
e.g.	*Exempli gratia* (for example)
ibid.	*Ibidem* (in the same place)
EEA	European Economic Area
PCT	Patent Cooperation Treaty

C. Literature

1. Journal Articles, Books, Electronic Articles

Allarakhia, Minna, and Walsh Steven. "Managing Knowledge Assets under Conditions of Radical Changes: The Case of the Pharamceutical Industry." *Technovation* 31 (2011): 105-17.

Allen, Robert C. "Collective Invention." *Journal of Economic Behavior & Organization* 4, no. 1 (1983): 1-24.

Allison, John, and Mark Lemley. "The (Unnoticed) Demise of the Doctrine of Equivalents." *Stanford Law Review* 59, no. 4 (2007): 955-84.

Anderson, Jonas. "Hiding Behind Nationality: The Temporary Presence Exception and Patent Infringement Avoidance." *Mich. Telecomm. & Tech. L. Rev.* 15 (2008): 1-51.

Antonio, Robert, and Alessandro Bonanno. "A New Global Capitalism? From "Americanism and Fordism" to "Americanization-Globalization"." *American Studies* 41, no. 2/3 (2000): 33-77.

Armitage, Edward. "The New British Patent Legislation." *IIC* (1978): 207.

Arora, Ashish. "Patents, Licensing, and Market Structure in the Chemical Industry." *Research Policy* 26, no. 4-5 (1997): 391-403.

Atkinson, Richard. "Public Sector Collaboration for Agricultural IP Management." *Science* 301, no. 5630 (2003): 174-75.

Attaran, A., and L. Gillespie-White. "Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment an Africa?". *JAMA* 286, no. 15 (2001): 1886-92.

Badham, Richard. "Post-Industrial Society." *Current Sociology* 32, no. 1 (1984): 55-65.

Bagozzi, Richard, and Paul Warshaw. "Trying to Consume." *Journal of Consumer Research* 17, no. 2 (1990): 127-40.

Baker, Scott, and Claudio Mezzetti. "Disclosure as a Strategy in the Patent Race." *Journal of Law and Economics* 48, no. 1 (2005): 173-94.

Baldwin, Carliss, Christoph Hienerth, and Eric von Hippel. "How User Innovations Become Commercial Products: A Theoretical Investigation and Case Study." *Research Policy* 35, no. 9 (2006): 1291-313.

Barton, John. "Reforming the Patent System." *Science* 287, no. 5460 (2000): 1933-34.

Beall, R., and R. Kuhn. "Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis." *PLoS Med* 9, no. 1 (2012).

Bee, Richard. "Experimental Use and an Act of Patent Infringement." *J. Pat. Off. Soc'y* 39, no. 5 (1957): 357-77.

Beier, Friedrich-Karl. "Ausschließlichkeit, gesetzliche Lizenzen und Zwangslizenzen im Patent- und Musterrecht." *GRUR* (1998): 185-95.

Benkard, Georg, and Editors. *Patentgesetz*. 10 ed. München: C.H. Beck, 2006.

Bently, Lionel, and Brad Sherman. "Limiting Patents." In *Compulsory Licensing. Practical Experiences and Ways Forward*, edited by Reto M. Hilty and Kung-Chung Liu, 313-31. Berlin Heidelberg: Springer, 2014.

Berman, Bruce. "Towards a Working Definition of Patent Quality." *Intellectual Asset Management* (May/June 2015): 39.

Bernhardt, Wolfgang. *Die Bedeutung des Patentschutzes in der Industriegesellschaft*. Köln: Heymann, 1974.

Bettencourt, Lance, Amy Ostrom, Stephen Brown, and Robert Roundtree. "Client Co-Production in Knowledge-Intensive Business Services." *California Management Review* 44, no. 4 (Summer2002 2002): 100-28.

Binyāmînî, Ammîrām. *Patent Infringement in the European Community*. Weinheim VCH, 1993.

Blakeney, Michael. *Trade Related Aspects of Intellectual Property Rights: A Concise Guide to the TRIPs Agreement*. London: Sweet & Maxwell, 1996.

Boettinger, Sara, and Dan L. Burk. "Open Source Patenting." *JIBL* 1 (2004): 221-31.

Bogers, Marcel, Allan Afuah, and Bettina Bastian. "Users as Innovators: A Review, Critique, and Future Research Directions." *Journal of Management* 36, no. 4 (2010): 857-75.

Boldrin, Michele, and David Levine. *Against Intellectual Monopoly*. Cambridge, Mass.: Cambridge University Press, 2010.

Borowiak, Craig. "Farmer's Rights: Intellectual Property Regies and the Struggle over Seeds." *Politics and Society* 32, no. 4 (2004): 511-43.

Bozicevic, Karl. "The Reverse Doctrine of Equivalents in the World of Reverse Transcriptase." *J. Pat. & Trademark Off. Soc'y* 71, no. 353 (1989).

Brandi-Dohrn, Matthias. "Some Critical Observations on Competence and Procedure of the Unified Patent Court." *IIC* (2012): 372-89.

Braun, Viktor, and Cornelius Herstatt. *User-Innovation. Barriers to Democratization and IP Licensing*. New York: Routledge, 2009.

Buanec, Bernard Le. "Protection of Plant-Related Innovations: Evolution and Current Discussion." *World Patent Information* 28 (2006): 50-62.

Buhring, Manfred. *Gerbrauchsmustergesetz*. 8 ed. Koln: Cark Heymanns Verlag, 2011.

Burk, Dan L., and Mark M. Lemley. *The Patent Crisis and How the Courts Can Solve It*. Chicago: University of Chicago Press, 2009.

Burton-Jones, Alan. *Knowledge Capitalism. Business, Work, and Learning in the New Economy* Oxford: Oxford University Press, 2004.

Busche, Jan. "Das Vorbenutzungsrecht im Rahmen des deutschen und europaischen Patantrechts." *GRUR* (1999): 645-48.

Busse, Rudolf. *Patentgesetz*. Berlin: de Gruyter, 2013.

Buth, Marcel A. *3D Printer: Patents and Innovations*. 1. English ed. Usingen: adrenalinemedia, 2013.

Callens, Pieter, and Sam Granata. *Introduction to the Unitary Patent and the Unified Patent Court. The (Draft) Rules of Procedure of the Unified Patent Court*. The Netherlands: Kluwer Law International, 2013.

Carlin, John, and Colin Cabral. "Hatch-Waxman Safe Harbor Construed in 'Merck v. Integra'." *New York Law Journal* 234, no. 5 (2005).

Chernoff, Michael. "Patent Kings- the Dominat Players in the US Patent Landscape." *IAM Magazine* (May/June 2015): 49-53.

Christensen, Clayton, Scott Cook, and Taddy Hall. "Marketing Malpractice: The Cause and the Cure." *Harvard business review* 83, no. 12 (2005): 74.

Chrocziel, Peter. "Zulassungshandlungen mit patentierten Arzneimttelerfindungen durch Zweitanmelder in der Bundesrepublik Deutschland und den USA." *GRUR Int.* (1984): 735 - 40.

Cohen, Lizabeth. "A Consumers' Republic: The Politics of Mass Consumption in Postwar America." *Journal of Consumer Research* 31 (2004).

———. *A Consumers' Republic: The Politics of Mass Consumption in Postwar America*. New York: Knopf, 2003.

Cohen, Seth A. "To Innovate or not to Innovate, That is the Question: The Functions, Failures, and Foibles af the Reward Function Theory of Patent Law in Relation To Computer Software Platforms." *Mich. Telecomm. & Tech. L. Rev.* 5 (1998): 1-34.

Cohen, Wesley M., Richard R. Nelson, and John P. Walsh. "Protecting Their Intellectual Assets: Appropriability Conditions and Why Us Manufacturing Firms Patent (or not)." 1-50: National Bureau of Economic Research 2000.

Cohen, William E. "Competition and Foreclosure in the Context of Installed Base and Compatibility Effects." *Antitrust Law Journal* 64, no. 3 (1996): 535-70.

Comor, Edward. "Contextualizing and Critiquing the Fantastic Prosumer: Power, Alienation and Hegemony." *Critial Sociology* 37, no. 3 (2011): 309-27/ 1-19.

Cornish, William, David Llewelyn, and Tanya Alpin. *Intellectual Property: Patents, Copyright, Trade Marks And Allied Rights*. 7 ed. London: Sweet & Maxwell, 2010.

Correa, Carlos M. "The Role of Intellectual Property Rights in Global Economic Governance " In *Initiative for Policy Dialogue Working Paper Series* New York Initiative for Policy Dialogue, 2011.

Crommelin, Daan, Teresa Bermejo, Marco Bissig, Jaak Damiaans, Irene Krämer, Patrick Rambourg, G Sctoccaro, B Strukelj, and Roger Tredree. "Pharmaceutical Evaluation of Biosimilars: Important Differences from Generic Low-Molecular-Weight Pharmaceuticals." *Eur J Hosp Pharm Sci* 11, no. 1 (2005): 11-7.

Dahmann, Gerd. *Patentwesen, technischer Fortschritt und Wettbewerb. Formulierung einer empirisch prüfbaren Patenttheorie und Bewährungstest am Beispiel der Rasiergeräteindustrie*. Frankfurt a. M., Bern: Peter D. Lang, 1981.

Daum, Juergen. *Intangible Assets and Value Creation*. England: John Wiley & Sons Ltd., 2003.

Davis, Michael. "Excluding Patentability of THerapeutic Methods, including Methods Using Pharmaceuticals, for the Treatment of Humans under Trade Related Aspects of Intellectual Property Rights Article 27(3)(A)." *Hofstra L. Rev.*, no. 43 (2014-2015): 185-206.

Deighton, John. "The Consumption of Performance." *Journal of Consumer Research* 19, no. 3 (1992): 362-72.

Denicolò, Vincenzo, and Luigi Alberto Franzoni. "The Contract Theory of Patents." *International Review of Law and Economics* 23, no. 4 (2003): 365-80.

Dent, Chris. "The TRIPS Agreement and an Experimental Use Exception for 'Research Tools'." *Australian Economic Review* 44, no. 1 (2011): 73-78.

Dewar, Robert, and Jane Dutton. "The Adoption of Radical and Incremental Innovations: An Empirical Analysis." *Management Science* 32, no. 11 (1986): 1422-33.

Dinaut, Nicole, and Stephanie White. "Experimental Use or Infringement? Location Matters." *Intellectual Asset Management*, no. 59 (July/August 2013): 113-16.

Doi, Etuso. "U.S. Supreme Court Judgment on Patent Exhaustion Rendered - A Comparative Overwiev with Japanese Patent Law - Quanta Computer, Inc. v. LG Electronics, Inc.". *Patents and Licensing* (Jun 2008): 34-37.

Doi, Teruo. *The Intellectual Property Law of Japan*. The Netherlands: Sijthoff&Noordhoff, 1980.

Dougherty, Dale. "The Maker Movement." *Innovations* 7, no. 3 (2012): 11-14.

Drathen, Christian von. "Patent Scope in English and German Law under the European Patent Convention 1973 and 2000." *IIC* (2008): 384-419.

Dreyfuss, Rochelle Cooper. "TRIPS-Round II: Should Users Strike Back?". *The University of Chicago Law Review* 71, no. 1 (2004): 21-35.

Drucker, Peter. "The Discipline of Innovation." *Harvard Business Review* 76, no. 6 (1998): 149-57.

Du Vall, Michal. *Prawo Patentowe*. Warszawa: Wolters Kluwer, 2008.

DuPre, John, and John Hamann. "Controlling Costs in Patent Litigation." *IAM Magazine - 2013 IP Value. Building and enforcing intellectual property value* (2013): 54-57.

Eck, Matthias. "Europaeisches Einheitspatent und Einheitspatentgericht - Grud zum Feiern?". *GRUR Int* (2014): 114-19.

Eisenberg, Rebecca S. "Patents and the Progress of Science: Exclusive Rights and Experimental Use." In *Cases and Materials on Patent Law*, edited by William H. Francis, Robert C. Collins, James D. Stevens, Andrew M. Grove and Matthew J. Schmidt, 83-88. St.Paul, Minn.: Thomas/West, 2007.

———. "Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research." *Virginia Law Review* 82, no. 8 (1996): 1663-727.

Ellis, Jack. "Change in Practice." *IAM Magazine* 65 (May/June 2014): 11-21.

———. "Keeping Secret." *IAM Magazine*, no. 62 (November/December 2013): 43-50.

Ettlie, John, William Bridges, and Robert O'Keefe. "Organisation Strategy and Structural Differences for Radical Versus Incremental Innovation." *Management Science* 30, no. 6 (1984): 682-95.

Fernandez, Esteban, Jose Montes, and Camilo Vazquez. "Typology and Strategic Analysis of Intangible Resources. A Resource-Based Approach." *Technovation* 20, no. 2 (2000): 81–92.

Flattmann, Gerald J., and Kaplan Jonathan M. "Licensing Research Tool Patents." *Nature Biotechnology* 20 (2002): 945-47

Ford, Sara M. "Compulsory Licensing Provisions under the TRIPs Agreement: Balancing Pills and Patents." *Am. U. Int'l L. Rev.* 941, no. 15 (1999-2000): 941-74.

Francisco, Michael. "Compulsory License Bandwagon Gains Momentum." *Nat Biotech* 30, no. 9 (09//print 2012): 814-14.

Franke, Nikolaus, and Frank Piller. "Value Creation by Toolkits for User Innovation and Design: The Case of the Watch Market." *Journal of Product Innovation Management* 21, no. 6 (2004): 401-15.

Franke, Nikolaus, Martin Schreier, and Ulrike Kaiser. "The "I Designed It Myself" Effect in Mass Customization." *Management Science* 56, no. 1 (2010): 125-40.

Franke, Nikolaus, and Sonali Shah. "How Communities Support Innovative Activities: An Exploration of Assistance and Sharing among End-Users." *Research Policy* 32, no. 1 (2003): 157-78.

Freeburg, Ruth. "No Safe Harbor and No Experimanl Use: Is It time for Compulsory Licensing of Biotech Tools." *Buff.L.Rev.* 351, no. 53 (2005-2006).

Fujino, Jinzo. "Latest Developments in Japan IP Cases." *AIPPI Journal* (Nov. 1997): 296-300.

Gans, Joshua, and Scott Stern. "The Economics of User-Based Innovation." *Working Paper* (1998).

Gervais, Daniel. *The TRIPS Agreement: Drafting History and Analysis*. 3rd ed. Yorkshire, UK: Thomson Reuters, 2008.

———. *The TRIPS Agreement: Drafting History and Analysis*. 4th ed. London: Thomson Reuters, 2012.

Gesthuysen, Hans Dieter. "Der „Formstein"-Einwand bei einer nach der Entscheidung „Befestigungsvorrichtung II" äquivalenten Ausführungsform." *GRUR* (2001).

Gladstone Mills III, John, Donald Cress Reiley III, and Robert Clare Highley. *Patent Law Basics*. MA: Thomson Reuters/West, 2012.

Gonsalves, Gregory, TC Beckett, and Barry Leff. "Trends in Inter Partes Review and Covered Business Method Review." *IAM Magazine*, no. 64 (March/April 2014): 20-27.

Gopalakrishnan, S., and F. Damanpour. "A Review of Innovation Research in Economics, Sociology and Technology Management,." *International Journal of Management Science* 25, no. 1 (1997): 15–28.

Gordon, Wendy J. "A Property Right in Self-Expression: Equality and Individualism in the Natural Law of Intellectual Property." *The Yale Law Journal* 102, no. 7 (1993): 1533-609.

Grabinski, Klaus. "„Schneidmesser" versus „Amgen" Zum Sinn oder Unsinn patentrechtlicher Äquivalenz." *GRUR* (2006): 714-20.

Grady, Mark F., and Jay I. Alexander. "Patent Law and Rent Dissipation." *Virginia Law Review* 78 (1992): 305-50.

Grimaldi, Rosa, Martin Kenney, Donald S. Siegel, and Mike Wright. "30 Years after Bayh–Dole: Reassessing Academic Entrepreneurship." *Research Policy* 40, no. 8 (2011): 1045-57.

Gruenewald, Theo, and Alexander Wurzer. "Translation of Patent Applications: A Challenge in Globalised IP Management." *IAM Magazine*, no. 62 (November/December 2013): 63-68.

Gruner, Richard S. "Intangible Inventions: Patentable Subject Matter for an Information Age." *Loy. L. A. L. Rev.* 35 (2001-2002): 355-470.

Guerinni, Christi. "Defining Patent Quality." *Fordham Law Review* 82, no. 6 (2014): 3091-141.

Haeckel, Stephan. *Adaptive Enterprise: Creating and Leading Sense-and Respond Organizations*. Vol. 1999, Boston: Harvard School of Business.

Haedicke, Maximilian. "Rechtsfindung, Rechtsfortbildung und Rechtskontrolle im Einheitlichen Patentsystem." *GRUR Int.* (2013): 609-17.

Haft, Klaus, Gunnar Baumgärtel, Jan Dombrowski, Benjamin Grzimek, Björn Joachim, and Michael Loschelder. "Die Erschöpfung von Rechten des Geistigen Eigentums in Fällen des Recyclings oder der Reparatur von Waren (Q 205)." *GRUR Int.* (2008): 944-53.

Hantman, Ronald D. "Experimental Use as an Exception to Patent Infringement." *Journal of the Patent & Trademark Office Society* 67, no. 12 (1985): 617-44.

Harabi, Najib. "Appropriability of Technical Innovations an Empirical Analysis." *Research Policy* 24, no. 6 (1995): 981-92.
Harhoff, Dietmar, Joachim Henkel, and Eric von Hippel. "Profiting from Voluntary Information Spillovers: How Users Benefit by Freely Revealing Their Innovations." *Research Policy* 32, no. 10 (2003): 1753-69.
Harmon, Robert L. *Harmon on Patents. Black-letter Law and Commentary*. Arlington: BNA Books, 2007.
Harris, Donald. "TRIPs after Fifteen Years: Success or Failure, as Measured by Compulsory Licensing." *J. Intell. Prop. L.* 367, no. 18 (2010-2011): 367 - 400.
Hatch, Mark. *The Maker Movement Manifesto. Rules for Innvoation in the New World of Crafters, Hackers, and Tinkerers*. McGrew-Hill Education eBooks, 2014.
Hawkins, Naomi. "An Exception to Infringement for Genetic Testing – Addressing Patient Access and Divergence Between Law and Practice." *IIC* (2012): 641-61.
Heath, Christopher, and Mineko Mohri. "Ending is Better than Mending - Recent Japanse Case Law on Repair, Refill and Recycling." *IIC* (2006): 856-64.
Heller, Michael A., and Rebecca S. Eisenberg. "Can Patents Deter Innovation? The Anticommons in Biomedical Research." *Science* 280, no. 5364 (1998): 698-701.
Henkel, Joachim. "Software Development in Embedded Linux — Informal Collaboration of Competing Firms." Chap. 5 In *Wirtschaftsinformatik 2003/Band II*, edited by Wolfgang Uhr, Werner Esswein and Eric Schoop, 81-99: Physica-Verlag HD, 2003.
Herdin, Garrett. "The Tragedy of Commons." *Science* 162, no. 13 (1968): 1243-48.
Hieber, Thomas. "Die Zulässigkeit von Versuchen an patentierten Erfindungen nach § 11 Nr. 2 PatG 1981." *GRUR* (1996): 439 - 47.
Hienerth, Christoph. "The Commercialization of User Innovations: The Development of the Rodeo Kayak Industry." *R&D Management* 36, no. 3 (2006): 273-94.
Hill, Alison. "Ambiguous Regulation and Questionable Patentability: A Toxic Future for in Vitro Companion Diagnostic Devices and Personalized Medicine." *Wis. L. Rev.* (2013): 1463-88.
Hilty, Reto, and Christophe Geiger. "Towards a New Instrument of Protection for Software in the EU? Learning the Lessons from the Harmonization Failure of Software Patentability ". *Max Planck Institute for Intellectual Property & Competition Law Research Paper No. 11-01* (2011): 1-38.
Hilty, Reto, Thomas Jaeger, Matthias Lamping, and Hanns Ullrich. "The Unitary Patent Package: Twelve Reasons for Concern." *Max Planck Institute for Intellectual Property & Competition Law Research Paper*, no. 12-12 (2012).
Hinkelmann, Klaus. *Gewerblicher Rechtsschutz in Japan*. Vol. 2., Köln, München: Carl Heymanns Verlag, 2008.
Ho, Cynthia M. "Patent Breaking or Balancing?: Spearating Strands of Facts form Fiction under TRIPS." *N.C.J. Int'l L. & Com. Reg.* 34, no. 371 (2008-2009): 371-469.
Hoeren, Thomas. "Chip Protection in Europe." *High Technology Law Journal (Comp. &High Techn. LJ)* 7, no. 19 (1991).
Hoffmann, Leonard Hubert. "Patent Construction." *GRUR* (2006): 720-24.
Holder, Niels. "Exogenous Equals Endogenous? Claim Construction After the Amgen Decision." *IIC* (2006): 662-69.
Hölder, Niels. "Mittelbare Patentverletzung und Erschöpfung bei Austausch- und Verschleißteilen Die „Flügelradzähler"-Entscheidung des BGH." *GRUR* (2005): 20-24.
Holzapfel, Henrik. "Die patentrechtliche Zulässigkeit der Benutzung von Forschungswerkzeugen." *GRUR Int* 10 (2006): 11-17.
Horowitz, David H. "The Record Rental Amendment of 9184: a Case Study in the Effort to Adapt Copyright Law to New Technology." *Colum.-Vla. J.L. & Arts* 31, no. 12 (1987): 34-38.
Humphreys, Ashlee , and Kent Grayson. "The Intersectiong Roles of Consumer and Producer: A Critical Perspective on Co-production, Co-creation and Prosumption." *Sociology Compass* 2/3 (2008): 963-80.

"Insight: Broken by a system that encourages bad behaviours, IPXI closes down." *IAM Magazine* 72 (July/August 2015): 4-6.
"Insight: Going In with Eyes Wide Open." *IAM Magazine*, no. 67 (September/October 2014): 4-6.
Jaeger, Thomas. "Hieronymus Bosch am Werk beim EU-Patent? Alternativen zur Einheitspatentlösung." *EuZW* (2013): 15-21.
———. "Shielding the Unitary Patent from the ECJ: A Rash and Futile Exercise." *IIC* (2013): 389-91.
Janis, Mark. "On Courts Herding Cats: Contending with the Written Description Requirement (And Other Unruly Patent Disclosure Doctrines)." *Wash. UJL & Pol'y* 2 (2000): 55-108.
Janis, Mark D. "Tale of the Apocryphal Axe: Repair, Reconstruction, and the Implied License in Intellectual Property Law." *Maryland Law Review* 58 (1999): 423-527.
Jewkes, John, David Sawers, and Richard Stillerman. *The Source of Invention*. 2 ed. Edinburgh: Macmillan, 1969.
Johnson, Alan, and Philip Westmacott. "Europe Has Spoken: Now It's Up to the Judges." *Intellectual Asset Management*, no. 57 (March/April 2013): 11-21.
Johnson, Jennifer A. "The Experimental Use Exception in Japan: a Model for U.S. Patent Law?". *Pacific Rim Law & Policy Journal Association* 12, no. 2 (2003): 499-533.
Julian-Arnold, Gianna "International Compulsory Licensing: The Rationales and the Reality." *IDEA* 33, no. 349 (1992-1993): 349-400.
Kadota, Kazuyo. "Claims Support in Japanese Patent Law." *IIC* (2012): 333-42.
Kahn, Alfred E. "Fundamental Deficiencies of the American Patent Law." *The American Economic Review* 30, no. 3 (1940): 475-91.
Katayama, Eiji. *Japanese Patent Litigation*. Eagan, MN: West, 2009.
Keukenschrijver, Alfred. "Zur sachlichen Reichweite des Vorbenutzungsrechts." *GRUR* (2001): 944-48.
Kitch, Edmund W. "The Nature and Function of the Patent System." *Journal of Law and Economics* 20, no. 2 (1977): 265-90.
Kock, Michael A., Susann Porzig, and Eva Willnegger. "Der Schutz von pflanzenbiotechnologischen Erfindungen und von Pflanzensorten unter Berücksichtigung der Umsetzung der Biopatentrichtlinie.". *GRUR Int.* (2005): 183-92.
Kohler, Josef. *Handbuch des Deutschen Patentrechts in rechtsvergleichender Darstellung*. Mannheim: Bensheimer, 1900.
Kotler, Philip. "The Prosumer Movement: A New Challenge for Marketers." *Advances in Consumer Research* 13, no. 1 (1986): 510-13.
Kraßer, Rudolf. "Auswirkungen einer Einbeziehung von Vorschriften über Inhalt und Grenzen der Verbietungsrechte des Patentinhabers in eine EU Verordnung zur Schaffung eines einheitlichen europäischen Patentschutzes ". EPLAW Patent Blog, 1.11.2011.
———. *Patentrecht*. 6 ed. München: C.H. Beck, 2009.
Kristandl, Gerhard , and Nick Bontis. "Construction of a Definition of Intangibles Using the Resource Based View of the Firm." *Management Decision* 45, no. 9 (2007): 1510 - 24.
Kuhnen, Rainer. "The Proposed Structure of the Unified Patent Court System in Europe." *Patents in Europe 2015/2016. Helping business compete in the global economy* (2014): 27-32.
Kur, Annette. "Of Oceans, Islands, and Inland Water - How Much Room for Exceptions and Limitations under the Three-Step Test." *Richmond Journal of Global Law & Business* 8, no. 287 (2008-2009).
———. "Two Tiered Protection - Designs and Databases as Legislative Models?". In *Common Principles of European Intellectual Property Law*, edited by Ansgar Ohly, 99-115. Tuebingen: Morh Siebeck, 2012.
Kuznetsov, Stacey, and Eric Paulos. "Rise of the Expert Amateur: DIY Projects, Communities, and Cultures." In *Proceedings of the 6th Nordic Conference on Human-Computer Interaction: Extending Boundaries*, 295-304. Reykjavik, Iceland: ACM, 2010.
Lamping, Matthias. "Enhanced Cooperation – A Proper Approach to Market Integration in the Field of Unitary Patent Protection?". *IIC* (2011): 879-925.

Lawson, Charles. "Public Interest Compulsory Licensing under the Patents Act 1990 (Cth): A Real Incentive or a Barrier to Working?". *Australian Intellectual Property Journal* 19, no. 3 (2003): 129-47.

Lee, Steve. "A Tale of Two Patent Battles: Key Lessons on IP and Business Strategy." *IAM Magazine*, no. 64 (March/April 2014): 37-43.

Lehmann, Michael. "Die Europaische Richtiline uber den Schutz von Computerprogrammen." *GRUR Int.* (1991): 327-37.

Lerner, Josh, and Jean Tirole. "Some Simple Economics of Open Source." *The Journal of Industrial Economics* 50, no. 2 (2002): 197-234.

Lesser, W. "Valuation of Plant Variety Protection Certificates." *Review of Agricultural Economics* 16, no. 2 (1994): 231-38.

Leßmann, Andreas. "Erschöpfung von Patentrechten bei Konzernvertrieb." *GRUR* (2000): 741.

Lettl, Christopher, Cornelius Herstatt, and Hans Georg Gemuenden. "Users' Contributions to Radical Innovation: Evidence from Four Cases in the Field of Medical Equipment Technology." *R&D Management* 36, no. 3 (2006): 251-72.

Leung, Peter. "India Rejects Another Compulsory Licence." *Managing Intellectual Property* http://www.managingip.com/Blog/3273950/India-rejects-another-compulsory-licence.html (6.11.2013 2013).

Levin, Richard C., Alvin K. Klevorick, Richard R. Nelson, Sidney G. Winter, Richard Gilbert, and Zvi Griliches. "Appropriating the Returns From Industrial Research and Development." *Brookings Papers on Economic Activity - Special Issue on Microeconomics* 1987, no. 3 (1987): 783-831.

Lim, Kwanghui. "The Many Faces of Absorptive Capacity: Spillovers of Copper Interconnect Technology for Semiconductor Chips." *Industrial and Corporate Change* (2009).

Linck, Nancy J. , and John E. McGarry. "Patent Procurement and Enforcement in Japan - A Trade Barrier." *Geo. Wash. J. Int'l L. & Econ.* 27, no. 411 (1993-1994): 411-32.

Lindenmaier, Fritz. "Über Erschöpfung des Patentrechts, Ausbesserung, Wiederherstellung und Ersatz in Verkehr gebrachter patentgeschützter Vorrichtungen und ihrer Teile ". *GRUR* (1952): 294-98.

Llewelyn, Margaret. "Schrodinger's Cat: An Observation on Modern Patent Law." In *Death of Patents*, edited by Peter Drahos, 11-66. London: Lawtext Publishing Limited, 2005.

Ludlow, Terry. "Sign of the Times: Trends in Technology IP Licensing." *IAM Magazine*, no. 66 (July/August 2014): 31-38.

Luginbühl, Stefan. "Das europäische Patent mit einheitlicher Wirkung (Einheitspatent)." *GRUR Int.* (2013): 305-10.

Lusch, Robert F., Stephen L. Vargo, and Matthew O'Brien. "Competing Through Service: Insights from Service-Dominant Logic." *Journal of Retailing* 83, no. 1 (2007): 5-18.

Lüthje, Christian, and Cornelius Herstatt. "The Lead User Method: An Outline of Empirical Findings and Issues for Future Research." *R&D Management* 34, no. 5 (2004): 553-68.

Lüthje, Christian, Cornelius Herstatt, and Eric von Hippel. "User-Innovators and "Local" Information: The Case of Mountain Biking." *Research Policy* 34, no. 6 (2005): 951-65.

Machlup, Fritz. *Die wirtschaftlichen Grundlagen des Patentrechts*. Weinheim/Bergstrasse: Verlag Chemie, 1962.

———. *An Economic Review of the Patent System*. Washington: US Government Printing Office, 1958.

Machlup, Fritz, and Edith Penrose. "The Patent Controversy in the Nineteenth Century." *The Journal of Economic History* 10, no. 1 (1950): 1-29.

Malik, Pramath, and Manikandan Balasubramanian. "The Search of the Next Patent War." *IAM Magazine* 72 (July/August 2015): 121-28.

Mansfield, Edwin. "How Rapidly Does New Industrial Technology Leak Out?". *The Journal of Industrial Economics* 34, no. 2 (1985): 217-23.

Matthews, Duncan. "WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?". *Journal of International Economic Law* 7, no. 1 (March 1, 2004 2004): 73-107.

Mazzoleni, Roberto, and Richard R. Nelson. "The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate." *Research Policy* 27, no. 3 (1998): 273-84.

McClure, Ian. "The Value of IP as a Commodity." *IAM Magazine*, no. 46 (May/June 2011): 29-37.

McManis, Charles. "A Rhetorical Response to Boldrin & Levine: Against Intellectual (Property) Extremism." *Review of Law & Economics* 5, no. 3 (2010): 92-111.

Meinberg, Henrik. *Zwangslizenz im Patent- und Urheberrecht als Instrument der kartellrechtlichen Missbrauchsaufischt im deutschen und europäischen Recht*. Hamburg: Verlag Dr. Kovac, 2006.

Mellstedt, H., D. Niederwieser, and H. Ludwig. "The Challenge of Biosimilars." *Annals of Oncology* 19, no. 3 (March 1, 2008 2008): 411-19.

Merges, Robert P., and John F. Duffy. *Patent Law and Policy*. 5 ed. Newark, NJ: LexisNexis, 2011.

Merges, Robert P., and Richard R. Nelson. "On the Complex Economics of Patent Scope." *Columbia Law Review* 90, no. 4 (1990): 839-916.

Mes, Peter. *Patentgesetz. Gebrauchmusterrecht.* 3 ed. Munchen: C.H. Beck, 2011.

Mills, Oliver. *Biotechnological Inventions. Moral Restraints and Patent Law*. Farnham: Ashgate, 2010.

Milone, Cheryl. "The Real Problem is Patent Quality, not NPEs." *IAM Magazine*, no. 61 (September/October 2013): 11-16.

Mitnovetsk, O., and D. Nicol. "Are Patent for Methods of Medical Treatment Contrary to the Ordre Public or morality or "generally inconvenient"?". *J Med Ethics*, no. 30 (2004): 470-75.

Mohri, Mineko. *Maintenance, Replacement and Recycling - Patentee's Rights in the Aftermarkets. Germany, the U.S. and Japan*. Munich: Herbert Utz Verlag, 2010.

———. "Patents, Repair and Recycling from a Comparative Perspective." *IIC* (2010): 779-805.

Montecinos, Amanda "Demystifying Patent Translation. Just as Patents Require Specialised Writing Skills, They also Require Specialised Translation Skills." *Communicator. The Institute of Scientific and Technical Communicators* (Autumn 2009): 24-25. http://www.multiling.com/Portals/0/NewsFiles/Communicator.pdf.

Moreau, C. Page, and Darren W. Dahl. "Designing the Solution: The Impact of Constraints on Consumers' Creativity." *Journal of Consumer Research* 32, no. 1 (2005): 13-22.

Morrison, Pamela, John Roberts, and Eric von Hippel. "Determinants of User Innovation and Innovation Sharing in a Local Market." *Management Science* 46, no. 12 (2000): 1513-27.

Mossinghoff, Gerald J. "Overview of The Hatch-Waxman Act and Its Impact on the Drug Development Process." *Food & Drug LJ* 54 (1999): 187.

Mowery, David C. *Ivory Tower and Industrial Innovation: University-Industry Technology Transfer before and after the Bayh-Dole Act in the United States*. Stanford: Stanford University Press, 2004.

Mowery, David C., Richard R. Nelson, Bhaven N. Sampat, and Arvids A. Ziedonis. "The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh–Dole Act Of 1980." *Research Policy* 30, no. 1 (2001): 99-119.

Mueller, Janice M. "The Evanescent Experimental Use Exemption from United States Patent Imfringement Liability: Implications for University and Nonprofit Research and Development." *Baylor Law Review* 56 (2004): 917-80.

———. "No Dilettante Affair: Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools." *Washington Law Review* 76, no. 1 (2001): 1-66.

———. *Patent Law*. 4 ed. New York: Wolters Kluwer Law & Business, 2013.

Munoz Tellez, Viviana. "Dispute Settlement under the TRIPS Agreement: the United States-Brazil (2000) and United States-Argentina (2002) Patent Disputes." In *Research Handbook an othe Interpretation and Enforcement of Intellectual Property under WTO Rules*, edited by Carlos M. Correa, 215-36. Cheltenham, UK: Edward Elgar, 2010.

Murphy, Colm. "Methods of Treatment: Is There Any Protection Available in Europe?". *Nature Biotechnology* 19 (May 2001): 481-82.

Mylly, Ulla-Maija. "An Evolutionary Economics Perspective on Computer Program Interoperability and Copyright." *IIC* (2010): 284-315.

Nagaoka, Sadao. "Determinants of High-Royalty Contracts and the Impact of Stronger Protection of Intellectual Property Rights in Japan." *Journal of the Japanese and International Economies* 19, no. 2 (6// 2005): 233-54.

Newman, Pauline. "Luncheon Speech to ABA-IPL Section." In *Cases and Materials on Patent Law*, edited by William H. Francis, Robert C. Collins, James D. Stevens, Andrew M. Grove and Matthew J. Schmidt, 77-82. St.Paul, Minn: Thomson/West, 2007.

Nieder, Michael. "Die mittelbare Patentverletzung - eine Bestandsaufnahme." *GRUR* (2006): 977-83.

Nowicka, Aurelia. "Programy Komputerowe a Wynalazki Mające Zdolność Patentową – Praktyczne Aspekty Badania Zdolności Patentowej." *Ochrona Wlasnosci Przemyslowej*, no. 46 (2014).

———. "Programy Komputerowe w Systemach Prawa Patentowego." *Ochrona Własności Przemysłowej*, no. 45 (2014).

Nuvolari, Alessandro. "Collective Invention during the British Industrial Revolution: the Case of the Cornish Pumping Engine." *Cambridge Journal of Economics* 28, no. 3 (2004): 347-63.

Ono, Nahoko. "Better than Nothing: Japan's Next Move on Patentability of Medical Methods." *IIC* (2006): 196-216.

Osenga, Kristen. "Linguistic and Patent Claim Construction." *Rutgers Law Journal* 38 (2006): 61-108.

Osterborg, Lise. "Gedanken zur Vereinheitlichung des Vorbenutzungsrechts fur Erfindungen im Gemeinsamen Markt." *GRUR Int* (1983): 97-109

Pagenberg, J.K. Jochen. "Clinical Trials I - Comment." *International Review of Intellectual Property and Competition Law* (1997): 112-13.

Pagenberg, Jochen. "New Trends in Patent Claim Interpretation in Germany - Good-bye to the "General Inventive Idea"." *IIC* (1988): 788.

Palfrey, John, and Urs Gasser. *Interop. The Promise and Perils of High Interconnected Systems*. New York: Basic Books, 2012.

Pauwelyn, Joost. "The Role of Public International Law in the WTO: How Far Can We Go?". *The American Journal of International Law* 95, no. 3 (2001): 535-78.

Pellegrino, Mike. "Apple, Samsung and the Battle for Patent Supremacy." *IAM Magazine*, no. 58 (May/June 2013): 64-76.

Peritz, Rudolph J.R. "Patents and Progress: The Economics of Patent Monopoly and Free Access: Where Do We Go from Here?". In *The Structure of Intellectual Property Law: Can One Size Fit All?*, edited by Annette Kur and Vyatuatas Mizaras, 40-48. Cheltenham: Elgar, 2001.

Phelps, Marshall, and David Kline. "Building a White-Hat Brand in the Patent Industry." *IAM Magazine*, no. 67 (September/October 2014): 41-48.

Pietzcker, Rolf. "Patentrechtliche Fragen bei klinischen Untersuchungen - eine Erwiderung." *GRUR* (1994): 319 - 21.

Pigott, Charles F. "Equivalents in Reverse." *J. Pat. Off. Soc'y* 48, no. 5 (1966): 291-340.

Piller, Frank T., and Dominik Walcher. "Toolkits for Idea Competitions: A Novel Method to Integrate Users in New Product Development." *R&D Management* 36, no. 3 (2006): 307-18.

Pilny, Karl H. "Schnittstellen in Computerprogrammen. Zum Rechschutz in Deutschland, den USA und Japan." *GRUR Int.* (1990): 431-41.

Pitz, Johann. *Patentverletzungsverfahren*. 2 ed. Munich: Beck, 2010.

Popp, Eugen. "Formstein-Einwand -reine Theorie?". *GRUR* (2009): 318-22.

Porcelli, Frank. "Bowman v. Monsanto and an Introdcution to the Patent Exhaustion/First Sale Doctrine in the United States." *GRUR Int.* (2013): 27-32.

Prahalad, C. K., and Venkat Ramaswamy. "Co-Creation Experiences: The Next Practice in Value Creation." *Journal of Interactive Marketing* 18, no. 3 (2004): 5-14.

Purdue, Derrick, Jörg Dürrschmidt, Peter Jowers, and Richard O'Doherty. "DIY Culture and Extended Milieux: Lets, Veggie Boxes and Festivals." *The Sociological Review* 45, no. 4 (1997): 645-67.

Raasch, Christina, Cornelius Herstatt, and Kerstin Balka. "On the Open Design of Tangible Goods." *R&D Management* 39, no. 4 (2009): 382-93.

Rahn, Guntram. "Recht und Rechtsmentalitat in Japan." *Reihe Japanwirtschaft* 11 (1981): 28.

———. "The Role of Industrial Property in Economic Development: The Japanese Experience ". *IIC* (1983): 449-92.

Ramanna, Anitha. "Shifts an India's Policy on Intellectual Property: The Role of Ideas, Coercion and Changing Interests." In *Death of Patents*, edited by Peter Drahos, 150-74. London: Lawtext Publishing Limited, 2005.

Ramirez, Rafael. "Value Co-Creation: Intellectual Origins and Implications for Practice and Research." *Strategic Management Journal* 20 (1999).

Rauh, Georg Andreas. "Mittelbare Patentverletzung in Deutschland, Japan und den USA." *GRUR Int.* (2010): 459-69.

Reimer, Eduard. "Für Professor Dr. jur. Dr.-Ing. e. h. Fritz Lindenmaier zum 75. Geburtstag Äquivalenz, Erfindungsgegenstand, allgemeiner Erfindungsgedanke in Theorie und Praxis." *GRUR* (1956): 387--404.

Rice, Ronald, and Everett Rogers. "Reinvention in the Innovation Process." *Science Communication* 1, no. 4 (1980): 499-514.

Richardson, Kent, and Erik Oliver. "The Brokered Patent Market in 2013." *IAM Magazine*, no. 63 (January/February 2014): 11-19.

Ritzer, George, and Nathan Jurgenson. "Production, Consumption, Prosumption: The Nature of Capitalism tn the Age of the Digital 'Prosumer'." *Journal of Consumer Culture* 10, no. 1 (March 1, 2010 2010): 13-36.

Roberts, Edward. "What We've Learned. Managing Invention and Innovation." *Research-Technology Management* 31, no. 1 (1988): 11-29.

Robertson, Thomas. "The Process of Innovation and the Diffusion of Innovation." *Journal of Marketing* 31, no. 1 (1967): 14-19.

Roffe, Pedro, and Christoph Spennemann. "Canada- Patent Protection of Pharmacutical Products." In *Research Handbook on the Interpretation and Enforcement of Intellectual Property under WTO Rules*, edited by Carlos M. Correa, 237-97. Chentelham, UK: Edward Elgar, 2010.

Rogers, Everett. *Diffusion of Innovations*. 3 ed. New York: The Free Press, 1983.

Rovner, Amber Hatfield "Practical Guide to Application of (or Defense against) Product-Based Infringement Immunities under the Doctrines of Patent Exhaustion and implied License." *Tex. Intell. Prop. L.J.*, no. 12 (2003-2004): 227-.

Rübel, Clemens. "Patentschutz bei Reparatur- und Ersatzteilfällen." *GRUR* 7 (2002): 561-65.

Rudolf, Krasser. "Developments in Utility Model Law." *IIC* (1995): 950-63.

Ruess, Peter. "Accepting Exceptions: A Comparative Approach to Experimental Use in the U.S. and German Patent Law." *Marq. Intell. Prop. L. Rev.* 10, no. 81 (2006).

Ruttan, Vernon. "Usher and Schumpeter on Invention, Innovation and Technological Change." *The Quarterly Journal of Economics* 73, no. 4 (1959): 596-606

Sasdi, Andreas. *Innovationsschutz im Trips-Übereinkommen. Unter besondere Berücksichtigung der Arzneimittelbezogenen Aspekte der Rechte des Geistigen Eigentums*. Berlin: Duncker & Humboldt, 2004.

Schau, Hope Jensen, and Mary C. Gilly. "We Are What We Post? Self-Presentation in Personal Web Space." *Journal of Consumer Research* 30, no. 3 (2003): 385-404.

Schellekens, Huub, and Ellen Moors. "Clinical Comparability and European Biosimilar Regulations." *Nature Biotechnology* 28, no. 1 (01//print 2010): 28-31.

Schumpeter, Joseph. *Theorie der wirtschaftlichen Entwicklung*. Berlin: Dunker Humbolt, 1964.

Scotchmer, Suzanne. "Standing on the Shoulders of Giants: Cumulative Research and the Patent Law." *The Journal of Economic Perspectives* 5, no. 1 (1991): 29-41.

Sedlmaier, Roman. *Die Patentierbarkeit von Computerprogrammen und ihre Folgeprobleme*. Munich: Herbert Utz Verlag, 2004.

Sekac, Matt. "For Patent Practinioners, Translation is Everywhere." *IAM Magazine*, no. 67 (September/October 2014): 77-84.

Senftleben, Martin. "Towards a Horizontal Standard for Limiting Intellectual Property Rights? WTO Panel Reports Shed Light on the Three-Step Test in Copyright Law and Related Tests in Patent and Trademark Law." *International Review of Intellectual Property and Competition Law* 37, no. 4 (2006): 407-38.

Shah, Sonali. "Sources and Patterns of Innovation in a Consumer Products Field: Innovations in Sporting Equipment." In *Working Paper, WP 4105 Sloan School of Management*, 1-27. Cambridge, MA: Massachusetts Institute of Technology, 2000.

Shah, Sonali K., and Mary Tripsas. "The Accidental Entrepreneur: The Emergent and Collective Process of User Entrepreneurship." *Strategic Entrepreneurship Journal* 1, no. 1-2 (2007): 123-40.

Shapiro, Carl. "Patent Reform: Aligning Reward and Contribution." In *Innovation Policy and the Economy*, edited by Adam B. Jaffe, Josh Lerner and Scott Stern, 111-56. Chicago: University of Chicago Press, 2008.

Sichelman, Ted M. "Markets for Patent Scope." *IP Theory* 1, no. 2 (2010): 42-49.

Sirjani, Fariba, and Dariush Keyhanii. "35 U.S.C. 287(C): Language Slightly Beyond Intent." *Buffalo Intellectual Property Law Journal* 3, no. 13 (2005): 13-45.

Skubisz, Ryszard. *Prawo Własności Przemysłowej*. Vol. 14A, Warszawa: C.H. Beck, Instytut Nauk Prawnych PAN, 2012.

Smith, Gordon, and Russell Parr. *Valuation of Intellectual Property and Intangible Assets*. 3 ed. New York: John Wiley & Sons, Inc, 2000.

Soltysinski, Stanislaw. "International Exhaustion of Intellectual Property Rights under the TRIPs, the EC Law and the Europe Agreements." *GRUR Int.* (1996): 316.

Staehelin, Alesch. *Das TRIPs-Abkommen. Immaterialguterrecht im Licht der globalisierten Handelspolitik*. Bern: Stampfli Verlag AG, 1999.

Stercks, Sigrid. "The Ethics of Patenting - Uneasy Justification." In *Death of Patents*, edited by Peter Drahos, 175-211. London: Lawtext Publishing Limited, 2005.

Story, Bruce. "America Invents Act Shines the Spotlight on Trade Secrets." *IAM Magazine*, no. 58 (May/June 2013): 79-84.

Strandburg, Katherine. "Patent Fair Use 2.0." *New York University Law and Economics Working Papers*, no. 268 (2011): 53.

———. "User Innovator Comunity Norms at the Boundary Between Academic and Industry Research." *Fordham Law Review* 77 (2009): 2237-74.

———. "Users as Innovators: Implications for Patent Doctrine." *University of Colorado Law Review* 79 (2008): 467-544.

———. "What Does the Public Get? Experimental Use and the Patent Bargain." *Wisconsin Law Review* 2004 (2004): 1-81.

———. "What If There Were a Business Method User Exemption to Patent Infringement?". *Mich. St. L. Rev.* 2008 (2008): 245-78.

Straus, Joseph. "Bedeutung des TRIPS für das Patentrecht." *GRUR Int.* (1996): 179.

———. "Zur Zulässigkeit klinischer Untersuchungen am Gegenstand abhängiger Verbesserungserfindungen." *GRUR* (1993): 308 - 19.

Ströbele, Paul. *Die Bindung der ordentlichen Gerichte an Entscheidungen der Patentbehoerden*. Köln: Heymann, 1975.

"Symposium: Striking the Right Balance between Innovation and Drug Price Competition - Understanding the Hatch-Waxman Act ". Food & Drug Law Journal Vol. 54, 2, 1999.

Takenaka, Toshiko. "The Doctrine of Equivalents in Japan." *CASRIP Symposium Publication Series: Rethinking International Intellectual Property*, no. 6 (2001): 125-32.

Tamai, Katsuya. "The Experimental Use Exception: a Japanese Prespective." *CASRIP Symposium Publication Series: Reconciling Competing Interests in Intellectual Property*, no. 7 (2002): 14-17.

Terrell, Thomas, and Editors. *Terrell on the Law of Patents*. 17 ed. London: Sweet & Maxwell, 2011.

Teschemacher, Rudolf. "Die Benutzung patentierter Erfindungen zu Veruschs- und Forschungszwecken." *GRUR Int.* (1987): 61 - 63.

Thiele-Wittig, Max, and Paul Claus. "Plant Variety Protection - A Fascinating Subject." *World Patent Information*, no. 25 (2003): 243-50.

Thoma, Jorg, and Bizer Kilian. "To Protect or not to Protect? Modes of Appropriability in the Small Enterprise Sector." *Research Policy* 42 (2013): 35-49.

Thums, Doris. "Patent protection for medical treatment - a distinction between patent and medical law." *IIC*, no. 27 (1996): 423-47.

Thursby, Jerry G.Thursby, Marie C. "University Licensing and the Bayh-Dole Act." *Science* 301, no. 5636 (2003): 1052.

Tilmann, Winfried. "Das Europäische Patentgericht nach dem Gutachten 1/09 des EuGH." *GRUR Int.* (2011): 499-500.

Timmann, Tobias. *Das Patentrecht im Lichte von Art. 14 GG*. Geistiges Eigentum und Wettbewerbsrecht. Vol. 22, Tubingen: Mohr Siebeck, 2008.

Todd, Martin. "Patentability of Methods of Medical Treatment: a Comperative Study." *J. Pat. & Trademark Off. Soc'y* 82 (2000): 381- 423.

Toffler, Alvin. *The Third Wave*. New York: William Morrow and Company, Inc, 1980.

Towse, Ruth, and Rudi Holzhauer. *The Econmics of Intelectual Property: Patents*. 8 ed. Aldershot: Elgar, 2002.

Tripp, Robert, Niels Louwaars, and Derek Eaton. "Plant Variety Protection in Developing Countries. A Report from the Field." *Food Policy* 32 (2007): 354-71.

"TRIPS Council: Debate over Effectiveness of System for Access to Medicine." *Bridges Weekly Trade News Digest* 14, no. 38 (2010).

Tritton, Guy, Richard Davis, and et al. *Intellectual Property in Europe* London: Sweet & Maxwell, 2008.

Uemura, Shozo, and Hiroshi Kato. "Japan's History of Intellectual Property Policy and Patent Act." In *Patent Practice in Japan and Europe. Liber Amicorum for Guntram Rahn*, edited by Bernd Hansen and Dirk Schlussler-Langeheine, 67-80. Aplhen, the Netherlands: Wolters Kluwer, 2011.

Ullrich, Hans. "Technologieschutz nach TRIPS: Prinzipien und Probleme." *GRUR Int* (1995): 623-41.

Usher, A.P. "Historical Implications of the Theory of Economic Development." *The Review of Economics and Statistics* 33, no. 2 (1951): 158-62.

———. *A History of Mechanical Inventions* Cambridge: Harvard University Press, 1954.

Van Zimmeren, Esther , and Geertrui Van Overwalle. "A Paper Tiger? Compulsory License Regimes for Public Health in Europe." *IIC* (2011): 4-40.

Vargo, Stephen L., and Robert F. Lusch. "Evolving to a New Dominant Logic for Marketing." *Journal of Marketing* 68, no. 1 (2004): 1-17.

Veryzer, Robert. "Discontinuous Innovation and the New Product Development Process." *Journal of Product innovation Management* 15, no. 4 (1998): 304-21.

Vinje, Thomas. "Die EG-Richtlinie zum Schutz von Compterprogrammen und die Frage der Interoperabilitaet." *GRUR Int.* (1992): 250-60.

von Hippel, Eric. *Democratizing Innovation* Cambridge, Massachusetts: MIT Press, 2005.

———. "The Dominant Role of Users in the Scientific Instrument Innovation Process." *Research Policy* 5, no. 3 (7// 1976): 212-39.

———. *The Sources of Innovation* New York Oxford: Oxford University Press, 1988.

———. "Successful Industrial Products from Customer Ideas." *Journal of Marketing* 42, no. 1 (1978): 39-49.

von Hippel, Eric, and Stan N. Finkelstein. "Analysis of Innovation in Automated Clinical Chemistry Analyzers." *Science and Public Policy* 6, no. 1 (February 1, 1979 1979): 24-37.
von Hippel, Eric, and Ralph Katz. "Shifting Innovation to Users via Toolkits." *Management Science* 48, no. 7 (2002): 821-33.
Von Hippel, Eric, and Georg Von Krogh. "Free Revealing and the Private-Collective Model for Innovation Incentives." *R&D Management* 36, no. 3 (2006): 295-306.
Von Meibom, Wolfang, and Johann Pitz. "Experimental Use and Compulsory Licence Under German Patent Law." *Patent World* (1997): 27-34.
Voss, Christopher. "The Role of Users in the Development of Applications Software." *Journal of Product Innovation Management* 2, no. 1 (1985): 113-21.
Walsh, John P., Ashish Arora, and Wesley M. Cohen. "Effects of Research Tool Patents And Licensing on Biomedical Innovation." In *Patents in the Knowledge-based Economy*, edited by Wesley M. Cohen and Steven A. Merrill, 285-340. Washington, DC: The National Academy Press, 2003.
Weston, Sally. "Software Interfaces - Stuck in the Middle: The Relationship Between the Law and Software Interfaces in Regulating and Encouraging Interoperability." *IIC* (2012): 427-50.
Williams, Colin C. "A Lifestyle Choice? Evaluating The Motives of Do-It-Yourself (DIY) Consumers." *International Journal of Retail & Distribution Management* 32, no. 5 (2004): 270-78.
Wolf, Marco, and Shaun McQuitty. "Understanding the Do-It-Yourself Consumer: DIY Motivations and Outcomes." [In English]. *AMS Review* 1, no. 3-4 (2011/12/01 2011): 154-70.
Xie, Chunyan, Richard Bagozzi, and Sigurd Troye. "Trying to Prosume: Toward a Theory of Consumers as Co-Creators of Value." [In English]. *Journal of the Academy of Marketing Science* 36, no. 1 (2008): 109-22.
Yamane, Hiroko. *Interpreting TRIPS. Globalisation of Intellectual Property Rights and Access to Medicines*. Oxford, UK: Hart Publishing, 2011.
Yamazaki, Junichi, Yasunori Ohtsuka, and Sakata Yasuhiro. "Recent IP High Court Decision Involving Infringment under Doctrine of Equivalents." *Patents and Licensing* (June 2010): 33-37.
Yosick, Joseph A. "Compulsory Patent Licensing for Efficient Use of Inventions." *University of Illinois Law Review* (2001): 1275-305.
Zuscovitch, Ehud. "The Economic Dynamics of Technologies Development." *Research Policy* 15, no. 4 (1986): 175-86.

2. Case Law

Abbott Lab. v. Brennan, 952 F.2d 1346 (1991).
Adams v. Burke, 84 U.S. 453 (1873).
Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200 (1991).
Aro Manufacturing Co. Inc. v. Convertible Top Replacement Co., Inc., 365 U.S. 336 (1961).
Atari Games Corp. v. Nintendo of Am., 897 F.2d 1572 (1990).
Atenolol, Hoge Raad, 18.12.1992, GRUR Int., 1993, 887.
Auchincloss v. Agricultural & Veterinary Supplies Ltd [1999] R.P.C. 397.
Ball Spline Bearing 3, Supreme Court 24.02.1998 AB-1997-5, IIC 1999, 443.
BBS Wheels 2, Tokyo High Court 23.03.1995 Case No. Hei 6 (ne) 3272.
BBS Wheels 3, Supreme Court 01.07.1997 H6-(Ne)-3272, IIC 1998, 331.
Beedle v. Bennett, 122 U.S. 71 (1887).
Klinischer Test, LG Berlin 25.09.1984 16 O 644/84, GRUR 1985, 375.
Betts v. Willmott, LR 6 Ch App 239 (1871).
Brenner, Commissioner of Patents v. Manson, 383 U.S 519 (1966).
British Leyland Motor Co. v. Amstrong Patents Company Ltd., [1986] F.S.R. 221.
Brooks Furniture Mfg., Inc. v. Dutailier Int'l, Inc., 393 F.3d. 1380 (2005).
Brown v. Duchesne, 60 U.S. (19 How.) 183 (1856).
Cali v. Japan Airlines, Inc., 380 F. Supp. 1120 (1974).

Canon Injekt Printer, IP High Court 21.01.2006 Hei 17 (ne) 10021, IIC 2006, 867.
Canon Kabushiki Kaisha v. Green Cartridge Co. (Hong Kong) Ltd., [1997] A.C. 7285.
Carvediol II, BGH, 19.12.2006 - X ZR 236/01 (BpatG) GRUR 2007, 404.
Catnic Components Ltd. v. Hill & Smith Ltd., [1981] R.P.C. 183.
Centrafarm BV and Others v. Sterling Drug ("Negram 2"), C-15/74.
Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1057 (2011).
Classen Immunotherapies, Inc. v. King Pharms., Inc,, 466 F.Supp.2d 621 (2006).
Continental Paper Bag Co. v. Eastern Paper Bag Co., 210 U.S. 405 (1908).
Cotton Tie Company v. Simmons, 106 U.S. 89 (1882).
CSU, L.L.C. v. Xerox Corp. Independent Service Organizations Antitrust Litigation 203 F.3d 1322 (2000).
Dana Corporation v. American Precision Co., , 827 F.2d 755 (1987).
DataCorporation v. Eagle Technologies [2011] R.P.C.17, 443.
Dawson Chemical Co. v. Rohm & Haas Co., 448 U.S. 176 (1980).
Desmopressin, BGH 12.6.2012 - X ZR 131/09, GRUR 2012, 895.
Deutrim Co. v. The United States 19 Cl. Ct. 624 (1990).
Diamond v. Chakrabarty 447 U.S. 303 (1980).
Diamond v. Diehr, 450 U.S. 175 (1981).
Douglas v. The United States, 510 F.2d 364 (1975).
Dunlop v. Longlite Battery, R.P.C. 473 (1958).
Eli Lily & Co. v. Zenith Goldline Pharm Inc., 471 F.3d 1369 (2006).
Elizabeth v. Pavement Co., 97 U.S. 126 (1877).
Embrex, Inc. v. Service Engineering Corp., , 216 F.3d 1343 (2000).
Ethofumesat, BGH 21.02.1989 X ZR 53/87, GRUR 1990, 997.
Fastener Co. v. Eureka Specialty Co., 77 F. 288 (1896).
Feldversuche [Field Experiments], LG Düsseldorf 5.3.1985 4 O 419/83, GRUR Int. 1986, 807.
Flügelradzähler [Impeller flow meter], BGH 4.5.2004 - X ZR 48/03, GRUR 2004, 758.
Förderrinne, BGH 21.11.1958 I ZR 129/57, GRUR 1959, 232.
Formstein [Moulded Curbstone], BGH 29.4.1987 X ZR 28/85, IIC 1987, 795.
Foster v. American Machine & Foundry Co. , 492 F.2d 1317 (1974).
Fullstoff BGH 10.9.2009 - Xa ZR 18/08, GRUR 2010, 47.
General Electric Company v. United States, 572 F.2d 745 (1978).
Gillette Safty Razor Co. v. Anglo-American Trading Co., [1913] R.P.C. 465.
Glatzenoperation [Baldness treatment], BGH 26. 9. 1967 - I a ZB 1/65, NJW 1968, 197.
Goodyear Shoe Machinery Co. v. Jackson, 112 F. 146 (1901).
Goodyear v. Beverly Rubber 10 F. Cas. 638 (1859).
Gottschalk v. Benson, 409 U.S. 63 (1972).
Graver Tank & Mfg. Co. Inc. et al., v Linde Air Products Co., 339 U.S. 605 (1950).
Halliburton Energy Services Inc. v. Smith International (North Sea) Ltd., [2006] R.P.C. 2.
Helitune v. Stewart Hughes [1991] F.S.R. 171, 207.
Heyer v. Duplicator Manufacturing, 263 U.S. 100 (1923).
Hickman v. Andrews, [1983] R.P.C. 147.
Highmark, Inc. v. Allcare Health Management Systems, Inc., 134 S.Ct. 1744 (2014).
Husky Injection Molding Systems Ltd. v. R&D Tool & Engineering Co., 291 F.3d 780 (2002).
Image Technical Services v. Eastman Kodak Co. , 125 F.3d 1195 (1997).
Improver Corporation v. Remington Consumer Products Ltd., [1990] F.S.R. 181.
In re Bilski, 545 F.3d 943 (2008).
Inhale Therapeutic Systems Inc. v. Qudrant Healthcare PLC, [2002] R.P.C. 21, 463.
Integra Lifescience I, Ltd v. Merck KgaA, The Scripps Research Institute, 331 F.3d 860 (2003).
Italian Republic v. Council of the European Union, Case C-295/11.
Jazz Photo Corp. v. United States ITC, 264 F.3d 1094 (2001).
John M.J. Madey v. Duke University, 307 F.3d 1351 (2002).

Judgment of the Court (Grand Chamber) of 16 April 2013 in Joined Cases C-274/11 and C-295/11.
Kabeldurchfurhrung [Cable Duct], BGH 04.02.1997 - X ZR 74/94, IIC 1999, 558.
Karate, BGH, 14. 12. 1999 - X ZR 61/98, JuS 2000, 612.
Karin-Amgen Inc. v. Hoechst Marin Roussel Ltd., [2005] R.P.C. 9.
Keeler v. Standard Folding Bed Co., 157 U.S. 659 (1895).
Kilby 3, Supreme Court vom 11.04. 2000 Hei 10 (O) 364, IIC 2004, 91.
Kingdom of Spain v Council of the European Union, Case C-147/13.
Kingdom of Spain v European Parliament and Council of the European Union, Case C-146/13.
Kingdom of Spain v. Council of the European Union Case C-274/11.
Klinische Versuche, BGH 11.7.1995 - X ZR 99/92, NJW 1996, 782.
Klinische Versuche II, BGH 11.4.1997 - X ZR 68/94, NJW 1997, 3092.
Lacktränkeinrichtung, BGH 07.01.1965 Ia ZR 151/63, GRUR 1965, 411.
Laufkranz [Flanged Tire], BGH 3.5.2006 - X ZR 45/05, GRUR 2006, 837.
LG Electronics Inc., v. Quanta Computer Inc., 453 F.3d 1364 (2006).
Machine Co. v. Murphy, 97 U.S. 120 (1878).
Mallinckrodt Inc. v. Medipart Inc. , 976 F.2d 700 (1992).
Markman v Westview Instruments, Inc. , 517 U.S. 370 (1996).
McDonald v. Graham [1994] R.P.C. 407.
Merck KGaA, Petitioner v. Integra Lifesciences I, LTD, et al., 545 U.S. 193 (2005).
Merck v. Stephar and Exler ("Modurethik"), C-187/80.
Mercoid Corp. v. Mid-Continent Inv. Co., 320 U.S. 661 (1944).
Merrell Dow Pharmaceuticals Inc. v. HN Norton & Co., Ltd., [1994] R.P.C. 1.
Mitchell v. Hawley, 84 U.S. 544 (1872).
Momenta Pharma, Inc. v. Amphastar Pharma., Inc., 686 F.3d 1348 (2012).
Monsanto Co v. Scruggs, 459 F. 3d 1328 (2006).
Monsanto Co. v. McFarling, 302 F.3d. 1291 (2002).
Monsanto Co. v. Stauffer Chemical Co., [1985] R.P.C. 515.
Monsanto Co. v. Stauffer Japan K.K., 1246 Hanrei Jiho 128 (Tokyo Dist. Ct. 1987), IIC 1989, 91.
Monsanto v. Bowmann, 686 F. SUpp. 2d 834 (2009).
Morgan Envelope Co. v. Albany Perforated Wrapping Paper Co. , 152 U.S. 425 (1894).
National Phonograph Company v. Menck, 28 R.P.C. 229 (1911).
Nesspresso Capsules, LG Düsseldorf 18.8.2012 4b O 81/12; BeckRS 2012, 17607.
Nobel's Explosives Co Ltd. v. Anderson [1984], 11 R.P.C. 519.
Octane Fitness, LLC v. ICON Health & Fitness, Inc., 134 S.Ct. 1749 (2014).
Opinion of the Court (Full Court) of 8 March 2011, Opinion 1/09.
Palettenbehälter 2 [Palett Container 2], BGH 17.7.2012 - X ZR 97/11, GRUR 2012, 1118.
Parke, Davis & Co. v. Probel and Others, C-24/67.
Parker v. Flook, 437 U.S. 584 (1978).
Pfaff v. Wells Elec. Inc., 525 U.S. 55 (1998).
Pflanzen-Transportwagen, Hanseatisches Oberlandesgericht Hamburg 18.02.1988 3 U 159/87: GRUR Int 1988, 781.
Pipettensystem, BGH 27.2.2007 - X ZR 38/06, GRUR 2007, 769.
Polyferon, BGH 05.12.1995 - X ZR 26/92, GRUR 1996, 190.
Procaterole, Tokyo High Court March 31, 1998, IIC 1999, 454.
Programs for Computers, The Enlarged Board of Appeal of the European Patent Office, G 0003/08.
Proveris Scientific Corp. v. InnovaSystems, Inc., 536 F.3d 1256 (2006).
PSN Illinois, LLC v Abbott laboratories and Abbott Bioresearch Center, Inc, U.S. Dist. LEXIS 108055 (2011).
Radio Broadcasting System, BGH 24.3.1987 X ZR 20/86, IIC 1988, 811.
Rigg, BGH 10.12.1981 X ZR 70/80, GRUR 1982, 165.
Roche Products Inc. v. Bolar Pharmaceutical Co., Inc., 733 F.2d 858 (1984).
Rollstuhlfahrrad, LG Düsseldorf 21.12.1993 4 O 235/92, GRUR 1994, 509.

Roussel Uclaf U.S. v. Hockley Inernational and Ltd. and Anr., [1996] R.P.C. 14, 441.
Ruth v. Stearns-Roger Mfg. Co., 13 F. Supp. 697 (1935).
Sanitary Refrigerator Co. v. Winters, 280 U.S. 30 (1929).
Sawin at al. v. Gulid, 21 F. Cas. 554, No. 12,391 (1813).
Schneidmesser I, BGH 12. 3. 2002 - X ZR 168/00, GRUR 2002, 515.
Schneidmesser I [Cutting Blade I], BGH 12.03.2002 - X ZR 168/00, IIC 2002, 873.
Schutz (UK) Ltd v. Werit UK Ltd., [2010] F.S.R. 22, 553.
Scripps Clinic v. Genentech, 927 F.2d 1565 (1991).
Sirdar Rubber Co. Ltd. v. Wallington, Weston & Co., [1907] 24 R.P.C. 539.
Smith Kline & French Laboratories Limited v. Evans Medical Limited, [1989] 1 F.S.R. 513.
Smith Kline and French Laboratories Ltd. v R.D. Harbottle (Mercantile) and Others, [1980] R.P.C. 363.
Solar Thomson Engineering Co. Ltd. v. Barton, [1977] R.P.C. 537.
Special Equipment Co. v. Coe, 324 U.S. 370 (1945).
Stapelbarer Transportwagen, OLG Düsseldorf 01.04.1993 2 U 96/92, GRUR 1994, 105.
State Street Bank and Trust Company v. Signature Financial Group, Inc., 149 F.3d 1368 (1998).
Stena Rederi AB v. Irish Ferries Ltd., [2002] R.P.C. 50.
Stephen Pitcairn, Agent v. The United States, 547 F.2d 1106 (1976).
Synthelabo, Nagoya Distric Court 06.03.1996, IIC 1997, 398.
T-PA 2, Osaka High Court 29.03.1996 Heisei 6(ne) 3292, IIC 1997, 391.
Tate Access Floors, Inc. v. Interface Architectural Resources, Inc. , 279 F.3d 1357 (2002).
Technip France SA's Patent, [2004] R.P.C. 46.
Terrapin v. Terranova C-119/75.
Texas Instruments, Inc., v. United States, 846 F.2d 1369 (1988).
Topliff v. Topliff, 145 U.S. 156 (1892).
United Wire Ltd. v. Screen Repairs Services (Scotland), [2001] R.P.C. 24, 439.
Vitamin Technologist, Inc. v. Wisconsin Alumni Research Foundation, 146 F.2d 941 (1945).
Westinghouse v. Boyden, 170 U.S. 537 (1898).
Whittemore v. Cutter, 29 F. Cas. 1120 (1813).
Wilbur-Ellis Co. v. Kuther 377 U.S. 422 (1964).
Wilson v. Simpson, 50 U.S. 109 (1850).
Windsurfing International, Court of Justice of the European Communities, Decision vom 25.02.1986 - Case No. 193/83, IIC 1986, 362.
Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd., [1985] R.P.C. 59.
Zwangslizenz, BPatG 07.06.1991 3 Li 1/90, GRUR 1994, 98.

3. Online Sources

"3d Systems Gets 6-Month Stay for Settlement Talks over Patent Lawsuit." Accessed 15.05.2014, http://www.sparpointgroup.com/News/Vol11No233dsuit/.
"15 Frequently Asked Questions about the 2012-2013 Ritonavir March-In Petition." Accessed 13.02.2014, Knowledge Ecology International, http://keionline.org/node/1815.
"About Adafruit Industries." Accessed 09.05.2014, https://plus.google.com/+adafruit/about.
" About Arduino." Accessed 09.05.2014, https://plus.google.com/+Arduino/about.
"About Limor Fried." Accessed 09.05.2014, https://plus.google.com/+ladyada/about.
"About Raspberry Pi." Accessed 10.05.2014, https://plus.google.com/+raspberrypi/about.
Alderman, Liz. "Nespresso and Rivals Vie for Dominance in Coffee War." Accessed 14.02.2013, http://www.nytimes.com/2010/08/21/business/global/21coffee.html.
"Annual Report 2014. Granted patents.". Accessed 11.06.2015, http://www.epo.org/about-us/amial-reports-statistics/annual-report/2014/statistics/granted-patents.html.
"Arduino." Accessed 09.05.2014, http://en.wikipedia.org/wiki/Arduino.

Atmel. "Laser Cutting and Engraving with Mr. Beam." Accessed 09.05.2014, http://atmelcorporation.wordpress.com/2014/05/09/laser-cutting-and-engraving-with-mr-beam%E2%80%A8%E2%80%A8/.
———. "President Obama proclaims National Day of Making." Accessed 19.06.2014, http://atmelcorporation.wordpress.com/2014/06/17/president-obama-proclaims-national-day-of-making%E2%80%A8%E2%80%A8/.
"Biosimilars-Info.de." Accessed 28.02.2013, www.biosimilars-info.de.
"BoingBoing." Accessed 16.05.2014, http://boingboing.net/.
"Cambia Enabling Innovation. FAQs - BiOS Agreements." Accessed 12.11.2014, http://www/cambia.org/daisy/cambia/69.html.
Chatterjee, Patralekha. "India's First Compulsory Licence Upheld, but Legal Fights Likely to Continue." Accessed 18.09.2013, http://www.ip-watch.org/2013/03/04/indias-first-compulsory-licence-upheld-but-legal-fights-likely-to-continue/.
"Chrystia Freeland: the Rise of the New Global Super-Rich." Accessed 18.04.2014, http://www.ted.com/talks/chrystia_freeland_the_rise_of_the_new_global_super_rich.
"Compulsory Licensing System for the Production and Export of Generic Medicinal Products to Developing Countries." Accessed 30.01.2014, http://europa.eu/legislation_summaries/development/sectoral_development_policies/l21172_en.htm.
Cox, Krista. "Notes from the March 18, 2013 NIH Call on the Ritonavir March-In Request." Accessed 13.02.2014, Knowledge Ecology International, http://keionline.org/node/1685.
Cullen, Amy. "Software, Patents and Interoperability - The UPC Regime and UK Implementation." Accessed 24.04.2015, Bristows. Law Firm, http://www.bristows.com/articles/software-patents-and-interoperability-the-upc-regime-and-uk-implementation

Dalakian II, Glen. "Iraq to be Reborn as Art & Science Hub through Baghdad Hackerspace." Accessed 01.07.2014, http://www.wamda.com/2012/09/iraq-reborn-art-science-hub-through-baghdad-hackerspace.
"DIY Ethic." Accessed 09.05.2014, http://en.wikipedia.org/wiki/DIY_ethic.
Doctorow, Cory "What's The Story with the Makerbot Patent?" Accessed 31.05.2014, http://boingboing.net/2014/05/30/whats-the-story-with-the-mak.html?utm_content=buffer50111&utm_medium=social&utm_source=plus.google.com&utm_campaign=buffer.
"Dorkbot. People Doing Strange Things With Electricity." Accessed 09.05.2014, http://dorkbot.org/
"Drag & Drop Programming with Pepino." Accessed 10.05.2014, http://atmelcorporation.wordpress.com/2014/05/08/drag-drop-programming-with-pepino/.
Duan, Charles. "How Amazon Got a Patent on White-Background Photography. A Drama in Five Acts: Bad Laws, Not Bad Examiners, Create Obvious Patents." Accessed 11.06.2014, http://arstechnica.com/tech-policy/2014/06/how-amazon-got-a-patent-on-white-background-photography/.
Electronic Frontier Foundation, EFF. "Find the Best Fee-Shifting Decisions." Accessed 21.02.2015, https://www.eff.org/files/2014/06/03/findthebest_fee-shifting_decisions.pdf.
———. "Join EFF's Efforts to Keep 3D Printing Open." Accessed 02.04.2014, https://www.eff.org/deeplinks/2012/10/join-effs-efforts-keep-3d-printing-open.
"Email from Michael Azrak, Merck (10 January 2014) Action Required: Agreement to Proceede with Stage 1 of IP campaign - due to Januar 15." Accessed 30.01.2014, http://keionline.org/sites/default/files/merck-email.pdf.
"EPLAW - The Unified Patent Court: EPLAW Resolution on the Draft Agreement." Accessed 23.01.2014, http://www.eplawpatentblog.com/eplaw/2011/09/eplaw-the-unified-patent-court-eplaw-resolution-on-the-draft-agreement.html.
"FabLab." Accessed 15.05.2014, http://en.wikipedia.org/wiki/Fablab.

"FORM 1: An Affordable, Professional 3D Printer by Formlabs." Accessed 09.04.2014, https://www.kickstarter.com/projects/formlabs/form-1-an-affordable-professional-3d-printer.

"Form 1+ High-Resolution 3D Printing." Accessed 09.04.2014, http://formlabs.com/products/form-1-plus/.

Fuest, Benedikt. "Die "Patenttrolle" blasen zum Sturm auf Deutschland." Accessed 24.06.2014, Die Welt Newspaper, http://www.welt.de/wirtschaft/webwelt/article124702746/Die-Patenttrolle-blasen-zum-Sturm-auf-Deutschland.html.

Gattari, Patrick, and Nicole Grimm. "Federal Courts Debate Safe Harbour Exemption for Patent Infringement under 35 U.S.C 271(E) Following Merck v. Integra." Accessed 05.02.2014, http://www.mbhb.com/pubs/xpqPublicationDetails.aspx?xpST=PubDetail&pub=247.

Generics and Biosilimars Initivative, GaBI. "Biosimilars Approved in Europe." Accessed 11.07.2015, http://gabionline.net/Biosimilars/General/Biosimilars-approved-in-Europe.

"George McKay: Professor, Writer, Musician. DIY protest." Accessed 15.05.2014, http://georgemckay.org/diy-protest/.

Giseburt, Rob. "3D Systems Suing Formlabs and Kickstarter for Patent Infringement." Accessed 09.04.2014, http://makezine.com/2012/11/21/3d-systems-suing-formlabs-and-kickstarter-for-patent-infringement/.

"Global Enterpreneurship and Maker Space Initative." Accessed 01.07.2014, www.gemsi.org.

Gokhale, Ketaki "Merck to Bristol-Myers Face More Threats on India Patents." Accessed 31.01.2014, http://www.bloomberg.com/news/print/2014-01-21/merck-to-bristol-myers-face-more-threats-on-india-patents.html.

Gonzales Otero, Begona. "On the Fence of Article 27(K) of the UPC: The Software Interoperability "Limitation"." Accessed 24.04.2015, http://kluwerpatentblog.com/2014/11/14/on-the-fence-of-article-27k-of-the-UPC-the-software-interoperability-limitation.html.

"Hackerspaces." Accessed 15.05.2014, http://hackerspaces.org/wiki/.

Hornick, John, and Dan Roland. "Many 3D Printing Patents Are Expiring Soon: Here's A Round Up & Overview of Them." Accessed 17.05.2014, http://3dprintingindustry.com/2013/12/29/many-3d-printing-patents-expiring-soon-heres-round-overview/.

Howard, Alex. "The Maker Movement's Potential for Education, Jobs and Innovation is Growing." Accessed 09.05.2014, http://radar.oreilly.com/2011/11/dale-dougherty-make-white-house.html.

Hull, Dana. "Tesla Motors Making Patents Public." Accessed 13.06.2014, http://www.mercurynews.com/business/ci_25949696/tesla-ceo-elon-musk-all-our-patented-tech.

IIPA, International Intellectual Property Alliance. "Special 301." Accessed 30.01.2014, http://www.iipa.com/special301.html.

Inc., Apotex. "Submission to the Standing Committee on Industry, Science and Technology Bill C-393; an Act to Amend the Patent Act (Drugs for International Humanitarian Purposes) and to Make a Consequential Amendment to Another Act." Accessed 15.11.2013, http://www.apotex.com/global/docs/submission_order_en.pdf.

"International HapMap Project." Accessed 21.11.2014, http://hapmap.ncbi.nlm.nih.gov/.

"Introducing EFF's Stupid Patent of the Month." Accessed 31.07.2014, https://www.eff.org/deeplinks/2014/07/inaugural-stupid-patent-month?utm_content=bufferff516&utm_medium=social&utm_source=plus.google.com&utm_campaign=buffer.

"IPXI Trading Innovation." Accessed 24.03.2015, https://www.ipxi.com/.

"KEI RN 2007:2 Recent Examples of Compulsory Licensing of Patents." Accessed 30.11.2013, http://keionline.org/content/view/41/1.

Kerstetter, Jim. "How much is that patent lawsuit going to cost you?" Accessed 21.02.2015, http://www.cnet.com/news/how-much-is-that-patent-lawsuit-going-to-cost-you/.

"Kickstarter Project by MURIS: Maker - A Documentary on the Maker Movement." Accessed 16.06.2014, https://www.kickstarter.com/projects/379201360/maker-a-documentary-on-the-maker-movement.
Lahart, Justin. "Tinkering Makes Comeback Amid Crisis." Accessed 16.04.2014, http://online.wsj.com/news/articles/SB125798004542744219.
"Latanoprost (Xalatan)." Accessed 30.11.2013, http://www.essentialinventions.org/drug/latanoprost.html.
Leiden, Jeffrey M. "Abbott Laboratories Comments at NIH Public Meeting Regarding Norvir® and Bayh-Dole March-in Provisions." Accessed 12.02.2014, http://www.natap.org/2004/HIV/060104_04b.htm.
"Limor Fried." Accessed 09.05.2014, http://en.wikipedia.org/wiki/Adafruit.
"LITTLE DEVICES @ MIT Affordable Health | Medical Technology | DIY Innovation." Accessed 04.04.2014, http://littledevices.org/.
Lloyd, Richard. "Conversant Launches New Anti-Patent Troll Campaign." Accessed 06.10.2014, http://www.iam-magazine.com/Blog?Detail.aspx?g=18d8fcc6-5ab0-43c4-82b-db50581b4e3c.
———. "Lemley: The Case for Congressial Patent Reform is Far Weaker Than It Was a Year Ago." Accessed 02.06.2015, http://www.iam-media.com/Blog?Detail.aspx?g=28572386-7cf9-4003-8513-12f3edb914a0.
Love, James. "Four NGOs ask NIH to Grant Open Licenses to Ritonavir Patents under Bayh-Dole March-In Provisions." Accessed 3.12.2013, Knowledge Ecology International, http://keionline.org/node/1573.
"MAKE:." Accessed 16.05.2014, http://makezine.com/.
"MAKE: FAQs." Accessed 15.05.2014, http://makezine.com/faq/.
"Maker Faire a Bit of History." Accessed 15.05.2014, http://makerfaire.com/makerfairehistory/.
"The Making of PI." Accessed 10.05.2014, http://www.raspberrypi.org/about/.
Makoni, Manyaradzi. "South Africa awaits Patent Reforms with Hope, Concern." Accessed 08.05.2015, Intellectual Property Watch, http://www.ip-watch.org/2015/02/27/south-africa-awaits-patent-reforms-with-hope-concern/.
"Massimo Banzi: How Arduino is Open-Sourcing Imagination." Accessed 09.05.2014, https://www.ted.com/talks/massimo_banzi_how_arduino_is_open_sourcing_imagination.
Meredith, Dennis. "Patent Policy Flaws Complicate Commercialization of Federally Funded University Discoveries. New Case Study of Cellpro Calls for Changes in the Bayh-Dole Act." Accessed 30.11.2013, http://www.eurekalert.org/pub_releases/2002-12/du-ppf120602.php.
Millien, Raymond. "Landscape 2013: Who are the Players in the IP Marketplace?" Accessed 04.05.2014, http://www.ipwatchdog.com/2013/01/23/ip-landscape/id=33356/.
Molitch-Hou, Michael. "Afinia Puts Up Its Dukes to Defend Against Stratasys Lawsuit." Accessed 20.05.2014, http://3dprintingindustry.com/2014/01/03/afinia-puts-dukes-defend-stratasys-lawsuit/.
"Mr Beam, a Portable Laser Cutter and Engraver Kit." Accessed 09.05.2014, https://www.kickstarter.com/projects/mrbeam/mr-beam-a-portable-laser-cutter-and-engraver-kit.
Mulier, Tom "Nespresso Will Survive `Plethora' of Knock-Offs, Inventor Says." Accessed 14.02.2013, http://www.bloomberg.com/news/2011-01-30/nespresso-will-survive-plethora-of-knock-offs-inventor-says.html.
Musil, Steven. "Patent Reform Bill Targeting Patent Trolls Shelved in Senate." Accessed 14.06.2014, http://www.cnet.com/news/patent-reform-bill-targeting-patent-trolls-shelved-in-senate/.
Musk, Elon. "All Our Patent Are Belong to You." Accessed 13.06.2014, http://www.teslamotors.com/blog/all-our-patent-are-belong-you.

Noonan, Kevin. "Nih Declines to Exercise March-In Rights over Abbott Laboratories' Norvir®." Accessed 08.05.2015, Patent Docs, http://www.patentdocs.org/2013/11/nih-declines-to-excercise-march-in-rights-ver-abbott-laboratories-norvir.html.

"Notes on the Bayh-Dole Act of 1980." Accessed 2.12.2013, Knowledge Ecology International, http://keionline.org/bayh-dole.

Pagenberg, Jochen. "Unitary Patent and Unified Patent Court - Resolution." Accessed 22.01.2014, http://www.eplawpatentblog.com/2011/November/EPLAW%2020Resolution%2020on%2020Regulation%202029%2020Oct%20202011%5B1%5D.pdf.

"Patent Progress's Guide to Federal Patent Reform Legislation." Accessed 01.10.2014, http://www.patentprogress.org/patent-progress-legislation-guides/patent-progresss-guide-federal-patent-reform-legislation/.

"Project Pepino." Accessed 09.05.2014, http://pepino.tovilevis.com/.

"Raspberry Pi." Accessed 10.05.2014, http://en.wikipedia.org/wiki/Raspberry_Pi.

"Registry of Standard Biological Parts." Accessed 12.11.2014, http://parts.igem.org/Main_Page?title=Main_Page.

"RepRap Project." Accessed 10.05.2014, http://en.wikipedia.org/wiki/RepRap_Project.

"RepRap.org." Accessed 09.05.2014, https://plus.google.com/communities/108419464619607320823.

Representative, U.S. Trade. "USTR Releases Annual Special 301 Report on Intellectual Property Rights." Accessed 30.01.2014.

"The Request of Essential Inventions, Inc to Robert Portman, dated 5 January 2007 ". Accessed 13.02.2014, http://www.essentialinventions.org/eii2omb-5jan07.pdf.

"Research on the Maker Movement." Accessed 29.09.2015, https://docs.google.com/document/d/1yRyWCpd1IpTuyM7ck6xWOvAzbqNmo9B1vKRbOu_-MeE/edit#.

Reuters. "Nestle Wins Nespresso Patent Battle." Accessed 14.02.2013, http://www.reuters.com/article/2012/04/19/nestle-nespresso-idUSL6E8FJE0F20120419.

"Ritonavir (Norvir)." Accessed 30.11.2013, http://www.essentialinventions.org/drug/ritonavir.html.

"Seven Things to Know about Kickstarter." Accessed 15.05.2014, https://www.kickstarter.com/hello?ref=footer.

Sharma, Rakesh. "Afinia Refuses to Buckle Down Against Stratasys; Claims Patent Misuse." Accessed 20.05.2014, http://www.forbes.com/sites/rakeshsharma/2014/01/03/afinia-refuses-to-buckle-down-against-stratasys-claims-patent-misuse/.

———. "Why Stratasys Sued Afinia." Accessed 14.05.2014, http://www.forbes.com/sites/rakeshsharma/2013/12/03/why-stratasys-sued-afinia/.

Sherman, Erik. "Patent Life Spans Shorter than Law Allows." Accessed 19.03.2014, http://www.cbsnews.com/news/patent-life-spans-shorter-than-law-allows/.

Silverman, Ed. "As Pharma Eyes Patent Changes in South Africa, a Government Minister Cries 'Genocide'." Accessed 31.01.2014, http://www.forbes.com/sites/edsilverman/2014/01/18/as-pharma-eyes-patent-changes-in-south-africa-a-government-minister-cries-genocide/.

———. "South Africa embraces Compulsory Licensing over AIDS Crisis." Accessed 13.11.2013, http://www.pharmalive.com/south-africa-embraces-compulsory-licensing-dueto-aids-crisis.

"South Africa, Pharmaceutical Industry face off on Patent Reform." Accessed 08.05.2015, International Centre for Trade and Sustainable Development, Bridges Africa (3, No.1), http://www/ictsd.org/bridges-news/bridges-africa/news/south-africa-pharmaceutical-industry-face-off-on-patent-reform-0.

"Stand up to the Demand Brought to You by Conversant." Accessed 06.10.2014, http://www.standuptodemand.com.

"Stiftung Jugend Forscht e. V.". Accessed 16.10.2014, http://www.jugend-forscht.de.

Taylor, Lynne. "S Africa pledges Action on Compulsory Licenses, Parallel Imports." Accessed 31.01.2014, PharmaTimes Online, http://www.pharmatimes.com/article/13-11-07/S_Africa_pledges_action_on_compulsory_licenses_parallel_imports.aspx#ixzz2rzkKHxvA

Technology, Consumer Project on. "Chapter IV: Misc Compulsory Licensing Programs." Accessed 30.11.2013.

"TechShop - About." Accessed 09.05.2014, https://plus.google.com/+TechShop/about.

"TechShop. Build Your Dreams Here." Accessed 09.05.2014, http://techshop.ws/index.html.

Teschemacher, Rudolf "EU - Unitary Patent / Actions Spain and Italy Against Enhanced Cooperation Dismissed." Accessed 22.01.2014, http://www.eplawpatentblog.com/eplaw/2013/04/eu-unitary-patent-actions-spain-and-italy-against-enhanced-cooperation-dismissed-.html.

"tlevis/Pepino." Accessed 10.08.2014, https://github.com/tlevis/Pepino.

Torgovnick May, Kate. "Urinalysis: There's Now An App For That." Accessed 03.11.2013, http://blog.ted.com/2013/05/15/urinalysis-theres-now-an-app-for-that/.

UK IPO, Intellectual Property Office. "Swansea Imports Ltd. v. Craver Technology Ltd, BL Number O/170/04." Accessed 28.11.2013, http://www.ipo.gov.uk/pro-types/pro-patent/pro-p-os/p-challenge-decision-results-bl?BL_Number=O/170/04.

"Ultra-Bot 3D Printer by William Steele." Accessed 16.04.2014, https://www.kickstarter.com/projects/wjsteele/ultra-bot-3d-printer/posts/362886.

"Ultra-Bot 3D Printer by William Steele. Questions about Open Source and our Patent Application." Accessed 03.04.2014, https://www.kickstarter.com/projects/wjsteele/ultra-bot-3d-printer/posts/362886.

"Unofficial Translation of Japan's Patent Act (Act No. 121 of 1959) ". Accessed 17.12.2012, http://www.jpo.go.jp/shiryou_e/s_sonota_e/fips_e/mokuji_e.htm#japan.

"US Keeps Thailand on Intellectual Rights Watch List." Accessed 07.05.2015, Bangkok Post, http://www.bangkokpost.com/news/general/548239/us-keeps-thailand-on-intellectual-rights-watch-list.html.

USPTO. "Answers to Common Questions about Abusive Patent Ligitation." Accessed 17.10.2014, http://www.uspto.gov/patents/litigation/index.jpg.

Watch, Intellecutal Property. " Bayer will appeal India Compulsory Licence on Its Cancer Drug." Accessed 18.09.2013, http://www.ip-watch.org/2013/03/05/bayer-will-appeal-india-compulsory-licence-on-its-cancer-drug/

Weinberg, Michael. "Afinia Responds to Stratasys II: You Failed To Disclose Old Patents, Printers." Accessed 14.05.2014, http://makezine.com/2014/01/31/afinia-responds-to-stratasys-ii-you-failed-to-disclose-old-patents-printers/.

———. "Afinia Responds to Stratasys: Your Patents Are Invalid and Your Threats are Anti-Competitive." Accessed 14.05.2014, http://makezine.com/2014/01/03/afinia-responds-to-stratasys-your-patents-are-invalid-and-your-threats-are-anti-competitive/.

———. "Stratasys Drops One Patent from Its Lawsuit Against Afinia." Accessed 01.09.2014, http://makezine.com/2014/08/05/stratasys-drops-one-patent-from-its-lawsuit-against-afinia/.

Weinberg, Michael "Stratasys Sues Afinia: Ramifications for the Desktop 3D Printing Industry." Accessed 10.05.2014, http://makezine.com/2013/11/27/stratasys-sues-afinia-ramifications-for-the-desktop-3d-printing-industry/.

WIPO. "Questionnaire on Exceptions and Limitations to Patent Rights." Accessed 17.07.2013, http://www.wipo.int/scp/en/exceptions/.

"Xalatan/Norvir - DHHS Secretary Thompson Asked to Grant Generic Manufacturers Licenses to Patents on Government Funded Inventions for Treatment of Glaucoma and Aids." Accessed 12.02.2014, http://www.essentialinventions.org/media/pr-29jan04.html.

4. Public Documents

AIPPI. "Germany. Report Q175. The Role of Equivalents and Prosecution History in Defining the Scope of Patent Protection."

———. "Japan. Report Q175. The Role of Equivalents and Prosecution History in Defining the Scope of Patent Protection."

———. "Japan. Report Q187. Limitation on exclusive IP Rights by competition law."

———. "Japan. Report Q202. The Impact of Public Health Issued on Exclusive Patent Rights."

———. "United Kingdom. Report Q187. Limitations on exclusive IP Rights by competition law."

———. "United States of America. Report Q187. Limitations on exclusive IP Rights by competition law."

"COMMISSION DIRECTIVE 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use." Official Journal of the European Union, L 159/46, 27.6.2003.

"COUNCIL DECISION of 10 March 2011 authorizing enhanced cooperation in the area of the creation of unitary patent protection (2011/167/EU)." Official Journal of the European Union, L 76/53, 22.3.2011.

"COUNCIL REGULATION (EC) No 2100/94 of 27 July 1994 on Community plant variety rights." (

"COUNCIL REGULATION (EC) No 2100/94 of 27 July 1994 on Community plant variety rights ". Official Journal of the European Communities, L 227/1, 1.9.1994.

"COUNCIL REGULATION (EU) No 1260/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements." Official Journal of the European Union L 361/89, 31.12.2012.

"Declaration on the TRIPS Agreement and Public Health. Adopted on 14 November 2001." Doha WTO Ministerial 2001, WT/MIN(01)/DEC/2, 2001.

"DIRECTIVE 98/44/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 July 1998 on the legal protection of biotechnological inventions." Official Journal of the European Communities L 213/13, 30.7.1998.

"DIRECTIVE 2001/82/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 November 2001 on the Community code relating to veterinary medicinal products." Official Journal of the European Communities L 311/1, 28.11.2001.

"DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 November 2001 on the Community code relating to medicinal products for human use." Official Journal of the European Communities L 311/67, 28.11.2001.

"DIRECTIVE 2004/27/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use." Official Journal of the European Union, L 136/34, 30.4.2004.

"DIRECTIVE 2004/48/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on the enforcement of intellectual property rights. (Text with EEA relevance)." Offical Journal of the European Union L 195/16, 2.6.2004.

"DIRECTIVE 2009/24/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 April 2009 on the legal protection of computer programs." Official Journal of the European Union, L 111/16, 5.5.2009.

"Examination Guidelines for Patent and Utility Model in Japan, as of April 2012." http://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/1312-002_e.htm (accessed 17.6.2013).

"Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. Decision of the General Council of 30 August 2003." WT/L/540 and Corr. 1, 1 September 2003.

Kappos, David J., and Teresa Rea Stanek. "Report on Prior User Rights." USPTO, 2012.

Leahy–Smith America Invents Act. Public Law 112–29—Sept. 16, 2011.

Longchambon, Henri. "Creation of a European Patent Office." In *Report of the Committee on Economic Affairs and Development of the Council of Europe*, 6 Septemeber 1949.

"Measuring Innovation. A new Perspective." OECD, 2010.

"The Plant Variety Protection Law (consolidated text of December 19, 1997)." PVP Gazette 86, December 1999.

"Proposal for a Council Decision Authorizing Enhanced Cooperation in the Area of the Creation of Unitary Patent Protection ". European Commission, COM (2010) 790, 2010/0384, 14 December 2010.

"Protocol on the Interpretation of Article 69 EPC." European Patent Office, the new text adopted 28 June 2001.

"REGULATION (EC) No 816/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems." Official Journal of the European Union, L 157/1, 9.6.2006.

"REGULATION (EC) No 1901/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 001/83/EC and Regulation (EC) No 726/2004." Official Journal of the European Union L 378/1, 27.12.2006.

"REGULATION (EC) No 1902/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 20 December 2006 amending Regulation 1901/2006 on medicinal products for paediatric use." Official Journal of the European Union L 378/20, 27.12.2006.

"REGULATION (EU) No 1257/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection ". Official Journal of the European Union L 361/1, 31.12.2012.

"REGULATIONS REGULATION (EC) No 469/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 May 2009 concerning the supplementary protection certificate for medicinal products." Official Journal of the European Union L 152/1, 16.6.2009.

Schacht, Wendy H. , and John R. Thomas. "CRS Report for Congress The “Hatch-Waxman” Act: Selected Patent- Related Issues ", 2002.

UK IPO, Intellectual Property Office. "Manual of Patent Practice." 2013.

WIPO. "Patent Related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels." CDIP/5/4 Rev., http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=131629, 2010.

———. "Questionnaire on Exceptions and Limitations to Patent Rights. Germany." http://www.wipo.int/scp/en/exceptions/replies/germany.html.

———. "Questionnaire on Exceptions and Limitations to Patent Rights. Japan." http://www.wipo.int/scp/en/exceptions/replies/japan_2.pdf.

———. "Questionnaire on Exceptions and Limitations to Patent Rights. The United Kingdom." http://www.wipo.int/scp/en/exceptions/replies/uk2.pdf.

———. "Survey on Compulsory Licenses Granted by WIPO Member States to Address Anti-Competitive Uses in Intellectual Properties Rights - CDIP/4/4 REV./STUDY/INF/5." 2011.

WTO. "Canada – Patent Protection of Pharmaceutical Products. Complaint by the European Communities and Their Member States." WT/DS114/R, 2000.