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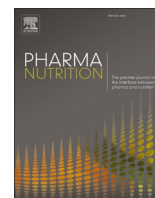
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To patent or not to patent? Consideration of the societal aspects of patenting across pharma-nutrition industries

As we have shown before, patenting is of paramount importance across pharma-nutrition industries [1]. By enabling actors to reap the benefits of investments in the development of new products and services, patents are seen as a key driver for innovation and business performance [1]. When investments in innovative products do not lead to successful introduction of novel products on the market, return on investments and subsequently the willingness for further investments are limited. Ultimately, disbelief in the potential of innovations to address unmet needs may lead to a lack of societal demand in a faulty valorisation cycle, and bring innovation to a halt, as shown for the probiotics industry [2]. The driving force of patents is thus not only important for actors in the business and development domain, but ultimately also for stakeholders in the market and society domains.

At the same time, the patent system has sparked fierce debate among economists, policy makers, legal scholars and industry stakeholders. For some years, critique on its validity, efficacy and fairness has been increasing [3]. Though stimulating industrial innovation and societal welfare is at the core of the system's objective, commentators have often concluded that empirical evidence is too thin or contradictory to support such intended effects [4]. Empirical studies on patents' potential to improve the innovative capacity of industries have proven to be rather complicated as it is difficult to distinguish between patent based incentives and other incentives in relation to market dynamics. Many interrelated factors influence R&D investments, innovation and the resulting societal impact, making it challenging to determine the independent effect of patents. Given that the majority of innovation barriers in the pharma-nutrition industry occur in the market and society domains [5], timely consideration of this impact is of crucial importance to prevent societal aspects of patenting from turning into innovation barriers themselves.

Here we provide a brief overview of major arguments for and against the patent system, complementing previously conducted studies on valorisation and technology transfer in innovative markets. Our aim is to outline the ongoing debate surrounding the topic and to highlight some of the commonly heard views and beliefs of stakeholders on the impact of patenting on society.

1. A brief history of the patent system: three waves of societal debate

The foundation of the IP system has been present since the 17th century and has ever since been a subject of debate. The first wave of the IP debate occurred in Britain in the 19th century when critical perspectives emerged based on the principles of free trade [6]. Well-known

inventors, economists, entrepreneurs, scientists and legal scholars were amongst the prominent activists. These liberals battled against protectionism and argued that free trade and competition should always be warranted as they stimulate and strengthen the economy. The debate peaked in the mid-1800s and is still considered one of the strongest campaigns ever undertaken against IP, almost leading to a complete abolishment of the patent system. Within that time, similar debates took place in other European countries, resulting in a delayed introduction of patents in Switzerland and a complete abolishment in the Netherlands from 1869 to 1912.

The second wave of the patent controversy is characterized by Fritz Machlup and the US Congressional debates in the mid-1900s. At that time, the Federal Trade Commission urged the US government to replace patents with compulsory licensing due to the fear that patents were helping corporations to monopolise whole industries. This advice was ignored by lawmakers as they believed the patent system could be perfected by another round of reforms. Commissioned by the US Subcommittee on Patents, Trademarks and Copyrights, Fritz Machlup was assigned to conduct a comprehensive economic review of the patent system [7]. In his report he voiced concerns of economists on the value of the system for society which claimed that in many cases patents were unnecessary to encourage innovation. Machlup's own view, however, was less conclusive, stating that there were no good models to replace the IP system and that it served useful purposes.

The final wave of the debate is currently taking place and concerns the global North-South IP asymmetry in international IP regimes. This North-South polarization has been of interest to academia, but attention amongst economists to specific issues of geographical IP protection is also growing. More so since the interrelation of IP and innovation in developing regions appears more complex and less understood [8]. Yet, the 1994's WTO's Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) made minimal IP rights mandatory in all WTO countries thereby further increasing the scope of international IP protection. While some argue it makes sense to further harmonize the procedures for securing IP internationally, experts warn for a growing IP divide, and the post-TRIPS period has revealed an ever-increasing polarisation between proponents and opponents of strong IP rights [9]. With the advent of the Nagoya Protocol, the relevance of securing access to asymmetrically distributed resources that lay at the foundation of new IP has been underscored even further [10].

2. The need for a contemporary view of the patent system

It has been over 60 years since Machlup conducted his

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comprehensive review on the patent system. In the meantime, supported by an increasing amount of empirical data, our collective potential to understand patents and their impact on society has grown significantly. Despite more data, however, it appears we are no closer to any convincing answer on the appropriateness of patents as a tool to stimulate innovation and benefit the public. Moreover, the debate on patents, often seen as a social contract between the inventor and society, appears skewed towards the value of patents for the inventor and the industry, only to a lesser extent taking into account the benefits and drawbacks for society.

With the democratization of science and innovation [11], more stakeholders have joined the debate on the societal impact of patenting. To bring the debate beyond its previously monodisciplinary view, we set out to gather an overview of contemporary views on benefits and drawbacks of the patent system, clustering them into societal impact domains described before [12]. This overview, shown in Table 1, outlines that societal impact transcends the themes of industrial innovative productivity and invention disclosure, and includes cost-benefit trade-offs in the research and knowledge generation domain, the industry and

business development domain, the market domain, and the society and policy domain.

Importantly, this stresses that the impact of the patent system cannot be seen separately from their wider societal impact. Here, we do not intend to come to an overall conclusion on the desirability or effectiveness of patents for society, nor aim to validate the arguments mentioned by proponents and opponents of the system. This editorial, however, should be read as a call to action for all those engaged in the IP debate that changes or revisions to the system should be made with caution. We have done so by stating commonly heard views and beliefs on the impact of patenting for society at large in the Table. As this endeavor might have missed relevant views, we believe that a comprehensive review of contemporary arguments and evidence is needed to fully understand the complexity of the patent system and the impact it has on society.

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Table 1
Arguments expressed in favor of and against the patent system encompass science, business, market and society domains.

	Arguments expressed in favor of patenting	Arguments expressed against patenting
A) Research and knowledge generation domain	<p>Provide incentive to commercialize research Patents provide incentives to (academic) research institutions to engage in translational research and further develop and commercialize the outcomes of publicly funded basic research, since these institutions retain the IP in inventions they develop under government-funded research programs.</p> <p>Promote dissemination of research Patents promote the dissemination of new research and technologies through compulsory publication. Without patenting, secrecy (i.e. trade secrets) becomes the primary tool to safeguard IP and appropriate innovation. Instead, patents facilitate knowledge sharing, and building on existing knowledge by requiring the details of the invention to be placed in the public domain.</p>	<p>Discourages to conduct research pursued elsewhere Patents and their market monopoly delay or discourage researchers from embarking on a course of research that is already being pursued elsewhere, despite the possibility that they may do better or more efficient work only because the first to invent or apply will be awarded a patent protection and granted a limited monopoly.</p> <p>Inhibit knowledge sharing and dissemination Patents inhibit research and knowledge sharing prior to filing for patent protection due to fear of creating novelty-destroying prior art. This renders researchers and companies initially more secretive in order to retain patentability. As such, the result of new research and details of an invention may be withheld until an inventor is in a position to apply for a patent.</p>
B) Industry and business development domain	<p>Attract funding for new market entrants Patents are a tool to signal the value and innovative potential of a company to investors. They can assist in obtaining funding for startup companies and thus increase the entry of new specialist into a market.</p> <p>Enhance bargaining power for small companies Patents and their market monopolies are, in principle, attainable for all types of stakeholders, regardless of their current market power or position. Strong patents enhance bargaining power for small and medium-sized enterprises when negotiating with larger firms.</p>	<p>Control and hinder competitors The vast bulk of patents have no innovation potential and are used primarily as tools to control and hinder competition through thickets. These thickets hinder innovation and new market entrants as it discourages firms from entering into markets out of fear of litigation.</p> <p>Privilege large established companies Patents are increasingly reserved for firms with extensive financial resources due to patent-associated costs (e.g. application procedures and patent attorneys). Additionally, enforcing patents requires resources for investigation and litigation. These resources are unequally distributed over R&D actors, therefore primarily benefiting large incumbent companies.</p>
C) Market domain	<p>Stimulate high risk R&D of products and services Patents grant limited monopolies allowing for marketing of products/services at premium prices, thereby stimulating investments in high-risk R&D and innovative productivity. Society benefits through new and improved products and services reaching the market and addressing unmet needs.</p> <p>Stimulate competition and increase product quality Patents offer market power and facilitate market entry of new firms, leading to increased competition in upstream and downstream markets. As a result, consumer prices may fall and product quality and consumer choice may increase.</p>	<p>Allow for artificially high pricing Society is paying a higher price for goods and services since patents grant a limited monopoly, enabling for artificially high, and potentially even unreasonable, pricing. Also, patent-related costs for companies that utilize protected inventions are high and are often transferred to the consumer, hindering the access to technology and services.</p> <p>Incentive weak for unprofitable markets The patent incentive is weak for unprofitable markets and for innovations that are not commercially marketable. An inventor's rationale to use patents is weakened when the end user is not able to pay for the end product, or when the inventor is forced by regulations to sell the product for a lower price.</p>
D) Society and policy domain	<p>Increase foreign direct investments Strong patent regimes with short application and examination times at patent office's increase the flow of foreign investments into a country and its patent heavy sectors.</p> <p>Invention details accessible to everyone in society Patents are indexed with IPC/CPC codes by independent reviewers which renders information on new inventions easier to retrieve than through other forms of (scientific) publications.</p>	<p>Approval process hinders fast moving industries Delays in the patent office hinder startups with high growth potential from obtaining financing in crucial early stages. The slow, fragmented and expensive bureaucratic system is problematic for fast moving industries and small and medium enterprises.</p> <p>Only accessible to the expert IPC/CPC indexing are excessively complex which limits their reasonable use to the highly trained and skilled in the arts. This is especially true, considering the readily available alternatives such as search engines that can be used for other domains of information.</p>

agencies in the public, commercial, or not-for-profit sectors.

Declaration of Competing Interest

The authors report no declarations of interest.

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