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Evans, GE

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University patent licensing for the research and development of pharmaceuticals in developing countries

Gail E. Evans

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***I.P.Q. 311** More than 80 per cent of the world's population lives in developing countries where communicable diseases account for 50 per cent of the disease burden.¹ The opening Recital of World Health Organization's *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property* affirms the need to construct a sustainable basis for research and development relevant to diseases that disproportionately affect developing countries.² Regrettably, the factors that drive pharmaceutical innovation are often biased against the kinds of diseases that are disproportionately found in low-income countries.³ Innovation to address diseases primarily affecting the poor ***I.P.Q. 312** is impeded by a combination of under-investment by the public sector and market failure.⁴

WHO Member States recognise that the global network of universities and publicly funded research institutions have a key role to play in the research and development (R & D) of medicines for neglected diseases, frequently in partnership with the private sector.⁵ The Bayh-Dole model of technology transfer⁶ encourages PROs to seek patent protection for inventions made using public funds and to license those inventions to the pharmaceutical industry with the goal of promoting their commercialisation and public availability.⁷

However, in view of the long duration and high cost of innovation, when negotiating with a university patentee pharmaceutical companies will normally seek an exclusive patent licence.⁸ The grant of an exclusive licence confers powers on the licensee that are equivalent to those of the proprietor insofar as it permits only the licensee and persons authorised by the licensee to exploit the invention.⁹ Under international patent ***I.P.Q. 313** law this gives the licensee exclusive rights of manufacture and sale of the invention for a 20-year term to the exclusion of the patentee.¹⁰ An exclusive licence will also exclude the licensor from using the invention. For example, assume that in 2000, the University of Distopia received a patent for a new vaccine against tuberculosis. Two years later the university granted an exclusive licence to Pharmco to develop and test the product. In 2009, almost 10 years after obtaining the patent, the vaccine is given regulatory approval. On the one hand, without exclusive access to the technology, Pharmco might not be prepared to take the risk of investing the resources necessary to develop the vaccine into a marketable product. The major pharmaceutical companies consider the market exclusivity and higher prices made possible by patent protection particularly important, owing to the large investment in research and clinical testing required prior to sale, and because the actual manufacturing process is relatively cheap and easy to replicate.¹¹

On the other hand, there is considerable debate about whether PROs should grant Pharmco an exclusive licence thereby potentially limiting further research and restricting dissemination of the technology.¹² The problem is that an exclusive licence to Pharmco, without due consideration of future development, tends to inhibit the ability of PROs to have a meaningful role in monitoring the development and future use of health technology. A recent illustrative response is to be found in the proposed changes to the Regulations accompanying South Africa's Intellectual Property Rights from Publicly Financed Research and Development Act,¹³ which would see funding recipients having to ensure that before granting an exclusive licence, the agreement contains terms requiring the licensee to provide a development plan and to ensure that the benefits of the intellectual property are reasonably accessible to the people of the Republic.¹⁴

As the South African proposal indicates, depending upon the goals and expectations with which the parties negotiate terms, there is considerable flexibility within the licensing agreement. The intersection of property and contract law provides an opportunity for university licensors in leading developing countries to reclaim the policy space needed in overcoming obstacles associated with pharmaceutical R & D. Given the importance of licensing to the development and availability of new products, licensing should be governed by terms that seek to meet commercialisation benchmarks; to

keep the licensed technology reasonably accessible to researchers; and ***I.P.Q. 314** to modify or terminate the contract if the public's reasonable health care needs are not met.

This article advances various licensing strategies that would allow universities and public research organisations¹⁵ (PROs) to negotiate with business partners in order to obtain the optimal development of pharmaceutical products. It aims to identify the goals of licensing policy for PROs in developing countries; and to examine the kinds of restriction and reservation clauses that PROs should consider including in patent licensing agreements. By such means, the author argues, developing countries can achieve a more appropriate balance between the needs of the pharmaceutical industry for patent protection and those of PROs to disseminate knowledge as broadly as possible among the research community.

In the exposition of this argument, this article is organised as follows: the first part examines various models of technology transfer from university to the business sector, in relation to patent licensing by universities in developing countries. The second part explains how public-private partnerships for drug development with universities and health institutes in developing countries, has been facilitated by the restructuring of the pharmaceutical industry and the entry of new manufacturing companies from India and China. The third part explains how universities in developing countries might utilise a mix of exclusive and non-exclusive licences in order to promote R & D. The fourth part offers drafting guidelines for restriction clauses as to field of use, territory and rights to improvements, in the light of European competition law. The fifth part explains the legal status and importance of negotiating exemptions for research and experiment use. The sixth part provides guidance for the drafting of reservation clauses for publication and access rights to scientific data. The article concludes with a recommendation for a termination clause in the licensing agreement capable of preserving rights negotiated for the use and dissemination of research.

TECHNOLOGY TRANSFER FROM UNIVERSITY TO INDUSTRY IN THE DEVELOPING WORLD

The modern university has become an important source for the direct application of scientific research to identifiable and pressing needs in medicine and the health sciences; and for the patenting of those inventions. Today, PROs play a crucial role in promoting the R & D of pharmaceuticals at each stage of the process, from the exchange of scientific data¹⁶ and personnel, to the facilitation of public-private partnerships for clinical trials ***I.P.Q. 315** and product manufacture.¹⁷ However, questions remain concerning the ostensible conflict of interests between the mission of PROs to conduct basic research in the public interest and those of the private sector to commercialise the results of publicly funded research. This debate becomes all the more acute in the case of developing countries, where questions arise as to the appropriate model for university-industry licensing. The author will begin with an appraisal of the Bayh-Dole model and its alternatives, before considering the relevance of these models to university-industry technology transfer in developing countries.

The Bayh-Dole Model

The United States Bayh-Dole Act of 1980¹⁸ established the "licensing" model of technology transfer from universities to the private sector. With the aim of encouraging the development of technologies based on university research, the Bayh-Dole legislation allows universities to patent inventions arising from publicly funded research. By this means universities may retain ownership rights over government funded research and license inventions on a non-exclusive or exclusive basis.¹⁹ The Bayh-Dole model requires universities establish a centralised technology transfer office (TTO) for the development and commercialisation of research. The TTOs are responsible for evaluating inventions, filing for patent applications on behalf of the university and finding a suitable licensee within the business sector.²⁰

***I.P.Q. 316** The focus of the Bayh-Dole model is to transfer title from individual researchers to PROs.²¹ It is a patent-centric model of R & D,²² characterised by the diligent filing of applications and the retention of ownership rights for transfer to the private sector through licensing. The 20-year term of patent protection permits prices that are higher than the marginal price of manufacturing. This exclusivity is said to constitute an incentive for the initial research and development of new health products.²³ The harm flowing from lessening competition by means of imitation is said to be outweighed by the advantage flowing from more innovation.²⁴

When it comes to making investments in order to transform the university-generated knowledge about

neglected diseases into a commercial application, the notional incentive becomes problematic.²⁵ The notion that patent protection would provide a financial incentive to drug firms to invest for tropical diseases has not materialised. The redistribution of resources to the private sector accompanied by the introduction of patents will not alone trigger the development of more drugs specifically related to the needs of the poor.²⁶ Even the relative boost in research and development for antiretroviral therapy is due to the fact that epidemics also involve developed countries. There is said to be a market failure for medicines in developing countries. Low-income countries do not constitute a market capable of inducing patent-driven investment.²⁷ In the majority of countries in Africa the profits have not existed to attract commercial development and public funding for diseases has been difficult to obtain and sustain.²⁸

***I.P.Q. 317** The Bayh-Dole model rests on the tidy hypothesis that innovation should spur a virtuous circle, generating revenue that can be applied to more basic research.²⁹ This combination raises concerns about the appropriate balance between pure and applied research. Concerns are expressed about the impact of rights to the exclusive use of patented medical technologies, as well as obligations to retain the confidentiality of research, on the public domain of science.³⁰ The single-minded promotion of the downstream application of university research potentially conflicts with policies favouring full and open access to research data. Yet the open science model is considered to be one of the main reasons why research universities have been so important in the process of economic growth.³¹ From the development of penicillin to the invention of recombinant DNA technology, research universities have spurred innovation. By its nature, the entrepreneurial model sparks misgivings that pressure to reap the financial fruit of patenting medical science will deflect universities from their traditional mission, the discovery and dissemination of new knowledge.

Variations of the Bayh-Dole model

The EU innovation model

In 2004 the European Commission published a report on the management of intellectual property in PROs that recommended an innovation model of technology transfer in parallel with an open science model.³² The Report recognised that the US “licensing” model was not entirely appropriate to the prevailing conditions for R & D in the EU, primarily because of a more fragmented market and a lower density of research based companies headquartered in Europe. Instead, the Report advocated an interactive “Innovation Model” in which the pure licensing model is supplemented by “a more active policy of collaborative research with industry” and by “a pro-active involvement in the creation of spinout companies”.³³ Even so, the licensing and innovation models share a common character, in so far as they both advocate the PROs' ownership and strategic management of the intellectual property deriving from their research results.

Most OECD countries have adopted “Bayh-Dole style” models of technology transfer.³⁴ In the more technologically advanced developing countries there is also ***I.P.Q. 318** evidence that governments are willing to legislate to ensure that intellectual property resulting from publicly financed research is disclosed, appropriately protected and commercialised for the benefit of the nation. For example, India's Council of Scientific and Industrial Research pursues a policy of patenting inventions, and China also encourages patenting by its universities and research institutions.³⁵ Most recently, the South African Government has proposed the creation of a National Intellectual Property Management Office to oversee the transfer and commercialisation of university research.³⁶ Nevertheless, in the case of middle to lower-income developing countries questions concerning the feasibility of the Bayh-Dole model remain particularly pertinent.

The WIPO “IP Hub”

For less technologically advanced developing countries, regional technology transfer hubs may prove a more viable model for strengthening R & D.³⁷ Developing countries, including Cameroon, Chad and Colombia, have benefited from a pilot project launched by the World Intellectual Property Organization (WIPO) in 2004, which established two networks of health research institutions in Africa and South America each with its own “IP Hub”.³⁸ Participating research institutions agreed to common policies and to share technology transfer services in order to minimise costs and optimise resources through economies of scale. The “IPHubs” offer intellectual property services including, managing and licensing patents owned by the research institutions and marketing the patent portfolio of the R & D network with a view to attracting further funding and promoting public-private partnerships.

PUBLIC-PRIVATE PARTNERSHIPS FOR RESEARCH AND INNOVATION

The *WHO Plan of Action on Public Health, Innovation and Intellectual Property* stresses the need for co-operation between public and private sectors to boost pharmaceutical innovation in developing countries and to facilitate the dissemination and use of research **I.P.Q. 319* and development outcomes.³⁹ This action is consistent with studies by the OECD which have concluded that greater use of public-private partnerships (PPPs) can enhance the efficiency of innovation by securing private finance and expertise for the development of publicly funded research.⁴⁰ Public-private partnerships, varying from small groups to more complex consortia between PROs, international organisations and private companies, have become a major source of new drug development for developing countries. For example, the World Health Organization's Special Programme for Research and Training in Tropical Diseases facilitates a partnership-oriented approach to drug discovery and development between public-sector organisations and private companies that permits projects to be launched with cost-effective budgets.⁴¹

Scientific collaboration between PROs in developed and developing countries has been expanding since the 1980s. In addition, South-South collaboration is becoming an increasingly important element in R & D, providing opportunities for the development of pharmaceuticals that are tailored to meet local needs.⁴² PRO partnerships in Africa might include a mix of institutions with well-established research activities as well as promising institutions that are developing their research potential. The way in which the Kenya Medical Research Institute (KEMRI) evolved is instructive for the development of PROs in other developing countries. It developed from a long-term partnership between KEMRI and the Wellcome Trust.⁴³ This partnership is fully integrated **I.P.Q. 320* into the KEMRI research infrastructure. The KEMRI-Wellcome Trust partnership is embedded within Kilifi District Hospital, building its research programmes around local medical infrastructure and contributing to healthcare delivery. KEMRI has developed collaborative links with a large number of regional and international collaborations including institutions such as National Institute of Medical Research in Tanzania and the British Medical Research Council.⁴⁴

The example of KEMRI confirms the trend towards the locus of innovation in pharmaceuticals moving beyond the confines of central R & D laboratories of the largest companies and spreading outwards to PROs, notably universities and their private sector partners in the industry.⁴⁵ The contention that university patent ownership will facilitate technology transfer from universities to private firms begins to have some substance when we consider first, the restructuring of the changing business model of the major pharmaceutical industry and, secondly, new entrants to pharmaceutical manufacturing from developing countries as potential business partners.

Restructuring Big Pharma's business model

The major pharmaceutical industry has acknowledged that the prevailing model, largely based on a vertical or fully integrated pharmaceutical companies (FIPCO), model is incapable of delivering sustainable growth. While the business climate for pharmaceutical companies has changed dramatically in the past five years, their business model has not kept pace. The pharmaceutical industry is facing a radical transition because the old business model shows diminishing returns.⁴⁶ Declining R & **I.P.Q. 321* D productivity, rising costs of commercialisation, increasing purchaser influence and shorter exclusivity periods have driven up the average cost in launching new products and reduced average expected returns on new investment.

The major pharmaceutical companies need a new business model to restore sound financial results. They are likely to transition to greater reliance on partnerships to manage risk and return, across both product pipelines and functions.⁴⁷ In the result, structural changes in the pharmaceutical industry portend a more favourable climate for PROs in leading developing countries to negotiate the terms of patent ownership and licensing. As "Big Pharma"⁴⁸ expands and restructures on a global scale, for companies wishing to outsource research, universities in developing countries are potentially attractive options.⁴⁹

New pharmaceutical manufacturers as potential business partners

Moreover, as new pharmaceutical manufacturers enter the market from leading developing countries such as India and China, the ability of universities in Africa and Asia to find industry partners is likely to increase further.⁵⁰ Developing countries with significant national innovation capacity such as India now possess a patent system strong enough to attract foreign direct investment, access foreign

technology **I.P.Q. 322* and encourage local R & D.⁵¹ The character of the Indian presence in Africa has the potential to assist product development. Whatever the infrastructural problems posed by the African continent, the increasing commercial activity of Indian pharmaceutical companies indicates their belief in the potential of the market and their ability to capture prospective profits. Indian pharmaceutical manufacturers are present in all the 53 markets of Africa,⁵² supplying AIDS, malaria, anti-cancer and cardiac drugs, antibiotics and a variety of other products.⁵³ The prices are becoming more competitive as more Indian firms establish manufacturing capacities in countries such as Kenya and Zambia.⁵⁴ They are also involved in technology transfer agreements with companies in Uganda, Nigeria, Gabon, Egypt, Morocco and Algeria. Yet other Indian companies, such as Flamingo, have formed joint ventures in African countries such as Ghana and Uganda with the aim of exploring the market.⁵⁵

At the very least, the rationale that ownership by PROs, as opposed to individual researchers provides greater legal certainty lowers transaction costs and fosters **I.P.Q. 323* more efficient channels for technology transfer, should be carefully considered in each case.⁵⁶ In fact, developing countries may find that it is more efficient for the government or a state sponsored entity such as a trust or holding company to receive title to the intellectual property on behalf of academic inventors. For example, under South Africa's Intellectual Property Rights from Publicly Financed Research and Development Regulations, if a university chooses not to seek patent protection, the National IP Management Office will have the right to reassess the decision and if necessary, seek ownership of the research and patentable assets.⁵⁷

STRATEGIC PATENT LICENSING FOR ONGOING DRUG DISCOVERY

Utilising the freedom of contract

The intersection of intellectual property and contract law within the patent licensing agreement offers PROs the potential to reclaim a space for ongoing R & D into neglected diseases that may otherwise be eroded by the strength of patent law. In addition to the negative rights to exclude unauthorised uses under art.28 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights,⁵⁸ the patentee also possesses the positive right to conclude licensing contracts.⁵⁹ Whereas the derogations from patent rights are narrow, when we turn from property rights to contract, the capacity of the parties to negotiate mutually acceptable terms begins to change. Within the normative framework of contract, there is an opportunity for the parties to implement their reasonable expectations. Contract allows the parties to set present values on probabilities of future outcomes. It requires a duty of good faith and fair dealing in negotiating the terms of the contract.⁶⁰

Of course, the final terms of the licensing contract depend on the negotiating power the parties bring to the table. While PROs in developing countries may not have the financial strength of their business partners, the so-called flexibilities of the TRIPs Agreement, as affirmed by the Doha Declaration on Public Health, may be invoked to support the **I.P.Q. 324* continuation and dissemination of research.⁶¹ Article 7 of the TRIPs Agreement echoes the International Covenant on Economic, Social and Cultural Rights,⁶² insofar as the transfer of technology should be made "in a manner conducive to social and economic welfare", free of conditions, and to the mutual advantage of producers and users of technological knowledge.⁶³

When a public research organisation negotiates with a private pharmaceutical manufacturer over the terms of a licensing agreement, the principle of freedom of contract provides a vehicle for addressing the parties' conflict of interests between the dissemination of research, and the need to recoup the costs of drug development. The process of offer and acceptance involves the quid pro quo of contract law and the final consensus of the parties ad idem. When they are "of one mind" intellectual property law becomes the background against which the parties negotiate and no longer the dominant factor in negotiations. Approaches to licensing, even for comparable technologies, can vary considerably from case to case based on circumstances particular to the parties, the invention and its commercial development. The absolute nature of the rights conferred on the patent holder may be organised to divide the fields of use of the invention, and to temper the prohibitions on third-party access and use of the invention with exclusive or non-exclusive licences.

Utilising the forms of licensing

Exclusive "co-exclusive" and non-exclusive licences

The capacity of licensing to accommodate the commercial exploitation of the patent and the dissemination of basic research lies in the dual nature of its character. A patent licence is not only a legal document, but also a way of doing business. Exclusive licences grant exclusive rights to produce and sell certain products in certain territories and **I.P.Q. 325* markets during the term of the licence. An exclusive licence permits only the licensee and persons authorised by the licensee to exploit the invention. An exclusive licence will also exclude the licensor from using the invention. In this regard, the grant of an exclusive licence is similar to an assignment, since an exclusive licence confers powers on the licensee that are equivalent to those of the proprietor.⁶⁴ Unsurprisingly therefore, in the evaluation of the Bayh-Dole model, there is considerable debate about whether PROs should grant exclusive licences to the private sector for discoveries that have benefited from public funds. By definition, exclusive licences limit the diffusion of technologies. The drawback is that if the chosen licensee does not effectively promote or sell the invention, the patentee cannot then do so, nor can the patentee grant further licences to others.

Alternatively, “co-exclusive” licences may be granted to a small, limited number of licensees. Such a licensing strategy has the advantage of permitting competitive product optimisation by motivating a number of licensees to compete to achieve product development and market penetration or to develop a product that is an improvement over the original.⁶⁵ This strategy, in which a small pool of licensees conduct their R & D in parallel, is especially appropriate where there is a substantial unmet need for a particular product (such as an urgently needed vaccine). More specifically, such a strategy reduces the delay that might be involved in an exclusive licence, where a failure to develop the product will require the licensor to terminate the licence, negotiate a new licence and recommence product development.⁶⁶

In contrast, a non-exclusive licence allows a PRO patentee to retain the right to exploit the licensed invention as well as the right to grant additional licences to third parties. Several licensees as well as the patent owner would have the right to use the patented technology. PROs should therefore consider the reasons for granting exclusive or non-exclusive licences, particularly in the light of the maturity of the technology and the organisation's business strategy.

Generally however, pharmaceutical innovation needs one company to invest heavily to commercialise the product. Pharmaceutical companies, when partnering with a PRO, will normally seek an exclusive patent licence to offset the high cost of innovation,⁶⁷ including the investment necessary to the performance of clinical trials. For their **I.P.Q. 326* part universities should strive to offset the impact that the exclusive licence may have on continuing research, unanticipated uses and future commercialisation efforts. University licensors should endeavour to ensure that the agreement grants only those rights necessary to the development of a particular technology.

Hybrid licences

By way of compromise, the licensing contract between developing country PRO and industry partner may contain terms granting some rights on an exclusive basis and others on a non-exclusive basis. Hybrid licence grants can expand the range of creative possibilities for defining an exclusive licensee's rights.⁶⁸ The ability of the licensing contract to accommodate a variety of business models is reflected in the Lambert Model Contracts that were drafted for the use of PROs by university, business and industry stakeholders in the United Kingdom.⁶⁹ Each model contract represents a different approach to the management of intellectual property rights.

“Convertible exclusive” licences permit the licensor to grant an exclusive licence either co-exclusive or non-exclusive, if a third party wishes to develop products not yet made available by the exclusive licensee, usually after the initial licensee has been given an opportunity to market the product within a limited timeframe.⁷⁰ More generally, over and above the failure to meet a product roll-out deadline, where the licensor agrees to an exclusive grant, it might possibly make the exclusivity subject to defeasance, in whole or in part, triggered by other performance shortfalls by the licensee, such as failure to meet performance or distribution requirements.⁷¹ If triggered, defeasance may take a variety of forms including the conversion of the entire licence grant from exclusive to non-exclusive; or the clawing-back of certain products or inventions from the exclusive licence grant, to either non-exclusive status, or total exclusion from the licence grant.⁷² In particular, a claw-back clause is normally used to remedy the licensee's failure to meet minimum net sales requirements.⁷³ However, it might also be used in respect of any one of a number of performance requirements relating to drug development and distribution.

A “non-exclusive exclusive” licence grant might begin with the classic non-exclusive language, but

also undertake not to grant to third parties the right to sell like products *I.P.Q. 327 if the licensee complies with all the terms and conditions of the licence agreement.⁷⁴ Usually, compliance is determined at the sole discretion of the licensor, which is to the advantage of licensor since there is no need to prove licensee default.⁷⁵ Licensees are likely to favour a “non-exclusive exclusive” grant over a standard non-exclusive grant, because it holds some degree of protection against competition.⁷⁶

Another variant within the hybrid licence includes a non-exclusive provision where it is not a breach if the licensor permits a third party to sell like products, but in the event of such a grant, the licensor agrees to provide the licensee with a reduction in royalties or other previously defined remedies.⁷⁷ Particularly when the licensor is seeking to get a new process used in a new geographical area by finding a manufacturing source there, a basic issue is likely to arise over exclusivity. It is usually a question of whether the licensee is to be guaranteed that neither the licensor nor other licensees will manufacture or sell, directly or indirectly, in its territory. A possible variation is the “convertible non-exclusive” licence, where if additional expressions of interest are not received within a defined period of time, then a non-exclusive licence converts to exclusivity, at least within a particular territory or field of use.⁷⁸

With a view to the promotion of research in mind, PROs may utilise time-limited clauses in order to ensure that the duration of exclusivity is limited to the period necessary to afford licensees the competitive advantage afforded by early market penetration and to permit them to earn a reasonable return on their investment in R & D, following which the grant may convert to a non-exclusive licence, allowing competitors access to the market.⁷⁹ The period may vary from several years for the discovery of a drug that requires relatively little in product development to considerably longer intervals for drugs requiring many years of development and testing to obtain regulatory approval.⁸⁰

PROMOTING DISSEMINATION USING RESTRICTION AND RESERVATION CLAUSES

The WHO Global Strategy and Plan of Action calls for “the further development and dissemination of publicly or donor-funded medical inventions and know-how *I.P.Q. 328 through appropriate licensing policies ...”.⁸¹ With the aim of reasserting their traditional commitment to open access and dissemination in the advancement of scientific research,⁸² PROs should begin by setting out these core values in a mission statement. The traditional mission of the university is to serve society as a centre of higher learning, providing lasting benefits through the discovery of new knowledge and the dissemination of advanced knowledge. By way of illustration, the University of Cambridge’s mission and core values speak specifically of the contribution the university can make to society through the pursuit, dissemination, and application of knowledge; the place of the university within the broader academic and local community; and creating opportunities for innovative partnerships with business, charitable foundations, and healthcare.⁸³ Such a mission statement can then be incorporated in the recitals to the contract as a statement of what the licensing agreement hopes to achieve.

By such means the contract provides a structure against which the core values of PROs in promoting the dissemination of research may be brought to bear on the bargain. The freedom of the licensing contract means that a developing country PRO has the opportunity to draft terms that allow it to reserve rights of access and use that are important for the dissemination and competitive commercialisation of drugs and diagnostic tools. For instance, it might agree to place certain inventions in the public domain, or alternatively, to create mechanisms for sharing the results and exploitation of research. By utilising in this way contractual terms that contain alternative arrangements, private and public partners can negotiate over alternative solutions to the dissemination of, and access to knowledge.

Drafting restriction clauses

The principle of freedom of contract provides the opportunity to define a space in which the value of basic research can be exempted in some measure from the restrictions associated with the exercise of patent rights. The licensing contract offers developing country PROs considerable advantages, not least the potential to control production, distribution in time and geographic area. To this end, the PRO, as licensor, can apportion particular uses of the patent; dividing use of the patent by territory; and by the number of licensees. The parties may test their expectations by inserting performance milestones.

Restrictions on field of use, territory and term

Universities in developing countries might deploy restrictions over field of use and territory terms in order to encourage development of the technology in hitherto under-served markets. A licence may be limited territorially or only for certain types of products covered by the patent. By this means the licensee can be kept to its own territory simply by not granting it manufacturing or sales licences under the patents of other territories. ***I.P.Q. 329** Field-restricted licences therefore enable the grant of rights that cover only particular products that a licensee is able, and will accept a firm commitment to develop. This approach protects the licensee's investment in a product, while nevertheless allowing an opportunity for other parties who are not operating in the field of the exclusive licence grant to undertake product development.⁸⁴ A licence that extends to all fields of use for the term of the licensed patent may have negative consequences if the subject technology is found to have unanticipated utility. This possibility is of particular concern if the licensee is not able or willing to develop the technology in fields outside of its core business.⁸⁵

Territorial restrictions and their interface with competition law

If the university gives the licensee the security of exclusivity it is normally on condition that it will respect the exclusivity of others, either licensor or exclusive licensee, in their territories.⁸⁶ The question then arises as to whether the licensee is to receive a guarantee that neither the licensor nor other licensees will manufacture or sell, directly or indirectly, into its territory.⁸⁷ For its part the licensee will be interested in ensuring protection of its investment, equipment, employees, distribution chains, advertising and other servicing that it may have to provide.⁸⁸ The greater the investment the more likely the licensee will insist on complete exclusivity in order to provide protection against potential price differences between territories and the parallel importing that these may engender.⁸⁹ However, such contractual terms will be enforceable only so long as the country of import neither treats an initial marketing outside its territory as exhausting patent rights, nor assumes that first sale abroad by one licensee implies a licence to export to other countries where parallel patents exist.⁹⁰

In most countries, national patent laws will give the necessary protection. In the European Union, however, where the principle of the free movement of goods qualifies patent law, such terms may fall foul of competition law. The Commission opposes restrictions as to territory, considering the creation of a common market justifies treating a licence to manufacture in one country of the Community as a licence to sell in all.⁹¹ The Community principle of the free movement of goods derives from art.30 of the foundational Treaty of Rome,⁹² which prohibits quantitative restrictions on imports and all measures having an equivalent effect thereto between Member States ***I.P.Q. 330** of the EC.⁹³ The exercise of a patent to block imports is considered a "measure having an equivalent effect". Article 36 provides that art.30 shall not prevent the protection of intellectual property. But the exclusion of "industrial and commercial property" intellectual property rights is based upon the requirement that any prohibitions or restrictions on imports arising therefrom shall not "constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States".⁹⁴

As a result we have a conflict between the free movement of goods across borders and the exercise of patents rights. Various attempts to use patents in the country of import to block parallel (unauthorised third-party) import of pharmaceutical products that were first placed on the market in another EU country have all foundered on the doctrine of exhaustion of rights. Generally speaking, the patent owner has the right to place the product first on the market within the European Economic Area (EEA), but not the right to block parallel imports from another EU Member State, where the product has been put on to the market in that Member State with the consent of the patentee.⁹⁵

The principle of exhaustion that pertains throughout the EU means that the licensor can still impose an obligation on a licensee not to sell licensed products outside its given territory as long as the terms of the licence fall within the scope of the Technology Transfer Block Exemption (TTBE).⁹⁶ However, it is not possible for a licensor to impose an obligation on its licensee, in the nature of an exclusive licence with absolute territorial protection, to prevent customers of that licensee from selling goods in other EU Member States. Likewise, a licensor should not seek to prevent imports from its own customers or another licensee in another EU Member State.

In *Nungesser v EC Commission*,⁹⁷ the European Court of Justice (ECJ) ruled against an indiscriminate application of art.81 of the Treaty Establishing the European Community, which prohibits agreements that have as their object the restriction of competition within the Common Market.⁹⁸ *Nungesser* concerned a licence for plant variety rights (PVRs) in a new form of maize seed. The developer of the new variety, INRA, a research institute financed by the French Ministry of Agriculture, had granted Nungesser, a German firm, an exclusive manufacturing and sales licence to

cultivate and sell in the German market four varieties of its hybrid maize seeds. By way of exclusivity, INRA ***I.P.Q. 331** agreed that it would not grant further licences in the German territory and that it would try to prevent the seeds grown in France from being exported to Germany, except to Nungesser.

On the one hand, the court found that, to the extent that the agreement sought to impose absolute territorial protection on Nungesser, by requiring that parallel importers should be prevented from obtaining the seed in France and exporting it to Germany, it fell foul of art.81(1) and could not be saved by the exemption in art.81(3).⁹⁹ On the other hand, because the agreement was in the nature of an open licence, that is one which related solely to the contractual relationship between the owner of the PVR and the licensee, insofar as it provided that neither INRA nor its French licensees would themselves export to Germany, nor compete with the licensee in the licensed territory, the court found the agreement compatible with art.81(1).¹⁰⁰ The exemption pertaining to open exclusivity was justified in view of the specific nature of the product in question. The court concluded that requiring INRA to introduce newly developed hybrid maize seeds, after years of research and experimentation, would involve such risks in cultivating and marketing that a potential licensee might have been deterred by the prospect of direct competition in the same product from other licensees.¹⁰¹ Such an outcome would be prejudicial to the dissemination of knowledge and techniques in the Community.¹⁰²

Following the decision in *Nungesser*, the EC Technology Transfer Block Exemption (TTBE) takes account of whether the parties are competitors and whether the licence constitutes a reciprocal or non-reciprocal agreement.¹⁰³ With regard to geographical limitations on production, these will be considered unacceptable divisions of markets where competitors enter into reciprocal agreements.¹⁰⁴ At the other end of the spectrum, if non-competitors are involved in a non-reciprocal agreement, the licence is normally acceptable.¹⁰⁵ At the mid-point of the spectrum, the agreement is likely to benefit from the block exemption, especially if the licence is other than exclusive.¹⁰⁶

***I.P.Q. 332** Likewise, restrictions on the sale of products are not permitted between competitors where the licensing arrangements are reciprocal.¹⁰⁷ In the case of a non-reciprocal agreement, however, they may simply undertake not to make active or passive sales in the other's territory.¹⁰⁸ Nevertheless, in different Member States, the parties are free to engage in passive sales in the territories of other exclusive licensees.¹⁰⁹ The purpose of these criteria is to protect the investment of licensees. As the ECJ remarked in the case of *Nungesser*, no licensee would take the risk of launching the new product on a new market if he were not protected against direct competition from the holder of the breeders' rights and from its other licensees.¹¹⁰

Improvement clauses

The patentee can obtain ownership or licence to any improvements made by the licensee if a right to improvements can be negotiated as a term of the licensing agreement. Nonetheless, caution is necessary. Reservations regarding patent rights in any improvements appear to be a stipulation that is consistent with universities' core values to promote ongoing research.¹¹¹ Rights to improvements may prove problematic with respect to competition law.¹¹² Let us take the case of a PRO that is attempting to patent and license an invention for the first time. Where the PRO licensor is involved in ongoing research and development, or the licensed technology is at an early stage of development, it is likely that improvements will be made to the process or product during the term of the licence agreement. Because novel technology is normally subject to further development, it is important to decide the extent to which new information is to be circulated between licensee and licensor. Further, if additional patent rights are acquired by one, the other party is likely to consider it is entitled to no less than a non-exclusive licence to the improvement.¹¹³ Sub-licensing is a further area where improvements are likely to be patentable or otherwise protectable. In this event, the licensor will want the right to use any such improvements developed by the licensee. This right might extend to the licensor being able to grant a sub-licence to other ***I.P.Q. 333** licensees in other territories and may involve the licensor using the improvements for other purposes. The patentee of the original invention will usually create a network of non-reciprocal licences, territory by territory.¹¹⁴ Assuming that each licensee will likely discover improvements, the patentee will normally wish to maintain control over the technology by requiring not only that licensees keep it informed of any improvements but also "grant back" by assignment or exclusive licence follow-on patents and rights to know-how acquired by the licensee.¹¹⁵ However, each licensee will consider this arrangement to its benefit only to the extent that it feels that there is an exchange of equal advantage. In the contrary case, not only will it be disinclined to disclose improvements, it may unwillingly discover improvements. In this situation, without a clear direction as to duration and termination of the licence, there may be difficulties about

the obligations concerning improvements which one side owes to the other at the date of termination.¹¹⁶

Even though licensees will likely want an obligation to grant access to future improvements of licensed inventions, such an undertaking may effectively yoke academic research in a particular area to a particular industry partner.¹¹⁷ This constraint would directly or indirectly diminish the capacity of the PRO and its scientists to garner alternative research funding and to engage in potentially fruitful collaborations with scientists employed by companies other than the licensee, perhaps having a chilling effect on collaboration with scientists in other research institutions.¹¹⁸ Even worse, if rights to improvement affect inventions in other parts of the university, then scientists who did not benefit from the licensing of the original invention may nonetheless have their prospects restricted by an overly broad clause enabling the licensee to develop the technology.

The PRO should therefore aim to limit the licensing of “future improvements”. When dealing with improvements, it is crucial the contract define the nature of an improvement and, thereby, what is covered by the licence and what constitutes a new, independently patentable technology.¹¹⁹ The latter case, depending on the national law, may necessitate a new licence agreement.¹²⁰ Given the potential to reduce ***I.P.Q. 334** capacity, exclusive licensees should not receive rights to “improvement” or “follow-on” inventions without prior consent. As a matter of practice, the licensees' rights should be limited to existing patent applications and patents, and to no more than those claims in any continuing patent applications that are either completely supported by information in an existing application or patent or; entitled to the priority date of that application or patent.¹²¹ In the event a licensee is granted patent rights to improvements, it is essential to restrict the scope of the clause so that it does not affect unrelated research and is limited as to its future operation.¹²² In addition, an improvements clause should be restricted to inventions that are owned and under the control of the licensor PRO.¹²³

Grant-back of improvements and EC competition law

Obliging a licensee to grant back improvements to a licensor on an exclusive basis may be considered anti-competitive. For example, art.5 of the Technology Transfer Block Exemption (TTBE)¹²⁴ sets out the excluded restrictions. If an agreement contains any of these restrictions, it is only the restriction in question that is excluded from the benefit of the block exemption, not the whole agreement.¹²⁵

Article 5(1) provides that the art.2 exemption shall not apply to any of the following obligations contained in technology transfer agreements:

- any direct or indirect obligation on the licensee to grant an exclusive licence to the licensor or to a third party designated by the licensor in respect of its own severable improvements to or its own new applications of the licensed technology;
- any direct or indirect obligation on the licensee to assign, in whole or in part, to the licensor or to a third party designated by the licensor, rights to its own severable improvements to or its own new applications of the licensed technology;
- any direct or indirect obligation on the licensee not to challenge the validity of intellectual property rights which the licensor holds in the common market, without prejudice to the possibility of providing for termination of the technology transfer agreement in the event that the licensee challenges the validity of one or more of the licensed intellectual property rights.

In the case of non-competing undertakings, art.5(2) further provides that the art.2 exemption shall not apply to any direct or indirect obligation limiting the licensees ***I.P.Q. 335** ability to exploit its own technology or limiting the ability of any of the parties to the agreement to carry out research and development, unless such latter restriction is indispensable to prevent the disclosure of the licensed know-how to third parties.¹²⁶ Best practice is therefore to ensure that there is no licence term that may be considered incompatible with ECart.81 insofar as it seeks to restrict competition within the Common Market by controlling not only what is made with the licensed technology but also the use which is to be made of it subsequently.¹²⁷

EXEMPTIONS FOR RESEARCH AND EXPERIMENTAL USE

As ongoing research may lead to new biomedical developments, it is important for the PRO to have the freedom to explore other applications of the research results. The law has traditionally exempted universities from paying fees for patented inventions they use in their own research following the

rationale that universities fulfil a public mission. For example, the UK Patents Act creates two general exceptions for private use and for experimental use.¹²⁸ However, as more public research is carried out with business for the promise of monetary reward, the rationale for such exemptions has become less clear.

Cautiously, therefore, the WHO Global Strategy and Plan of Action calls upon Member States to “consider, where appropriate, use of a ‘research exception’ to address public health needs in developing countries consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights”.¹²⁹ The circumspect wording of the appeal is undoubtedly due to the uncertain position regarding exemptions for research and experimental use in national patent laws. The extent and status of this exemption differs across countries and is often ill defined. Moreover, the patchwork of national research exemptions is being eroded by legal challenge.

***I.P.Q. 336** Traditionally, patent laws admitted such an exception for experimental use for the non-commercial activities of the research scientist in a university or government laboratory. However, where the experimental use relates to the subject-matter of patents over successful pharmaceutical products,¹³⁰ the exemption has proven increasingly controversial.¹³¹ Once it has been shown that a use has been carried out for an experimental purpose, it is necessary to show that the experiment relates to the subject-matter of the patent. In the English Court of Appeal in *Auchincloss v Agricultural and Veterinary Supplies*,¹³² Aldous L.J. said that the subject-matter of the invention must be ascertained from the patent as a whole. For example, a third party who wishes to test a cure for cancer using a genetically modified mouse cannot rely on the defence of experimental use against a claim by the patentee of the mouse.¹³³ A researcher wishing to use diagnostic kits containing patented processes or products to test other subject-matter will need to obtain a licence.

Recent developments within Contracting States to the European Patent Convention (EPO)¹³⁴ indicate that the exception may also apply to research that is carried out for profit. Such an interpretation may have been prompted by the arrangement of the exceptions in the domestic legislation of members.¹³⁵ However, it is necessary to distinguish between research which aims to improve the invention and unrelated research activities. Use of the invention for experiments on unrelated subject-matter will be difficult to defend. Likewise the defence is unlikely to cover trials to see whether a third party can produce commercially according to the patent. The English courts have on occasion, been willing to entertain a broad interpretation of “experimental”.¹³⁶ Yet it is unlikely that the research exemption will be held to apply where the defendant conducts none of the exploitation of technology for its own experimental purposes, but where, the defendant in each instance, is seeking to exploit and sell its technology to third parties.¹³⁷ In this respect, English law seems to have recently moved somewhat closer to the experimental use exception as it is applied in the United States.

***I.P.Q. 337** Recent US jurisprudence, as exemplified by the case of *John M.J. Madey v Duke University*,¹³⁸ favours a restrictive interpretation of the exemption. In *Madey* the US Court of Appeals for the Federal Circuit took a narrow view of acts done privately for experimental use such that use of patented technologies in the course of university research should be limited to strictly philosophical inquiry.¹³⁹ In the result, in view of the heterogeneous character of modern research funding, universities will largely be obliged to pay licensing fees for research inputs that are protected by law.¹⁴⁰

Notwithstanding the attempt in *Madey* to distinguish between a university’s “legitimate business objectives” and commercial applications for the fruits of its academic research, at least two problematic situations may be identified. First, consider a situation where the defendant conducts tests and independently discovers beneficial properties of a substance which falls within the plaintiff’s patent but which differs from the product marketed by the plaintiff.¹⁴¹ In such a case, experiments to legitimately discover further information about the properties of the defendant’s substance will be permissible, but tests to provide further evidence of already known qualities fall outside the research exemption.¹⁴² For example, in *Monsanto v Stauffer*,¹⁴³ Stauffer had developed a market variant of Monsanto’s successful patented weed-killer “Roundup” for which Stauffer established tests both inside and outside a research farm where interested parties could observe the results. The English Court of Appeal limited the interpretation of the word “experimental” in accordance to its size, scale, recipient and methodology. Accordingly, the court allowed the defendant to continue its in-house experiments, but disallowed tests done outside a research farm on the basis that trials carried out in order to demonstrate to a third party that a product works cannot be regarded as acts done for experimental purposes.

Secondly, consider a situation where the defendant is testing for new uses and further information

about the properties of a patented product, including the results of clinical trials with patients.¹⁴⁴ In 2004, the EU introduced an extension of the experimental use exception to cover experimental testing for the purpose of seeking regulatory approval, thus bringing the position somewhat closer to that prevailing under the US Hatch-Waxman legislation.¹⁴⁵ It is the accepted view that the purpose of art.10(6) of the **I.P.Q. 338* Medicinal Products for Human Use Directive¹⁴⁶ is to provide a Bolar-type exemption from patent infringement in respect of experiments and trials, pre-clinical and clinical, conducted in pursuance of seeking regulatory approval for a generic or similar biological medicinal product. Nevertheless, care with drafting reservation clauses is particularly important in this area because it is not clear which “trials and studies” are exempted. In particular, there is uncertainty regarding the application of the experimental use exception in art.10(6) in cases where a third party wishes to conduct tests for the purposes of developing a new drug on the basis that the data may ultimately be used for an application for a marketing authorisation for that new drug.

There is likely to be greater uncertainty as to the scope of the experimental use exemption in the sphere of biotechnology, where it may be more difficult to draw a distinction between basic research and its commercial application.¹⁴⁷ It is important that this science, so vital to diagnostics and drug discovery, should remain open to experimentation and further progress.¹⁴⁸ The Gowers Review of Intellectual Property, commissioned by the UK Government suggested that, in terms of a dividing line, the exception should only operate in those cases where licences of the existing patent are unlikely to be given--such as where a patentee is seeking to monopolise further experimentation.¹⁴⁹

Draft clauses for the use and practice of the invention

Academic research

Consequently, it is advisable to prepare for the worst case, by considering the definitions of non-commercial use in light of *Madey*.¹⁵⁰ Licensing contracts should seek to ensure **I.P.Q. 339* that universities are reserving rights that are broader than those of an unlicensed party, and that activities held under *Madey* to constitute the university's “legitimate business objectives, including educating ... students and faculty participating in [research] projects”, are within the scope of reserved rights.¹⁵¹ For example for the purposes of such a clause “Non-Commercial Research Purposes” should be defined to include:

“Use or practice of *licensed patent rights* for academic research and other not-for-profit or scholarly purposes which are undertaken at a non-profit or governmental institution that does not involve the production or manufacture of products for sale or the performance of services for a fee.

Without limiting the foregoing:

(i) ‘academic research and other not-for-profit or scholarly purposes’ includes, in non-limiting fashion, research that leads, or may lead, to patentable or unpatentable inventions that maybe licensed or otherwise transferred, either directly or indirectly, to third parties; and

(ii) neither (A) receipt of license revenues on account of such inventions or receipt of reimbursements for the costs of preparation and shipping of samples of materials provided to third parties as a professional courtesy, in response to post-publication requests or otherwise in accordance with academic custom nor (B) receipt of funding to cover the direct and/or indirect costs of research, shall constitute sale of products or performance of service for a fee.”¹⁵²

In summary, in drafting reservation of rights clauses and associated definitions, it is important to keep in mind the relatively restricted scope of the research exemption.¹⁵³

Rights to use

Similarly, universities should reserve the right to practice licensed inventions with a view to ensuring that other scholars are able to substantiate scientific data without concern for patents, and that scientists are able to publish the results of their research in theses, conference papers and peer-reviewed journals.¹⁵⁴ To this end, even when the invention is licensed exclusively to a commercial entity, PROs should nevertheless consider reserving rights in entire fields of use, for themselves and other non-profit research laboratories.¹⁵⁵ Such a general reservation should clearly articulate the scope **I.P.Q. 340* of reserved rights to practise inventions and to use associated information and data for research and educational purposes, including research sponsored by

commercial entities; and to transfer tangible research materials (such as biological materials and chemical compounds) and intangible materials (such as databases and know-how) to others in the non-profit and governmental sectors.¹⁵⁶ For example, such a reservation clause should include a definition of non-commercial use, to read:

“The University reserves the rights, for itself and others, to

- i) make and use, solely for Non-Commercial Research Purposes, the subject matter described and claimed in patent rights and covered by property rights; and
- ii) provide to others the Biological Materials;

As used herein, the term ‘Non-Commercial Research Purposes’ means: Use of patent rights for academic research or other not-for-profit or scholarly purposes which are undertaken at a non-profit or governmental institution that does not use patent rights in the production or manufacture of products for sale or the performance of services for a fee.”¹⁵⁷

PUBLICATION AND ACCESS RIGHTS

In this section we consider how the terms of the licensing contract might preserve publication and access rights to the results of research and to new medical technologies. The global network of PROs shares a responsibility in advancing the medical knowledge of researchers in developing countries. One of the ways in which they can do this is by preserving open access to the results of scientific research.¹⁵⁸ The success of WHO's Access to Research Initiative “HINARI” depends not only on major publishers enabling developing countries to access medical journals, but also on the extent to which PROs facilitate early publication.

However, since PROs began patenting the results of research, publication and access to scientific data connected with the subject-matter of the patent have become a contentious issue. Pre-grant, as soon as the technology is identified for patent protection, **I.P.Q. 341* the confidentiality needed to preserve the art in the invention comes into conflict with the goal of the PRO for the dissemination of research. Premature publication in articles, research papers and at conferences may destroy the novelty of a patentable invention.¹⁵⁹

The licensing contract should reflect the necessary trade-off between the potential for future patent protection and the ability to freely publish the results of research. By way of compromise, the competing interests of the parties will typically be addressed by specifying withholding periods for publication; and providing industry partners with the opportunity to review any proposed publication, exclusive of the right to prohibit publication.

There is considerable scope for the self-regulation of publication in the licensing contract, as the following example illustrates:

“Nothing in this Agreement will be deemed to limit the right of the Institution to publish any and all technical data resulting from any research performed by the Institution relating to the Invention and to make and use the Invention, Licensed Product, and Licensed Services and to practice the Licensed Method and associated technology and allow other educational and non-profit institutions to do so for educational and research purposes.”¹⁶⁰

Apart from the problem of jeopardising the novelty of the invention by early publication, there is a further issue, which is more difficult to address. There is considerably less awareness of what needs to be done in the period that starts with the first patent filing and ends at most one year later with the filing of follow-up applications. Researchers may well assume that having secured a priority date through a first application, they have effectively secured patent protection for an invention and that they are therefore free to publish their research. However, under European patent law, there are situations where such a publication may have adverse consequences for the patenting process.¹⁶¹ If patentability of the original claims appears doubtful, the publication may need to be postponed in order to allow the filing of a follow-up application with additional features that were not disclosed in the priority application.¹⁶²

Post-grant, the patentee will desire to maintain monopoly over the use of the invention. Instances of restricted access to proprietary research tools (for example, for genetic testing) risks slowing research and raising costs in developing countries.¹⁶³ It **I.P.Q. 342* may potentially lead to a loss of expertise and information among other researchers. One notorious example is the monopoly Myriad acquired

on BRCA1 and 2 genes. The University of Utah, the National Institutes of Health (NIH) and the firm Myriad Genetics co-owned the BRCA1 patent covering the methods and materials used to isolate the gene associated with susceptibility to breast and ovarian cancer. In short, the initial US patent covered not only the DNA sequence of the genes, and therefore any reproduction, but also all diagnostic and therapeutic applications.¹⁶⁴ Initially, Myriad Genetics was not the sole beneficiary of the patent. By 1998, however, it succeeded in obtaining from rival patentees all the patents on the BRCA1 and BRCA2 genes. In turn, this gave Myriad unchallenged control over the main research materials concerning genes coding for breast and ovarian cancer susceptibility, thereby allowing it to make further discoveries and ultimately to file further patent applications as a result of such discoveries. In this case the legal effect of Myriad's US patents was that it was able to monopolise the data collection, analysis and price of the genetic tests in that country.¹⁶⁵

By definition, exclusive licences limit the diffusion of medical technologies. In order to manage the potential conflict relating to the dissemination of knowledge and the commercialisation of research, technology transfer officers should consider including clauses in licence agreements to protect access to the research tools for future research and discovery. The drafting of such an exclusive licence should specify that the licence is exclusive for the sale, but not use, of such products and services. By such means the PRO seeks to ensure that it is free to license non-exclusively to others the right to use the patented technology.¹⁶⁶

Further, recalling that patent law provisions concerning research exemptions differ across countries. In order to ensure that the conditions and cost of basic research remain manageable, technology transfer officers should seek to clarify the terms of access rights to research within the licensing contract. Negotiators should consider a series of contractual terms that are aimed at promoting the diffusion of university research.

Where patent law allows, such provisions may include:

1. Providing for a grace period for protecting the PRO against a publication of the invention before the filing date. By such means, if a scientist wishes to publish the invention, he or she may do so and the PRO may still validly file an application which will be considered novel despite the publication, provided that the filing is made during the grace period following the publication.¹⁶⁷

***I.P.Q. 343** 2. Making a provisional filing of the patents on improvement with a one-year option for possible future filing, where the patent office allows.¹⁶⁸

The provisional patent application keeps an option open to file patent applications internationally for one year. The one-year Paris Convention period may be used to conduct further development on the product and also to test the product in the marketplace to see if the product is successful and if it is worthwhile to proceed with the patenting procedure. At the end of the one year Paris Convention period,¹⁶⁹ the applicant may proceed to file complete patent applications in foreign countries of interest.

Alternatively, and to delay the costs of filing patent applications in the various countries, it is possible to file an "international" patent application, or "PCT" application.¹⁷⁰ A further advantage is that an international patent examiner conducts an independent novelty search and provides a written opinion on the patentability of the invention. The examination report can provide a good indication of whether it is worthwhile to proceed to file patent applications internationally.

TERMINATION AND CONCLUSION

This article has been premised upon the notion that the patent licensing contract is capable of creating some further space for the research and development of health products. Nevertheless, the asymmetrical relationship between property and contract can ultimately pose risks for the licensor, depending on the degree to which it may be considered in competition with the licensee. The PRO licensor therefore has an interest in protecting its intellectual property against internal attack from a licensee who decides to challenge the validity of the patent. The simplest means to guard against such a prospect is for the licensor to include a contractual provision indicating that, upon any challenge of the patented technology, the licensing agreement will be immediately ***I.P.Q. 344** terminated.¹⁷¹ In such an event, the licensee would no longer be in a position to reap the benefits of the licence and the licensor could immediately look for another licensee.¹⁷² Then again, since preserving the commercial relationship is important to a public-private partnership, the licensor may prefer to add a clause providing pre-suit notification. This provision would give the licensor the opportunity to renegotiate the agreement or evaluate the strength of the licensee's claim.¹⁷³

The foregoing analysis has shown how patent licensing may offer a self-regulatory solution to the inherent tension between strong international patent protection and the norms of open science.¹⁷⁴ Owing to the conflict of interests associated with the transfer of technology from university to the business sector, it is necessary to safeguard the mission of universities to disseminate medical research for the public benefit. In order to address the interests of universities in developing countries in continued research into local diseases, as well as those of industry partners in minimising the financial risks of product development, patent licensing agreements need to include appropriately tailored restriction and reservation clauses.¹⁷⁵ While many inventions do not merit the expense of filing for patent protection, those that do depend on technology transfer officers utilising an appropriate mix of licences, and drafting terms that promote pharmaceutical R & D for the greater welfare of under-served patient populations.

Queen Mary, University of London, Centre for Commercial Law Studies, 67-69 Lincoln's Inn Fields, London, <http://www.gaileevans.com> [Accessed June 25, 2009].

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1. Sixty-First World Health Assembly, *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*, WHA61.21, May 24, 2008, Annex, p.5. See also UN Development Report, 2007-2008, *Fighting Climate Change: Human Solidarity In A Divided World* at p.40: Every year there are 350-500 million cases of malaria, with 1 million fatalities: Africa accounts for 90% of malarial deaths and African children account for over 80% of malaria victims worldwide: <http://hdr.undp.org/en/reports/global/hdr2007-2008> [Accessed June 25, 2009].
 2. Sixty-First World Health Assembly, *Global Strategy and Plan of Action*, WHA61.21, May 24, 2008 Element 1, paras. 27 & 28: "Prioritising research and development needs: ...mapping global research and development with a view to identifying gaps in research and development on diseases that disproportionately affect developing countries": http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf [Accessed June 25, 2009].
 3. Concerning the three types of diseases of diseases that "disproportionately affect developing countries" e.g., maternal conditions are a major contributor to the global burden of disease, yet the pipeline of new drugs specifically for maternal health is small. Only 17 drugs are under active development for maternal health indications, less than 3% of the pipeline in cardiovascular health. There were an estimated 536,000 maternal deaths in the world in 2005, of which 533,000 (99%) occurred in developing countries: WHO, UNICEF, UNFPA and the World Bank, *Maternal Mortality in 2005* (2007): http://www.who.int/reproductive_health/publications/maternal_mortality_2005/ [Accessed June 25, 2009]. Further on the economic foundations of markets for patents, see Maria Pluvia Zuniga and Dominique Guellec, "Who Licenses out Patents and Why? Lessons from a Business Survey" (OECD, 2009), pp.7-9.
 4. Concerning the factors pertinent to an environment conducive to innovation, see: WHO, Fifty-Sixth World Health Assembly, Report by the Secretariat, *Intellectual Property Rights, Innovation and Public Health*, A56/17, May 12, 2003, pp.1 and 2. Concerning under-investment, the "Global plan to Stop TB: 2006-2015" estimates that US\$ 9000 million need to be invested over the period 2006-2015 in research and development for new tools for use against tuberculosis: vaccines, medicines and diagnostics: cited in WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property, *Draft Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, Mapping the Funding for Research and Development for Neglected Diseases*, Report by the Secretariat, A/PHI/IGWG/2/INF.DOC./2, August 28, 2007, p.6.
 5. Fifty-Ninth World Health Assembly, *Public Health, Innovation, Essential Health Research and Intellectual Property Rights: Towards A Global Strategy and Plan of Action*, Resolution WHA59.2427, May 2006, p.3.
 6. United States Bayh-Dole Act of 1980, Pub. L. No.96-517, §6(a), 94 Stat. 3015, 3019-28 (1980) (codified as amended at 35 USC §§200-212 (2000)).
 7. A patent licence is a contract by which the patent holder authorises another party to use its invention under certain, normally financial, conditions: A. Arora, and A. Fosfuri, "Licensing the Market for Technology" (2003) 52(2) *Journal of Economic Behavior & Organization* 277. A licence provides a party with permission to do an act that would otherwise be prohibited. A patent is licensed when the owner of the patent (the licensor) grants permission to another (the licensee) to use the patented invention for mutually agreed purposes. In such cases, a licensing contract is signed between two parties, specifying the terms and scope of their agreement.
 8. On the importance of patent protection to the pharmaceutical sector see Bruce Lehman, "The Pharmaceutical Industry and the Patent System", 2003, pp.5 and 7: <http://www.earth.columbia.edu/cgsd/documents/lehman.pdf> [Accessed June 25, 2009]. See also Organisation for Economic Co-operation and Development (OECD), "Patents and Innovation: Trends and Policy Challenges" (2004), p.22: <http://www.oecd.org/dataoecd/48/12/24508541.pdf> [Accessed June 25, 2009]. Concerning the cost of pharmaceutical R & D, see the originator industry claims that the cost of a new medicine from basic research to launch amounts to at least US\$ 800 million: European Commission, *Pharmaceutical Sector Inquiry, Preliminary Report*, November 2008, p.55: <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html> [Accessed June 25, 2009].
 9. UK Patents Act 1977 (as amended) s.130 states: "'exclusive licence' means a licence from the proprietor or applicant for a patent conferring on the licensee, or on him and persons authorised by him, to the exclusion of all other persons (including the proprietor or applicant), any right in respect of the invention to which the patent or application relates, and 'exclusive licensee' and 'non-exclusive licensee' shall be construed accordingly."
 10. TRIPs art.28, concerning the rights conferred on the patentee, stipulates that during the term of the patent, any person imitating the invention not having the consent of the patent holder, is committing an act of infringement: http://www.wto.org/english/tratop_e/trips_e/t_agm3c_e.htm#5 [Accessed June 25, 2009].
 11. In an empirical study of 1365 licensing contracts, Anand and Khanna (2000) show that, in industries where IPRs are important, notably chemicals and pharmaceuticals, licensing of patents tends to be high. They find that 80% of licensing transactions are made in chemicals-pharmaceuticals: cited in Zuniga and Guellec, "Who Licenses Out Patents and Why?", OECD, 2009, p.8.
 12. See Report of the Commission on Intellectual Property Rights, Innovation and Public Health, *Public Health, Innovation and Intellectual Property Rights*, WHO (April 2006), p.71.
 13. Act 51 of 2008.

14. "Intellectual Property Rights from Publicly Financed Research and Development Regulations", *Government Gazette*, April 9, 2009, No.32120, p.4: regs 8(3)(a) and 9(4)(a).
15. The article is concerned primarily with research universities and research centres funded by public funds (collectively public research organisations or PROs).
16. Further on the importance of dissemination see Fifty-Eighth World Health Assembly Resolution on eHealth, WHA58.28, May 25, 2005: <http://www.who.int/africahealthinfoway/strategy/en/index.html> [Accessed July 20, 2009] and various related initiatives including the UN's Health Internetwork Access to Research Initiative, a project to make scientific journals accessible: <http://www.who.int/hinari/en/> [Accessed June 25, 2009]; Africa Health Infoway, an ICT-based network of e-health solutions, to support health at districts in 53 African countries: <http://www.who.int/africahealthinfoway/en/> [Accessed June 25, 2009].
17. See WHO eHealth strategy, at the (Fifth Eighth World Health Assembly, Resolutions A58.21 and R58.28), which, inter alia, aims to foster public-private partnerships in research and development for priority eHealth systems and applications for the benefit of Member States: <http://www.who.int/africahealthinfoway/strategy/en/index.html> [Accessed June 25, 2009].
18. Pub. L. No. 96-517, §6(a), 94 Stat. 3015, 3019-28 (1980) (codified as amended at 35 USC §§ 200-212 (2000)). See generally, "The Bayh-Dole Act: A Guide to the Law and Implementing Regulations" (1999): http://www.cogr.edu/docs/Bayh_Dole.pdf [Accessed June 25, 2009].
19. "It is the policy and objective of Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development ... [and] to promote the collaboration between commercial concerns and nonprofit organizations, including universities." 35 USC §200 (2000).
20. In view of the organisational and educational tasks required to secure patent rights, most universities have an R & D department or knowledge transfer office as well as a company that provides commercialisation services to the university. Once invested with the legal power to exercise control over property, including intellectual property, the PRO will then have the power to contract with its employees concerning the assignment and ownership of intellectual property. As a department, institute or centre in itself does not have the required legal personality, a corporation as a legal entity is the most effective means of ensuring that the PRO has the legal capacity to assume ownership and control of intellectual property. The intellectual property will be owned by the university or a nominee company of the university (e.g. "Unisearch Incorporated"). Organisation of Economic Co-operation and Development (OECD), "Turning Science into Business, Patenting and Licensing at Public Research Organisations" [2003] *Science, Technology & Industry* 1.
21. Nonetheless, generating revenue for universities was not the actual goal of the Bayh-Dole Act, which requires that the profits accruing to the beneficiary non-profit organisations "be utilized for the support of scientific research or education". 35 USC §202(c)(7) (2000).
22. Jay P. Kesan, "Transferring Innovation" (2009) *Fordham Law Review, Symposium Issue*, forthcoming; U. Illinois Law & Economics Research Paper No. LE09-011; Illinois Public Law Research Paper No. 08-25. Available at SSRN: <http://ssrn.com/abstract=1371810> [Accessed June 25, 2009].
23. William M. Landes and Richard A. Posner, *The Economic Structure of Intellectual Property Law* (2003), p.13.
24. Patenting statistics at MIT reflect the relationship between patents, markets and profits. See Archive of AUTM licensing reports for 2004-2007, <http://www.autm.net/Surveys.htm> [Accessed July 20, 2009].
25. Between 1975 and 1996, research and development for diseases in developing countries has declined rather than increased. Of the new chemical entities developed between 1975 and 1996, only 11 were for the treatment of tropical diseases. Patrice Trouiller and Piero Ollario, "Drug Development Output from 1975 to 1996: What Proportion for Tropical Diseases?" (1999) 3 *Int'l. J. Infectious Diseases* 61, 61-63.
26. Addressing the Lack of Research and Development for Neglected Diseases, see "Drugs for Neglected Diseases Initiative", <http://www.dndi.org/index.php/overview-dndi.html?ids=1> [Accessed July 20, 2009].
27. Therefore for tropical diseases affecting 90% of the world population, only 10% of the research is allocated to them. UK Parliamentary Report, *Fighting Diseases of Developing Countries* (Postnote, June 2005), p.1, <http://www.parliament.uk/documents/upload/POSTpn241.pdf> [Accessed June 25, 2009].
28. See World Bank, "Africa Development Indicators" (2008/9), Health at p. 100, <http://siteresources.worldbank.org/EXTSTATINAFR/Resources/ADI-200809-essay-EN.pdf> [Accessed July 20, 2009].
29. Henry Wasser, "Changes in the European University: From Traditional to Entrepreneurial" (1990) 44(2) *Higher Education Quarterly* 110.
30. J.H. Reichman and Paul Uhlir, "A Contractually Reconstructed Research Commons for Scientific Data In A Highly Protectionist Intellectual Property Environment" (2003) 66 *Law & Contemp. Probs.* 315, 320.
31. See generally Paul A. David, David Mowery and W. Edward Steinmueller, "Analysing the Economic Payoffs from Basic Research" (1992) 2 *Econ. of Innovation and New Tech.* 73; Partha Dasgupta and Paul A. David, "Toward a New Economics of Science" (1994) 23 *Poly Res.* 487, available at <http://www.compilerpress.atfreeweb.com> [Accessed June 25, 2009].
32. See European Commission, Directorate-General for Research Management of Intellectual Property in Publicly-Funded Research Organisations: "Towards European Guidelines" (2004), p.11: <http://ec.europa.eu/research/era/pdf/iprmanagementguidelines-report.pdf> [Accessed June 25, 2009].
33. European Commission, "Towards European Guidelines", 2004, p.1.
34. Convention on the Organisation for Economic Co-operation and Development on December 14, 1960 has 30 members, the majority of which are developed countries: <http://www.oecd.org> [Accessed June 25, 2009].
35. See Report of the Commission on Intellectual Property Rights, Innovation and Public Health, *Public Health, Innovation and Intellectual Property Rights*, WHO (April 2006), p.70.
36. Intellectual Property Rights from Publicly Financed Research and Development Regulations, *Government Gazette*, April 9, 2009, No.32120, p.4: reg.4(1) and (2).
37. Two "IP Hubs" were established in Colombia, SECOPI, and in the CEMAC region, SECOVIPI, using local researchers, lawyers and managers selected among the 130 persons that had been trained by WIPO. With the support of SECOPI in Colombia, patents have been filed nationally and through the PCT (Patent Cooperation Treaty) on a kit for the diagnosis of various cancers. With the support of SECOVIPI, the participating research institute in Gabon has also filed patent applications for plant extracts to produce drugs against cancer: See "Project Boosts Strategic Use of Intellectual Property by Health Research Institutes in Developing Countries", WIPO Press Release, Geneva, September 25, 2007: http://www.wipo.int/pressroom/en/articles/2007/article_0068.html [Accessed July 20, 2009].
38. See "Research Networks and Intellectual Property, 2004-2006", WIPO Publication, No.921(E): http://www.wipo.int/freepublications/en/intproperty/921/wipo_pub_921.pdf [Accessed July 20, 2009].

39. Sixty-First World Health Assembly, *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*, WHA61.21, May 24, 2008, p.10, para.30, 2.1(a) on promoting research and development, states that "supporting governments [are] to develop or improve national health research programmes..." and with other relevant stakeholders "promote cooperation between private and public sectors on research and development." See also 2.5 with regard to "establishing and strengthening national and regional coordinating bodies on research" at (b) on facilitating "the dissemination and use of research and development outcomes".
40. OECD (Organization for Economic Cooperation and Development), *Public-Private Partnerships, In Pursuit of Risk Sharing and Value for Money*, 2008, Ch.3, "The Economics of Public Private Partnerships: Is the PPP Route the Best Alternative?" See also OECD, "Economic Policy Reforms 2009, Going for Growth", Annex 6.A1: "Public-Private Partnerships: An Indicator of Framework Conditions". See further, on the advantages of PPPs, Kevin Outterson, "Access to Global Disease Innovation" (November 15, 2006). Available at SSRN: <http://ssrn.com/abstract=884241> [Accessed June 26, 2009]; and Solomon Nwaka and Robert G. Ridley, "Virtual Drug Discovery and Development for Neglected Diseases through Public-Private Partnerships" (2003) 2 *Nature Reviews, Drug Discovery* 919, 920.
41. See Special Programme for Research and Training in Tropical Diseases (TDR) at: <http://apps.who.int/tr> [Accessed July 20, 2009].
42. A number of scientific organisations, such as the Academy of Sciences of the Developing World (TWAS), Consortium on Science, Technology and Innovation for the South (formerly the Third World Network of Scientific Organizations), the African Union (AU) and the OIC's (Organisation of the Islamic Conference) Standing Committee on Science and Technology (COMSTEC), are promoting South-South research collaboration by means of policy interventions and initiatives. Developing countries of similar economic standing are also increasingly building bilateral and multilateral collaborations, such as the India-Brazil-South Africa Collaboration. Athar Osama, "Opportunities and Challenges in South-South Collaboration", May 14, 2008: <http://www.scidev.net/en/science-andinnovation-policy/south-south-cooperation> [Accessed June 26, 2009]. See also Roberto Mazzoleni and Richard R. Nelson, "Public Research Institutions and Economic Catch-Up" (2007) 36 *Res. Pol'y* 1512, 1515.
43. KEMRI received an award for Quality Scientific Research and excellent management in the International Quality Summit Awards Ceremony in 2007 in New York. See "BioChem Solutions: Product Development", <http://www.biochemsolutionsinc.com/development.php> [Accessed July 20, 2009].
44. Local and regional collaborators include universities, hospitals, government agencies such as the Kenyatta National Hospital, the Suez Canal University-Egypt; Noguchi Memorial Institute of Medical Research, Ghana; the Ethiopia Health and Nutrition Research Institute; Makerere University Medical School; University of Zambia Medical School and; the Medical Research Council of South Africa. International collaborators include the World Health Organization (WHO); Japan International Cooperation Agency (JICA); Walter Reed Army Institute of Medical Research (WAIR); United States Agency for International Development (USAID) and; the Royal Tropical Institute, Amsterdam. Kenya Medical Research Institute: Collaborators: <http://www.kemri.org/> [Accessed July 21, 2009]. Of note also is the Centre for Health Policy and Strategic Studies in Lagos, Nigeria, founded in 1995. Among Nigeria's Medical Schools, the University of Ibadan and the College of Medicine at the University of Lagos are particularly active in R & D.
45. The OECD Science, Technology and Industry Scoreboard 2007 analyses shares of NPL (non-patent literature) in citations across patent classes in order to provide insights into the technologies that are closer to scientific R & D and thus more dependent on the progress of scientific knowledge. An analysis of over 540, 000 international patent applications filed under the Patent Cooperation Treaty (PCT), published by the European Patent Office (EPO) shows that in the last 15 years the International Patent Classification (IPC) sub-classes with a higher than average share of citations to NPL (over 15%) are mainly in the fields of biotechnology, pharmaceuticals, other fine organic chemistry and ICT. This is consistent with other observed patterns of science-industry linkages in these fields such as university spin-offs, industry-university co-operation in R & D and the tendency for biotechnology companies to cluster around universities. See OECD: STI 2007, http://www.oecd.org/document/10/0,3343,en_2649_33703_39493962_1_1_1_1,00.html [Accessed July 20, 2009].
46. Joanna Von Braun and Meir P. Pugatch, "The Changing Face of the Pharmaceutical Industry and Intellectual Property Rights" (2005) 8 *J. World Intell. Prop.* 599 (discussing the need for change based on the instability of the revenue stream for the development and marketing of innovative products).
47. James Gilbert, Preston Henske and Ashish Singh, "Rebuilding Big Pharma's Business Model", (2003), pp.1-10, http://www.bain.com/bainweb/publications/publications_detail.asp?id=14184&menu_url=publications_results.asp [Accessed July 20, 2009] (explaining that the blockbuster business model that underpinned the major pharmaceutical companies' success is irreparably broken).
48. The phrase "Big Pharma" is commonly used to refer to pharmaceutical companies such as Novartis, Hoffmann-La Roche and GlaxoSmithKline with revenue in excess of \$3 billion, or R & D expenditure in excess of \$500 million. See Select Committee on Health, House of Commons, Fourth Report, 2004-5, H.C. 42-1, available at <http://www.publications.parliament.uk/pa/cm200405/cmselect/cmhealth/42/4205.htm> [Accessed June 26, 2009].
49. GlaxoSmithKline has announced it will reinvest a fifth of any residual profits made in developing countries in improving local healthcare, and share with other researchers the intellectual property on any of its experimental chemical compounds that could treat "neglected" developing world diseases: Andrew Jack, "GSK Limits Drug Prices in Poor Nations, *Financial Times*, February 14, 2009. See also Kazuhiro Asakawa and Ashok Som, "Internationalization of R&D in China and India: Conventional Wisdom Versus Reality" [2008] *Asia Pac. J. Mgmt.* (discussing the growing trend of foreign research and development investment in China and India). Further concerning the move by Big Pharma to outsource R & D to developing countries see "Gearing up for a Global Gravity Shift: Growth, Risk and Learning in the Asia Pharmaceutical Market", pp.24-27, <http://www.pwc.com/extweb/pwcpublications.nsf/docid/76DEF9E310AB1DCD802572DF002C5ECA> [Accessed July 20, 2009].
50. See "Strengthening China and India's Trade and Investment Ties to the Middle East and North Africa", World Bank, 2009: explaining how China and India's economic rise over the last two decades has accelerated their trade and investment flows with the Middle East and North Africa. The major strengths the Indian pharmaceutical industry has to offer PROs in developing countries include a cost-competitive manufacturing base that extends to clinical studies; extensive skills in chemistry and process development; the ability to manufacture over 50% of the bulk drugs needed for its pharmaceutical production activities locally; the emergence of a promising biotechnology industry; the availability of local scientists and R & D personnel of a high scientific quality; and a wide network of organisations performing various aspects of pharmaceutical R & D. Sampath, *Economic Aspects of Access to Medicines Post-2005: Product Patent Protection and Emerging Firm Strategies in the Indian Industry*, study conducted for CIPIH of the WTO, pp.700-702, <http://www.who.int/intellectualproperty/studies/PadmashreeSampathFinal.pdf> [Accessed June 26, 2009].
51. Ranbaxy is but one Indian pharmaceutical company that announced plans to spin off its drug-discovery division to a new subsidiary, to be called Ranbaxy Life Science Research that will enable the company to create intellectual property at a faster pace while also positioning for future expansion. "Ranbaxy to Demerge R&D Unit into a Subsidiary", *Econ. Times*, February 20, 2008, <http://www.stockwatch.in/ranbaxy-demerge-drug-discovery-unit-stock-surges-5-2468> [Accessed July 20, 2009]. For more information concerning the capacity of developing countries with innovation capacity to access foreign technology, see S. P. Agarwal, Ashwani Gupta and R. Dayal, "Technology Transfer Perspectives in Globalising India (Drugs and Pharmaceuticals and Biotechnology)" (2007) 32 *J. Tech. Transfer* 397, 397-423; John H. Barton and E.J. Emanuel, "The Patents-Based Pharmaceutical Development Process: Rationale, Problems, and Potential Reforms" (2005) 294 *J. Am. Med. Ass'n* 2075, 2075-2082.
52. The Indian pharmaceutical company Cipla has a presence in all the 53 markets of Africa. Nandini Patwardhan, "India on African Safari", *Express Pharma*, <http://w.expramaonline.com/20070630/market01.shtml> (explaining how Indian pharmaceutical companies consider the potential demand for drugs within Africa as an opportunity not to be ignored). See further Sampath, *Economic Aspects of Access to*

- Medicines Post-2005*, study conducted for CIPIH of the WTO, p.139, <http://www.who.int/intellectualproperty/studies/PadmashreeSampathFinal.pdf> [Accessed June 26, 2009].
53. Latest anti-malarials, single and multi-dose combination, as approved by WHO and ARVs are in high demand. India is the preferred country to source pharmaceutical products because of its quality and its competitiveness. India's full compliance with the TRIPs Agreement will affect newer, patented medicines, particularly those that have been patented since 2005. But the impact will be sizeable, as it will affect disease categories that show a high speed of new product development due to emerging resistance, such as antibiotics and anti-infectives (e.g. ARVs, TB drugs, anti-malarials), and new drug classes such as those for cancer and diabetes which have little therapeutic competition/substitution. Sampath, *Economic Aspects of Access to Medicines Post-2005*, study conducted for CIPIH of the WTO, p.718, <http://www.who.int/intellectualproperty/studies/PadmashreeSampathFinal.pdf> [Accessed June 26, 2009].
 54. Patwardhan, "India on African Safari", Express Pharma, <http://www.expresspharmaonline.com/20070630/market01.shtml> [Accessed July 20, 2009]. Further, Ranbaxy Laboratories recently acquired Be-Tab's Pharmaceuticals, the largest manufacturer of penicillin formulations in South Africa. According to the company's press release, the acquisition makes Ranbaxy the fifth largest generic pharmaceutical company in South Africa. "Ranbaxy Concludes Be-Tab's Buyout in S. Africa", Hindu Bus. Line, May 9, 2007, <http://www.thehindubusinessline.com/bline/blnri/2007/05/09/stories/2007050904010200.htm> [Accessed July 20, 2009].
 55. See generally PricewaterhouseCoopers, "Gearing up for a Global Gravity Shift: Growth, Risk and Learning in the Asia Pharmaceutical Market," 2007, <http://www.pwc.com/extweb/pwcpublications.nsf/docid/76DEF9E310AB1DCD802572DF002C5ECA> [Accessed July 20, 2009].
 56. Council on Governmental Relations, "The Bayh-Dole Act: A Guide to the Law and Implementing Regulations", pp.1-4 (1999), <http://www.cogr.edu/docs/BayhDole.pdf> [Accessed July 20, 2009].
 57. Government Gazette, April 9, 2009, No.32120, p.4, "Acquisition of Intellectual Property Rights by the State and Non-Commercialisation": reg.11(1) and (2).
 58. Marrakesh Agreement Establishing the World Trade Organization (April 15, 1994), reprinted in World Trade Organization, *The Results of the Uruguay Round of Multilateral Trade Negotiations: The Legal Texts* 4 (1995), p.4 (WTO Agreement); Annex IC: Agreement on Trade-Related Aspects of Intellectual Property Rights, reprinted in World Trade Organization, *The Results of the Uruguay Round of Multilateral Trade Negotiations: The Legal Texts* 321 (1995), p.321 (TRIPs Agreement).
 59. The UK Patents Act 1977 as amended, at s.30(4)(b) provides that "a licence may be granted under any patent or any such application for working the invention which is the subject of the patent or the application". Further see Phillip B.C. Jones, "Violation of a Patent License Restriction: Breach of Contract or Patent Infringement?" (1993) 33 IDEA: J. of Law & Tech. 225.
 60. See Lorelei Ritchie de Larena, "License to Sue?" (FSU College of Law, Public Law Research Paper No.279, October 2, 2007), available at <http://ssrn.com/abstract=1018715> [Accessed June 26, 2009] (discussing the intersection of normative values between intellectual property and contract law).
 61. See especially TRIPs art.8, providing that "Members may, in ... their laws and regulations, adopt measures necessary to protect public health". See to the same effect, para.4 of the Declaration on the TRIPs Agreement and Public Health: "We agree that the TRIPs Agreement does not and should not prevent members from taking measures to protect public health."
 62. ICESCR art.2(1) states that each "State Party to the present Covenant undertakes to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures." International Covenant on Economic, Social and Cultural Rights art.2(1), January 3, 1976, available at http://www.unhchr.ch/html/menu3/b/a_ceschr.htm [Accessed July 20, 2009]. Additionally, art.23 specifically identifies "the furnishing of technical assistance" as well as other activities, as being among the means of "international action for the achievement of the rights recognized". Further see TRIPs art.66(2) reaffirming this obligation in respect of least-developed country members.
 63. Concerning the current balance of rights and obligations, see Resolution 2000/7 of the UN Sub-Commission on Human Rights stating, "that since the implementation of the TRIPs Agreement does not adequately reflect the fundamental nature and indivisibility of all human rights, including the right of everyone to enjoy the benefits of scientific progress and its applications, the right to health ... there are apparent conflicts between the intellectual property rights regime embodied in the TRIPs Agreement, on the one hand, and international human rights law, on the other": E/CN.4/Sub.2/2000/L.20: <http://www.unhchr.ch/Huridocda/Huridocda.nsf/0/c462b62cf8a07b13c12569700046704e?Opendocument> [Accessed July 20, 2009].
 64. An exclusive licensee can sue infringers in their own right. See, e.g., s.67(1), Patents Act 1977 (as amended) (Eng.) which states that "the holder of an exclusive licence under a patent shall have the same right as the proprietor of the patent to bring proceedings in respect of any infringement of the patent committed after the date of the licence; and references to the proprietor of the patent in the provisions of this Act relating to infringement shall be construed accordingly."
 65. Association of University Technology Managers (AUTM), "In the Public Interest: Nine Points to Consider in Licensing University Technology" (2007), p.12, http://www.autm.net/Content/NavigationMenu/TechTransfer/WhitePapers/Points_to_Consider_letter.pdf [Accessed July 20, 2009].
 66. AUTM, "In the Public Interest", 2007, p.12, http://www.autm.net/Content/NavigationMenu/TechTransfer/WhitePapers/Points_to_Consider_letter.pdf [Accessed July 20, 2009].
 67. Exclusivity is also important to university spin-offs in the biomedical field because both rely on protected intellectual property as their main asset in raising capital for development. Organisation for Economic Co-operation and Development (OECD), "Patents and Innovation: Trends and Policy Challenges" (2004), p.22, <http://www.oecd.org/dataoecd/48/12/24508541.pdf> [Accessed June 26, 2009].
 68. AUTM, "In the Public Interest", 2007, p.13, http://www.autm.net/Content/NavigationMenu/TechTransfer/WhitePapers/Points_to_Consider_letter.pdf [Accessed July 20, 2009].
 69. The Lambert Model contracts were constructed by stakeholders from the UK University Research & Industry Links (AURIL), the Confederation of British Industry (CBI) and the Small Business Service (SBS). Lambert Working Group on Intellectual Property, "Model Agreements" (2005), <http://www.innovation.gov.uk/lambertagreements/index.asp?vl1=2&vl2=0&vl3=0&vl4=0> [Accessed June 26, 2009].
 70. AUTM, "In the Public Interest", 2007, p.12, http://www.autm.net/Content/NavigationMenu/TechTransfer/WhitePapers/Points_to_Consider_letter.pdf [Accessed July 20, 2009].
 71. Oliver Herzfeld and Richard Bergovoy, "Trademark Licensing Made Easy, Part I", *Managing Intellectual Property*, July 2007, <http://www.managingip.com> [Accessed June 26, 2009].
 72. Herzfeld and Bergovoy, "Trademark Licensing Made Easy", *Managing Intellectual Property*, July 2007, <http://www.managingip.com> [Accessed June 26, 2009].
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74. Herzfeld and Bergovoy, "Trademark Licensing Made Easy", *Managing Intellectual Property*, July 2007, <http://www.managingip.com> [Accessed June 26, 2009].
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77. Herzfeld and Bergovoy, "Trademark Licensing Made Easy", *Managing Intellectual Property*, July 2007, <http://www.managingip.com> [Accessed June 26, 2009].
78. AUTM, "In the Public Interest", 2007, p.12, http://www.autm.net/Content/NavigationMenu/TechTransfer/WhitePapers/Points_to_Consider_letter.pdf [Accessed July 20, 2009].
79. AUTM, "In the Public Interest", 2007, p.13, http://www.autm.net/Content/NavigationMenu/TechTransfer/WhitePapers/Points_to_Consider_letter.pdf [Accessed July 20, 2009].
80. AUTM, "In the Public Interest", 2007, p.13, http://www.autm.net/Content/NavigationMenu/TechTransfer/WhitePapers/Points_to_Consider_letter.pdf [Accessed July 20, 2009].
81. Sixty-First World Health Assembly, *Global Strategy and Plan of Action*, WHA61.21, May 24, 2008, p.11, para.30, 2.4(d).
82. See National Institutes of Health, Report of the National Institutes of Health (1998), <http://www.nih.gov/news/researchtools/index.htm> [Accessed June 26, 2009]; see also Centre for Science in the Public Interest, <http://www.cspinet.org/about/mission.html> [Accessed April 12, 2008].
83. University of Cambridge, Mission and Core Values, <http://www.admin.cam.ac.uk/univ/mission.html> [Accessed June 26, 2009].
84. AUTM, "In the Public Interest", 2007, p.12, http://www.autm.net/Content/NavigationMenu/TechTransfer/WhitePapers/Points_to_Consider_letter.pdf [Accessed July 20, 2009].
85. AUTM, "In the Public Interest", 2007, p.2, http://www.autm.net/Content/NavigationMenu/TechTransfer/WhitePapers/Points_to_Consider_letter.pdf [Accessed July 20, 2009].
86. William Cornish and David Llewelyn, *Intellectual Property: Patents, Copyrights, Trademarks and Allied Rights* (2007), p.284.
87. Cornish and Llewelyn, *Intellectual Property*, 2007, p.284.
88. Cornish and Llewelyn, *Intellectual Property*, 2007, p.284.
89. Cornish and Llewelyn, *Intellectual Property*, 2007, p.284.
90. Cornish and Llewelyn, *Intellectual Property*, 2007, p.284.
91. Cornish and Llewelyn, *Intellectual Property*, 2007, p.292.
92. Consolidated Version of the Treaty Establishing the European Community [2002] OJ C 325 art.28 <http://www.interreg3c.net/sixcms/media.php/5/EC+Treaty.6806.pdf> [Accessed June 26, 2009].
93. See generally David T. Keeling, *Intellectual Property Rights in EU Law: Free Movement and Competition Law* (2003), pp.6-7.
94. Treaty Establishing the European Economic Community art.30.
95. In *Centrafarm BV v Sterling Drug* (15/74) [1974] E.C.R. 1147, the ECJ held that the owner of the patent in Holland could not use its patent to block imports into Holland of drugs which had been put on to the market in the UK with its consent under the protection of its UK patent; see also *Merck Inc v Stephar BV* (187/80) 1981 E.C.R. 2063. Regarding trade marked pharmaceuticals, see *Boehringer Ingelheim KG and Boehringer Ingelheim Pharma GmbH & Co KG v Swingward* (C-348/04) [2007] E.C.R. I-3391, available at <http://oami.europa.eu/en/mark/aspects/pdf/JJ040348.pdf> [Accessed June 26, 2009]. The ECJ held that rules allowing trade mark owners to object to parallel imported pharmaceuticals within the European Economic Area (EEA) apply to re-labelled, as well as re-boxed, products.
96. The TTBE (Commission Regulation 772/2004 [2004] OJ L127 provides a block exemption that creates a safe harbour. Note that the technology transfer agreement must concern the production or supply of goods. Note further that R & D agreements are not covered by the TTBE, but Commission Regulation 2659/2000 [2000] OJ L304.
97. *L.C. Nungesser KG & Kurt Eisele v Commission of the European Communities* (258/78) [1982] E.C.R. 2015.
98. Treaty Establishing the European Community art.28.
99. Cornish and Llewelyn, *Intellectual Property*, 2007, pp.292-293. Article 81(3) of the ECTreaty provides by way of exception that "the provisions of paragraph 1 may, however, be declared inapplicable in the case of: any agreement ... between undertakings", which contributes to promoting technical or economic progress and "which does not afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question."
100. Cornish and Llewelyn, *Intellectual Property*, 2007, pp.292-293. See also Opi, "The Approaches of the European Commission and the U.S. Antitrust Agencies towards Exclusivity Clauses in Licensing Agreements" (2000) 85 B.C. Int'l & Comp. Law Rev. 85, 102-103.
101. *Nungesser* [1982] E.C.R. 2015 at [57].
102. [1982] E.C.R. 2015 at [57].
103. The test of whether an agreement may benefit from the block exemption is whether the parties to the agreement fall within specified market share thresholds. Where the parties are competitors, the threshold is reached if their combined market share is 20% or more. Where they are not, the threshold is only crossed if either of them separately has a 30% share or more. See TTBE art.3. There is reciprocity when each party is licensing competing technologies to the other. For the definitions of reciprocal and non-reciprocal agreements, see TTBE art.1(c)-(d).
104. Cornish and Llewelyn, *Intellectual Property*, 2007, p.293.
105. Cornish and Llewelyn, *Intellectual Property*, 2007, p.293.
106. Cornish and Llewelyn, *Intellectual Property*, 2007, p.293. On the distinction between absolute and open exclusivity, see Commission Notice, Guidelines on the Application of Article 81 of the EC Treaty to Technology Transfer Agreements [2004] OJ C101 (Article 81 Guidelines).

107. Cornish and Llewelyn, *Intellectual Property*, 2007, p.293.
108. Cornish and Llewelyn, *Intellectual Property*, 2007, p.293. Active sales by the licensee are made by actively approaching individual customers inside another distributor's exclusive territory by for instance, direct mail or visits or other promotions specifically targeted at that customer group; whereas sales in response to unsolicited requests from individual customers are considered passive sales. Commission Notice, Guidelines on Vertical Restraints, para.50 [2000] O.J. C 291.
109. e.g. Article 81 Guidelines, paras 63, 64, 77.
110. *Nungesser* [1982] E.C.R. 2015 at [44].
111. The standard improvement clause in a patent licence would stipulate: "If during the continuation of this Agreement the Owner shall develop or discover any improvement to any of the Inventions ('Improvement'), the Owner shall promptly notify the Licensee and provide full details to the Licensee." See also "Commission Notice, Guidelines on Vertical Restraints, para.50 [2000] OJ C 291.
112. *Terrell on Patents*, 16th edn (Sweet and Maxwell, 2005), para.10-52. See also Richard Binns and Bryan Driscoll, "Intellectual Property Issues in R&D Contracts, *Pharmaceutical Science & Technology* (1998) 1(3) *Today* 95, 99.
113. Philip Mendes, International Trade Center, "Licensing and Technology Transfer in the Pharmaceutical Industry, in *Exporting Pharmaceuticals: A guide for small and medium-sized exporters*" (2005), p.17, available at http://www.wipo.int/sme/en/documents/pharma_licensing.html [Accessed June 26, 2009].
114. Cornish and Llewelyn, *Intellectual Property*, 2007, Ch.7 "Property Rights and Exploitation", pp.284 *et seq.*
115. Cornish and Llewelyn, *Intellectual Property*, 2007, pp.254 *et seq.* See also Donald M. Cameron and Rowena Borenstein, "Key Aspects Of IP License Agreements" (2003), p.22, at <http://www.jurisdiction.com/lic101.pdf> [Accessed June 26, 2009].
116. See generally *National Broach v Churchill Gear* [1965] R.P.C. 516 CA.
117. AUTM, "In the Public Interest", 2007, p.4, http://www.autm.net/Content/NavigationMenu/TechTransfer/WhitePapers/Points_to_Consider_letter.pdf [Accessed July 20, 2009].
118. AUTM, "In the Public Interest", 2007, p.4, http://www.autm.net/Content/NavigationMenu/TechTransfer/WhitePapers/Points_to_Consider_letter.pdf [Accessed July 20, 2009].
119. Where the nature of the licensed subject-matter leaves any room for uncertainty, the licensor may be advised to add an exclusionary clause pointing out that "improvement" does not include developments to materials or processes useful in practicing the inventions of the licensed patents, but which do not themselves infringe the licensed claims of the licensed patent: Harold Einhorn, revisions by Thomas J. Parker, *Patent Licensing Transactions* (LexisNexis, first published 1968), Ch.6A "Government, University and Biotechnology Licensing", para.6A03[c], <http://www.lexisnexis.com/practiceareas/ip/pdfs/531CH6A.pdf> [Accessed June 29, 2009].
120. Under US patent law, if the licensee participated in the improvement enough to qualify as a named inventor he will have the right of use regardless of a licence. See 35 USC §262 (2001).
121. AUTM, "In the Public Interest", 2007, p.4, http://www.autm.net/Content/NavigationMenu/TechTransfer/WhitePapers/Points_to_Consider_letter.pdf [Accessed July 20, 2009]. Note that the "priority date" or the date of filing of the first application marks the point at which the patent will be examined for novelty, both at home and in the case of subsequent foreign applications: Paris Convention for the Protection of Industrial Property art.4.
122. AUTM, "In the Public Interest", 2007, p.4, http://www.autm.net/Content/NavigationMenu/TechTransfer/WhitePapers/Points_to_Consider_letter.pdf [Accessed July 20, 2009].
123. AUTM, "In the Public Interest", 2007, p.4, http://www.autm.net/Content/NavigationMenu/TechTransfer/WhitePapers/Points_to_Consider_letter.pdf [Accessed July 20, 2009].
124. European Commission Regulation on the Application of Article 81(3) of the Treaty to Categories of Technology Transfer Agreements (Commission Regulation 772/2004 [2004] OJ L123.
125. See TTBE art.5 and Recital 14.
126. The Commission may withdraw the benefit of the block exemption pursuant to art.29(1) of Regulation 1/2003 (the Modernisation Regulation) where it finds in a particular case that a technology transfer agreement to which the exemption provided for in art.2 has certain effects which are incompatible with the conditions laid down in art.81(3) of the EC Treaty. Council Regulation 1/2003 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty [2003] OJ L1/1. See TTBE art.6 and Recital 16.
127. *Intel Corp v Via Technologies Inc* [2002]EWCA Civ 1905 perMorritt V.C. at [72]: <http://www.bailii.org/ew/cases/EWCA/Civ/2002/1905.html> [Accessed June 26, 2009].
128. UK Patents Act s.60(5)(a). Note: although both art.69 and the Protocol of the European Patent Convention (EPC) specify that the scope of the right is determined by the terms of the claims, the experimental use exception in Europe has its origins in art.31(b) of the 1975 Luxembourg Convention on the Community Patent (Community Patent Convention). This provision became art.27(b), by means of the 1989 Agreement relating to Community Patents (Council Agreement 89/695 Relating to Community Patents, 1-27, [1989] OJ L401/1-27) that amended the 1975 Convention. The same text of art.27(b) is now found in art.9(b) of the draft Community Patent Regulation of 2004 which states that a "Community Patent shall not extend to acts done for experimental purposes relating to the subject matter of the patented invention". Proposal 10786/00 for a Council Regulation on the Community Patent art.9(b) [2000] OJ C337.
129. Sixty-First World Health Assembly, *Global Strategy and Plan of Action*, WHA61.21, May 24, 2008, p.12. Concerning the use of research exemptions, see also Report of the Commission on Intellectual Property Rights, Innovation and Public Health, *Public Health, Innovation and Intellectual Property Rights*, WHO (April 2006), pp.68-69.
130. See, e.g., Indian Patents Act s.60(5)(b).
131. Cornish and Llewelyn, *Intellectual Property*, 2007, pp.254-255.
132. *Auchincloss v Agricultural and Veterinary Supplies* [1999] R.P.C. 397 CA (Civ Div).
133. Lionel Bentley and Brad Sherman, *Intellectual Property Law* (2002), p.545.
134. EPC art.64(3) provides that any infringement of a European patent shall be dealt with by national law. See <http://www.epo.org/patents/law/legal-texts/html/epc/1973/e/ma1.html> [Accessed June 26, 2009]. Therefore no provision regarding defences to infringement is found in the EPC. Concerning the membership of the EPC, see Member States of the European Patent Organisation, <http://www.epo.org/about-us/epo/member-states.html#contracting> [Accessed June 26, 2009].
135. Most Members of the EPO have introduced a uniform, general non-industry specific experimental use exception in their patent statutes.

- For example, s.60(5)(a) and (b) of the UK Patents Act, refer to an act which is “done privately and for purposes which are not commercial” followed immediately by reference to an act which “is done for experimental purposes relating to the subject-matter of the invention”. See also Cornish and Llewelyn, *Intellectual Property*, 2007, p.254.
136. See *Monsanto v Stauffer Chem. Co* [1985] R.P.C 515 CA (Civ Div); *Smith Kline & French Laboratories Ltd v Evans Medical Ltd* [1989] F.S.R 513 Ch D. The court in the latter case observed that “what is or is not an experiment must depend upon the facts of each case but can include experiments designed with a commercial end in view”.
137. *Inhale Therapeutic Systems Inc v Quadrant Healthcare Plc* [2002] R.P.C. 21 Ch D.
138. *John M.J. Madey v Duke University* 307 F. 3d 1351 (Fed. Cir. 2003), cert. denied, 123 S. Ct 2639 (2003).
139. The later concept reflects the common law experimental use exception, considered to have originated in the remarks of Justice Story that the legislature could not have intended to punish those who undertook “philosophical experiments” with protected items: *Whittemore v Cutter* 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813).
140. Similarly see *Merck KGaA, Petitioner v Integra Lifesciences I, Ltd* 545 U.S. 193 (2005), where the US Supreme Court held academic research too remote from the regulatory filing process to fall within the scope of the exemption allowable under the safe harbour provision of the Hatch-Waxman Act (Drug Price Competition and Patent Term Restoration Act of 1984, 35 USC §271(e)(1) (2006).
141. Cornish and Llewelyn, *Intellectual Property*, 2007, p.254.
142. Cornish and Llewelyn, *Intellectual Property*, 2007, p.254.
143. *Monsanto v Stauffer* [1985] R.P.C. 515.
144. Cornish and Llewelyn, *Intellectual Property*, 2007, p.255.
145. The Hatch-Waxman Act is also known as the Drug Price Competition and Patent Term Restoration Act of 1984. 35 USC §271 (2006). It allows generics to win FDA marketing approval by submitting bioequivalence studies. Manufacturers of generic pharmaceuticals are permitted to use the technology of a patented pharmaceutical to perform work that would assist in the marketing or regulatory approval of the generic product, while the patent is in force. This “Bolar” provision then allows the generic producer to market and manufacture their goods as soon as the patent expires. It also grants a period of additional marketing exclusivity to make up for the time a patented pipeline drug remains in development. This extension cannot exceed five years, and it is in addition to the 20-year exclusivity granted by the issuance of a patent.
146. “Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.” Council and European Parliament Directive 2004/27 amending Directive 2001/83 on the Community Code Relating to Medicinal Products for Human Use [2004] OJ L136/6 art.10. This provision was implemented in the UK Patents Act as follows: “An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if ... it consists of: (i) an act done in conducting a study, test or trial which is necessary for and conducted with a view to the application of paragraphs 1 to 5 of Article 13 of Directive 2001/82/EC or paragraphs 1 to 5 of Article 10 of Directive 2001/83/EC, or (ii) any other act which is required for the purpose of the application of those paragraphs.” UK Patents Act s.60(5). Note the trade-off is that the Directive introduced an eight-year data exclusivity period with an additional two years of market exclusivity so that a generic medicinal product “shall not be placed on the market until ten years have elapsed from the initial authorization of the reference product”.
147. Cornish and Llewelyn, *Intellectual Property*, 2007, p.255.
148. A narrow interpretation of the experimental use exception in *Madey v Duke* 307 F. 3d 1351 (Fed. Cir. 2002) impedes the “Progress of Science and useful Arts”. Brief of Amici Curiae Consumer Project on Technology and Public Knowledge in Support of Petition for Writ of Certiorari, 307 F. 3d 1351 (Fed. Cir. 2003).
149. Andrew Gowers, *Gowers Review of Intellectual Property* (2006), pp.45-76, http://www.hm-treasury.gov.uk/gowers_review_index.htm [Accessed July 20, 2009].
150. *Madey* 307 F. 3d 1351, 1362 (Fed. Cir. 2002).
151. AUTM, “In the Public Interest”, 2007, p.11, http://www.autm.net/Content/NavigationMenu/TechTransfer/WhitePapers/Points_to_Consider_letter.pdf [Accessed July 20, 2009].
152. AUTM, “In the Public Interest”, 2007, p.11, http://www.autm.net/Content/NavigationMenu/TechTransfer/WhitePapers/Points_to_Consider_letter.pdf [Accessed July 20, 2009].
153. See Joshua D. Sarnoff and Christopher M. Holman, “Recent Developments Affecting the Enforcement, Procurement, and Licensing of Research Tool Patents” (2008), paras 99.40-99.50. Available at SSRN: <http://ssrn.com/abstract=1118473> [Accessed June 26, 2009]. This work discusses a variety of alternatives to the experimental use and regulatory approval exceptions that could facilitate access and continued use of patented technologies in scientific research and commercial development.
154. AUTM, “In the Public Interest”, 2007, p.2, http://www.autm.net/Content/NavigationMenu/TechTransfer/WhitePapers/Points_to_Consider_letter.pdf [Accessed July 20, 2009].
155. AUTM, “In the Public Interest”, 2007, p.2, http://www.autm.net/Content/NavigationMenu/TechTransfer/WhitePapers/Points_to_Consider_letter.pdf [Accessed July 20, 2009].
156. AUTM, “In the Public Interest”, 2007, p.2, http://www.autm.net/Content/NavigationMenu/TechTransfer/WhitePapers/Points_to_Consider_letter.pdf [Accessed July 20, 2009]. See, e.g., Gene Service, “Material Transfer Agreements for the Supply of Biological Matter”, www.geneservice.co.uk/products/mtas/ce_acad_mta_USA.pdf [Accessed July 20, 2009].
157. AUTM, “In the Public Interest”, 2007, p.2, http://www.autm.net/Content/NavigationMenu/TechTransfer/WhitePapers/Points_to_Consider_letter.pdf [Accessed July 20, 2009].
158. The OECD “Principles and Guidelines for Access to Research Data from Public Funding” serve to stress the importance of publication and access to scientific research in meeting the challenges of health care: OECD, 2007: <http://www.oecd.org/dataoecd/9/61/38500813.pdf> [Accessed June 26, 2009].
159. The requirements of patent law for novelty and non-obviousness involve searching for *prior art*, i.e. earlier publications that show the invention is not new or obvious. See *Massachusetts Institute of Technology v AB Fortia* 774 F. 2d 1104 (Fed. Cir. 1985).
160. AUTM, “In the Public Interest”, 2007, p.10, http://www.autm.net/Content/NavigationMenu/TechTransfer/WhitePapers/Points_to_Consider_letter.pdf
161. See European Patent Office, DG3: DBA case G 0003/93 EBA (August 16, 1994), available at

- <http://legal.european-patent-office.org/dg3/biblio/g930003ep1.htm> [Accessed June 26, 2009] (regarding the underlying legal principles EPO Enlarged Board of Appeals).
162. See European Patent Organisation, "The Patent Process", <http://www.epo.org/about-us/office/annualreports/2005/business-report/patent-process.html> [Accessed June 26, 2009] (paying a filing fee during the priority application leads to EPO issuance of a search report and a written opinion, which may provide the applicant with advanced notice of the doubtfulness of patentability).
163. Michael A. Heller, "The Tragedy of the Anticommons: Property in the Transition from Marx to Markets" (1998) 111 Harv. L. Rev. 621, 626.
164. Benjamin Coriat and Fabienne Orsi, "Are 'strong patents' Beneficial to Innovative Activities? Lessons from the Genetic Testing for Breast Cancer Controversies" (2005) 14 Indus. & Corp. Change 1205, 1212-1213.
165. Coriat and Orsi, "Are 'strong patents' Beneficial to Innovative Activities?" (2005) 14 Indus. & Corp. Change 1205, 1213. Note, however, the difficulties Myriad Genetics experienced in attempting to dominate the European market, the grant of three patents on BRCA genes by the European Patent Office (EPO) to the company provoked significant controversy.
166. AUTM, "In the Public Interest", 2007, p.5, http://www.autm.net/Content/NavigationMenu/TechTransfer/WhitePapers/Points_to_Consider_letter.pdf [Accessed July 20, 2009].
167. See, e.g., Conditions for Patentability; Novelty and Loss of Right to Patent, 35 USC §102 (2008) (providing a "grace period" of one year prior to the date of application in the United States). Disclosures by the inventor during the "grace period" do not have a patent-defeating effect. In contrast, other patent laws, including that in the European Patent Convention (EPC), have an "absolute novelty" requirement such that any disclosures, including those by an inventor himself, made prior to the date a patent application is filed, are considered prior art.
168. See, e.g., South African Institute of Intellectual Property Law, Copyright Information, <http://www.saiipl.org.za/introductio-patents.htm> [Accessed June 26, 2009] (explaining that in South Africa it is possible to file a provisional patent application, a complete patent application, or a Patent Cooperation Treaty (PCT) International Patent Application which also designates South Africa). If the idea has not been finalised in detail then a provisional patent application is usually the first step in obtaining patent protection while having 12 months during which to conduct further experiments and make further improvements.
169. Paris Convention for the Protection of Industrial Property art.4.
170. See World Intellectual Property Organization, Patent Cooperation Treaty (June 19, 1970), available at <http://www.wipo.int/pct/en/texts/articles/atoc.htm> [Accessed June 26, 2009]. Currently, 124 countries in the world are members of the PCT, with South Africa having joined in 2000. World Intellectual Property Organization, "PCT: One Million and Counting" (2004), p.2, <http://www.wipo.int/export/sites/www/pct/en/million/leaflet.pdf> [Accessed June 26, 2009]. The cost of filing a PCT application typically ranges from £4,000-£6,000 (excl.VAT). The main advantage of filing a PCT application is that the deadline for filing patent applications in countries or territories of interest is delayed by a further 18 months.
171. TTBE art. 5(1)(c) states that the exemption will not apply to "any direct or indirect obligation on the licensee not to challenge the validity of intellectual property rights which the licensor holds in the common market, without prejudice to the possibility of providing for termination of the technology transfer agreement in the event that the licensee challenges the validity of one or more of the licensed intellectual property rights".
172. See *Lear v Adkins* 395 U.S. 653 (1969) (regarding the enforceability of such a provision).
173. See, e.g., the Drug Price Competition and Patent Term Restoration Act, 21 USC §301 (1984), which provides for a notification process similar to that by Generic Drug Manufacturers under para.IV of s.505(j) of the Drug Price Competition and Patent Term Restoration Act of 1984.
174. Concerning the need for R & D that also facilitates access to technologies for health. See WHO, *Fifty-Sixth World Health Assembly Report by the Secretariat, Intellectual Property Rights, Innovation and Public Health*, A56/17, May 12, 2003, pp.2 and 3.
175. An express reservation of rights in a licensing agreement can ensure that the PRO's institutional objectives to support humanitarian applications of its technology are not inhibited by an overly broad definition of the licensee's rights: Alan B. Bennett, "Reservation of Rights for Humanitarian Uses" in Centre for Management of Intellectual Property in Health Research and Development (MIHR), *Intellectual Property Management in Health and Agricultural Innovation, Intellectual Property Handbook Of Best Practices*, Executive Guide Ch.2.1 at p.41, <http://www.iphandbook.org/handbook/ch02/p01/> [Accessed July 20, 2009].