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Strategic Patent Licensing for Public Research Organizations: Deploying Restriction and Reservation Clauses to Promote Medical R&D in Developing Countries

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In May 2006, at the World Health Assembly, the governments of Kenya and Brazil called on fellow nations to promote the development of the public health tools necessary to build the research capacity of developing countries. That call was again made at the G8 Summit in June 2007,[1] when the national science academies of the G8 nations and Brazil, China, India, Mexico and South Africa signed a statement on the promotion and protection of innovation. Highlighting the need to balance the protection of intellectual property with the need to foster access to knowledge and remove barriers to innovation, the statement calls on world leaders to:

> Work with developing countries to build systems of science, technology and innovation for economic and social development, and to promote the education and training of their future leaders particularly in science, engineering, technology, and medicine.[2]

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[1] The Group of Eight (G8), also known as Group of Seven and Russia, is an international forum for the governments of Canada, France, Germany, Italy, Japan, Russia, the United Kingdom and the United States. Together, these countries represent about 65% of the world economy and the majority of global military power. The group's activities include regular meetings and policy research, culminating with an annual summit meeting attended by the heads of government of the member states. The European Commission is also represented at the meetings. Recently the Group was expanded to include five developing countries: Mexico, China, India, Brazil, and South Africa. This new Group is known as the G8+5. *See* Press Release, Joint Science Academies' Statement on Growth and Responsibility: The Promotion and Protection of Innovation (May 2007), www.royalsociety.org/displaypagedoc.asp?id=25502.

[2] *Id.*

As to the means of working with developing countries to build innovative capacity, the Network of African Science Academies (NASAC), made the following recommendations to the leaders of the G8 countries:

> That the G8 governments provide financial, scientific and technical support for the efforts of the African scientific community, including NASAC and the Association of African Universities (AAU), to work with the academies of science, engineering and medicine in G8 countries, to promote International cooperation in science and technology for the purposes of advancing the Millennium Development Goals (MDGs) in Africa.[3]

The prominence of public health within the internationally agreed framework of eight goals and eighteen targets provides an indication of the magnitude of the problem. Public health issues feature in no less than four of the eight millennium development goals. Goals Four, Five and Six speak respectively of reducing child mortality, improving maternal health, and combating epidemic diseases such as HIV/AIDS and malaria. Over and above the goals specifically directed to public health, Goal Eight is especially relevant for the development of an indigenous supply of affordable medicines. The eighth MDG aspires to create a "Global Partnership for Development" that is, in turn, offset by Target Seventeen, entitled "Access to Medicines." This Target exhorts fellow Members of the United Nations, in cooperation with pharmaceutical companies, to provide access to affordable, essential drugs in developing countries.[4]

According to the World Health Organization (WHO), the principal causes of death in the developing world are respiratory infections, HIV/AIDS, infections at birth, diarrhoeal disease[5] and tropical diseases such as malaria.[6]

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[3] *See* Press Release, Network of African Science Academies, Joint Statement by the Network of African Science Academies (NASAC) to the G8 on Sustainability, Energy Efficiency, and Climate Change (May 2007), royalsociety.org/downloaddoc.asp?id=4226. Further, in May 2008, the World Health Organization Intergovernmental Working Group on Public Health gave renewed emphasis to the need for the promotion of "upstream research and product development in developing countries," support for "early-stage drug research and development in developing countries," and "improving cooperation, participation and coordination of health and biomedical research and development." World Health Organization Intergovernmental Working Group on Public Health, Innovation and Intellectual Property [WHO IGWG], White Paper: Draft Global Strategy on Public Health, Innovation, and Intellectual Property, paras. 30(2.1) and 30(2.2) (May 3, 2008), *available at* www.who.int/phi/documents/IGWG_Outcome_document03Maypm.pdf.

[4] At the Millennium Summit in September 2000 the UN Millennium Declaration was adopted, committing nations to a new global partnership to reduce extreme poverty. It set out a series of time-limited targets that have become known as the Millennium Development Goals (MDGs) and have a deadline of 2015. UN Millenium Project: About MDGs, www.unmillenniumproject.org/index.htm (last visited Apr. 12, 2008). *See generally* Lawrence O. Gostin, *Meeting Basic Survival Needs of the World's Least Healthy People, Toward a Framework Convention on Global Health*, 96 Geo. L.J. 331 (2008).

[5] Diarrhoeal diseases account for 17% of deaths among children under five years of age worldwide, or nearly 2 million child deaths every year, making them the second most common cause of child deaths globally. *See* UNICEF End Decade Databases, www.childinfo.org/eddb/Diarrhoea/index.htm (last visited Apr. 12, 2008).

[6] Many commentators have suggested that the elite pharmaceutical industry is failing to devote sufficient R&D effort towards finding effective cures and treatments for tropical infectious diseases including malaria, leishmaniasis, leprosy, and Guinea worm. These so-

Nevertheless, it is commonly claimed that only 10% of the world's medical research is devoted to conditions that account for 90% of the global disease burden.[7] Irrespective of whether such estimates represent an accurate indication of the imbalance between R&D and the risks to public health, a sustainable supply of affordable medicines will require action to mobilize collaborations between public research organizations (PROs) for drug discovery and partnerships for drug development within the pharmaceutical industry.[8] Thus, there remains a need to develop better drugs and vaccines for diseases that are largely confined to developing countries.

Many drugs for diseases prevalent in the developing world are antiquated or have serious side effects and many organisms that cause these diseases are developing resistance to treatment.[9] Although effective medicines are available for many of the most prevalent diseases, ensuring access in resource-poor countries is of major concern due to problems of cost, delivery, and healthcare support. The factors that are expected to catalyze the need for indigenous R&D in developing countries are epidemics, an aged population and the growing incidence of lifestyle-related diseases giving rise to increased healthcare expenditure.[10] Hence, the developing countries at the G8 Summit called for financial and technical help to make the strengthening of research capacity a central goal of public health policy.

Today, a combination of deep economic integration and the increasing harmonization of patent law means that developing countries that are seeking to build innovative capacity in medical technologies are confronted with an historically distinct set of circumstances. By 2005, developing countries were required to implement in domestic legislation all the substantive and enforcement provisions of the WTO Agreement on Trade-Related Aspects of

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called 'neglected' diseases predominantly effect poor populations in low income countries. Patrice Trouiller, for example, has pointed out that of the 1,393 total new drugs approved between 1975 and 1999, only 1% (16 drugs) were specifically indicated for a tropical disease. Patrice Trouiller et al., *Drug development for Neglected Diseases: A Deficient Market And A Public-Health Policy Failure*, 359 THE LANCET 2188, 2188 (2002), *cited in* PHILIP STEVENS, DISEASES OF POVERTY AND THE 10/90 GAP, 3-4 (2004), www.who.int/intellectualproperty/submissions/InternationalPolicyNetwork.pdf.

[7] MEDECINS SANS FRONTIERES & THE DRUGS FOR NEGLECTED DISEASES WORKING GROUP, FATAL IMBALANCE: THE CRISIS IN RESEARCH AND DEVELOPMENT FOR DRUGS FOR NEGLECTED DISEASES 10 (2001), www.doctorswithoutborders.org/publications/reports/2001/fatal_imbalance_short.pdf.

[8] In terms of mortality rates, neglected diseases often do not represent the most pressing public health priorities in low-income countries. They constitute a small fraction of their total disease burden. According to the 2002 World Health Organization's (WHO) World Health Report, tropical diseases accounted for only 0.5% of deaths in high-mortality poor countries, and only 0.3% of deaths in low mortality poor countries. *See* WHO, WORLD HEALTH REPORT 81-82 (2008) (Figure 4.8 concerning the "Amount and patterns of burden of disease in developing and developed countries" and Figure 4.9 concerning "Global distribution of burden of disease attributable to 20 leading selected risk factors").

[9] For example, the treatment of leishmaniasis relies on drugs developed in the 1940s, which can cause kidney failure. Also, the parasite that causes malaria rapidly adapts itself to new drugs. *See* Parliamentary Office of Science and Technology, *Fighting Diseases of Developing Countries*, 241 POSTNOTE 1, 1 (2005), www.parliament.uk/parliamentary_offices/post/pubs2005.cfm.

[10] Increasing economic development means that the nature of diseases suffered by both low- and high-income countries is converging. For example, non-communicable diseases such as cancers and cardiovascular diseases now represent over 60% of the total global disease burden, affecting both rich and poor countries. STEVENS, *supra* note 6, at 5.

Intellectual Property Rights (TRIPS),[11] including patent protection for pharmaceutical products.[12] To this end, TRIPS Article 28, concerning the rights conferred on the patentee, stipulates that during the term of the patent, any person imitating the invention or new manufacturing process, not having the consent of the patent holder, is committing an act of infringement.[13]

The conclusion of the TRIPS Agreement in 1994 thereby changed two common elements of past economic development.[14] First, it required the implementation of mandatory and enforceable standards of intellectual property rights.[15] Second, to the extent that firms in advanced economies now have the means to enforce their intellectual property rights worldwide, developing countries have to generate strategies for access to technologies on reasonable terms and eschew outright imitation.[16] For these reasons, government innovation policy for the pharmaceutical sector must focus not only on manufacture but also on supporting the development of a research infrastructure.[17]

To date, the attention of legal scholars to issues of public health in the developing world has of necessity focused on the rapid procurement of affordable medicines by means of compulsory licensing and parallel importing. While these means are necessary to address the national emergencies of epidemic disease, they are not the means to build a sustainable public health program for the provision of essential and affordable medicines.

This paper seeks to move the legal debate upstream by focusing on the potential of patent licensing contracts between public research organizations (PROs) and the private sector to provide greater access to the kinds of medicines needed by patient populations in developing countries. In affirmation of the need to build research capacity in developing countries, this paper will therefore examine the content and potential scope of reservation and restriction clauses in patent licensing contracts. By this means, it is argued that developing countries can achieve an appropriate balance between the needs of the pharmaceutical industry for patent protection and those of PROs to disseminate knowledge as broadly as possible. In conclusion, it is submitted that the intersection of property and contract law provides an opportunity for developing country PROs as licensors to utilize the patent

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[11] Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations (Apr. 15, 1994), *reprinted in* World Trade Organization, The Results of the Uruguay Round of Multilateral Trade Negotiations: The Legal Texts 2 (1995); Marrakesh Agreement Establishing the World Trade Organization (Apr. 15, 1994), *reprinted in* World Trade Organization, The Results of the Uruguay Round of Multilateral Trade Negotiations: The Legal Texts 4 (1995) [hereinafter 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) [hereinafter TRIPS Agreement].

[12] *See, e.g.*, The Patents (Amendment) Act, 2005, No. 15 of 2005, Acts of Parliament, 2005, *available at* www.patentoffice.nic.in/ipr/patent/patent_2005.pdf.

[13] TRIPS Agreement, *supra* note 11, at Art. 28.

[14] Roberto Mazzoleni & Richard R. Nelson, *Public Research Institutions And Economic Catch-Up* 36 Res. Pol'y 1512, 1515 (2007).

[15] *Id.* at 1516.

[16] *Id.*

[17] *Id.*

licensing contract to reclaim the policy space needed in overcoming the obstacles relating to the research and development of medicines.

In the exposition of this argument, the paper is organized as follows: Part I explains how universal standards of intellectual property protection under the TRIPS Agreement have recast the parameters of economic catch-up. Part II describes how, post TRIPS, PROs have a central role to play in advancing pharmaceutical research and development. Part III evaluates the Bayh-Dole model of technology transfer from public to private sector, in relation to the feasibility of patent ownership by PROs in developing countries. Part IV considers the case for developing-country PROs negotiating restriction and reservation clauses. Part V describes how PROs as licensors might utilize a mix of exclusive and non-exclusive licenses to promote R&D. Part VI offers drafting guidelines for restrictive clauses as to field of use and territory. It also considers the potential impact of competition law, as exemplified by the European Commission Technology Transfer Block Exemption (TTBE),[18] on the operation and scope of such clauses. Part VII offers drafting guidelines for reservation clauses for research, publication and experimental use. Finally, with a view to preserving the benefits of the licensing transaction, Part VIII considers the validity of no-challenge clauses after the US Supreme Court decision in *Medimmune*.

I. POST TRIPS DYNAMIC OF INNOVATION AND ECONOMIC CATCH-UP

A. UNIVERSAL MINIMUM STANDARDS OF PATENT PROTECTION

The universal standards of intellectual property protection within the TRIPS Agreement have recast the parameters of economic catch-up.[19] The kind of policy "space" India enjoyed for more three decades is no longer possible. A major contributor to the development of a pharmaceutical industry in India was the speed with which its scientists were able to develop cost-effective manufacturing processes for molecules already invented and patented in other countries — a practice supported by the Indian Patents Act

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[18] The Technology Transfer Block Exemption, laid out in the European Commission Regulation on the Application of Article 81(3) of the Treaty to Categories of Technology Transfer Agreements (Commission Regulation 772/2004, 2004 O.J. (L 123) (EC) [hereinafter TTBE]), applies to technology transfer agreements including patent licensing agreements; know-how licensing agreements; software copyright licensing agreements and combinations of these. For a summary of this legislation, *see* SCADPLUS: Technology Transfer Agreements, europa.eu/scadplus/leg/en/lvb/l26108.htm (last visited Apr. 12, 2008). The rationale for the TTBE is provided by Article 81(1) of the EC Treaty which prohibits anticompetitive agreements unless they can be saved under Article 81(3), which prohibits anticompetitive licensing agreements affecting trade between Member States. *See* Consolidated Versions of the Treaty on European Union and of the Treaty Establishing the European Community, 2006 O.J. (C 321 E) [hereinafter EC Treaty]. Further *see* Cyril Ritter, *The New Technology Transfer Block Exemption under EC Competition Law*, 31 LEGAL ISSUES ECON. INTEGRATION 161 (2004).

[19] *See generally* Benjamin Coriat, Fabienne Orsi & Cristina d'Almeida, *TRIPS and the International Public Health Controversies: Issues and Challenges*, INDUS. & CORP. CHANGE 1033, 1059-60 (2006) (contrasting the supply of medicines in developing countries before and after the conclusion of the TRIPS Agreement, arguing that TRIPS needs greater accommodation for the manufacture of generic medicines).

1970.[20] That Act introduced restrictive changes related to the patenting of inventions, especially in the field of pharmaceuticals.[21] Such restrictive changes included:

- Withdrawing patent grant for inventions claiming substances intended for use as, or capable of being used as, a medicine or drug or substances resulting from chemical processes, permitting patentability only for claims for methods or processes of manufacture;[22]
- Reducing the term of process patents for inventions related to processes in the filing of foods, medicines or drugs to seven years from the date of filing of the complete specification or five years from the date of sealing the patent, whichever is shorter.[23]

The TRIPS Agreement requires developing countries to implement in their national law the universal minimum standards of patent protection. Article 27 of the TRIPS Agreement provides an inclusive definition of patentable subject matter. It stipulates that patents "shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."[24] Article 28, confers on the patentee the negative right "to prevent third parties not having the owner's consent from acts of making, using, offering for sale, selling, or importing for these purposes that product." As of 2005, it is no longer possible for developing countries that are unable to invest in R&D to exclude pharmaceutical products (as distinct from processes) from patentability so as to allow the possibility for copies of patented drugs to be produced locally or imported from other similarly placed developing countries.

Further, Article 27 makes it clear that the patentee is entitled to the rights conferred therein irrespective of "whether products are imported or locally produced." Prior to TRIPS it was open to developing countries to issue

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[20] The Patents (Amendment) Act, 1970, No. 39 of 1970, Acts of Parliament, 1970, *available at* www.wipo.int/clea/en/details.jsp?id=2393.

[21] Section 3 lists the subject matter that is deemed non-patentable to include: inventions that are "injurious to public health, mere discoveries, admixtures and trivial re-arrangements" as well as: "any process for the medicinal, surgical, curative, prophylactic or other treatment of human beings . . . to render them free of disease or to increase their economic value or that of their products." *Id. See generally* Dwijen Rangnekar, *Context and Ambiguity in the Making of Law: A Comment on Amending India's Patent Act*, 10 J. WORLD INTELL. PROP. 365, 375 (2007); Padmashree Gehl Sampath, *India's Product Patent Protection Regime: Less or More of "Pills for the Poor"?* 9 J. WORLD INTELL. PROP. 694, 700-02 (2006) [hereinafter Sampath].

[22] *See* The Patents Act, 197012, at § 5(1) (providing that in the case of "inventions-claiming substances intended for use, or capable of being used, as food or as medicine or drug, . . . no patent shall be granted in respect of claims for the substances themselves, but claims for the methods or processes of manufacture shall be patentable").

[23] *See id.* at § 53(1) (providing that "in respect of an invention claiming the method or process of manufacture of a substance, where the substance is intended for use, or is capable of being used, as food or as a medicine or drug, be five years from the date of sealing of the patent, or seven years from the date of the patent whichever period is shorter; and in respect of any other invention, be fourteen years from the date of the patent").

[24] TRIPS Agreement, *supra* note 11, at Art. 28.

compulsory licenses for lack of exploitation of patents, in accordance with Article 5A(2) of the Paris Convention.[25] This type of obligation was intended to require foreign companies to establish on national territory in order to exploit their patents, with resultant technology transfer. Nevertheless, Article 27 of TRIPS and Article 5A(4) of the Paris Convention as incorporated therein, appear to allow foreign patentees to import their patented products without having to transfer related technology. For example, the definition of "failure to work" in Article 68 of Brazil's Industrial Property Law may be read as failure to manufacture or failure to completely manufacture a patented process in the territory of Brazil.[26] That law appears to allow for import only in the case of failure to work due to economic viability and in that respect it is arguably in breach of TRIPS Article 27. In January 2001, the United States challenged the Brazilian law.[27] There was no definitive interpretation by the WTO Appellate Body, as the request for the establishment of a Panel was withdrawn when the parties came to a settlement.[28] In this respect, TRIPS has rendered the position more uncertain for developing countries that are attempting to effect technology transfer. Whereas the Paris Convention expressly authorizes, on certain conditions, compulsory licensing for the failure to work patents locally, TRIPS does not contain such a clear and express authorization.

B. LIMITED EXEMPTIONS FROM PATENT PROTECTION

The defenses to patent infringement within the TRIPS Agreement are few and narrow in application. Article 8 expressly affirms that "[m]embers may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health." Article 7 speaks of a "a balance of rights and obligations." It affirms that the transfer and dissemination of technology should be to the mutual advantage of both producers and users of technological knowledge, should be made in a manner conducive to social and economic welfare, and should be expressed free of conditions.[29] Article 30

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[25] *See* TRIPS Agreement, *supra* note 11, at Art. 2 (incorporating Article 5 of the Paris Convention as amended in 1883); Paris Convention for the Protection of Industrial Property Art. 5, Mar. 20, 1883, 21 U.S.T. 1583, 828 U.N.T.S. 305 [hereinafter Paris Convention].

[26] *See* Paul Champ & Amir Attaran, *Patent Rights and Local Working under the WTO TRIPS Agreement: An Analysis of the U.S.-Brazil Patent Dispute*, 27 YALE J. INT'L L. 365, 365-70 (2002) (arguing against too simplistic an interpretation of the relationship between Article 68 of Brazil's Industrial Property Law concerning local working requirements and Articles 27 and 28 of the TRIPS Agreement); *see also* Michael Halewood, *Regulating Patent Holders: Local Working Requirements and Compulsory Licences At International Law*, 35 OSGOODE HALL L. J. 243, 247 (1997) (similarly arguing that that domestic law requiring mandatory working and compulsory licensing would not contradict the substantive provisions of the NAFTA and the TRIPS Agreements).

[27] *See* Request for the Establishment of a Panel by the United States, *Brazil – Measures Affecting Patent Protection*, WT/DS 199/3 (Jan. 8, 2001) (concerning the U.S. complaint that Brazil discriminated against the availability and enjoyment of patent rights on the basis of whether products are imported or locally produced).

[28] *See* Notification of Mutually Agreed Solution, *Brazil – Measures Affecting Patent Protection*, WT/DS199/4G/L/454, IP/D/23/Add.1 (July 19, 2001). Without prejudice to their respective positions, the United States and Brazil agreed to enter into bilateral discussions prior to Brazil's invoking Article 68 against a U.S. patent holder.

[29] *See also* Sub-Comm'n on the Promotion & Prot. of Human Rights, Res. 2001/21, U.N. Doc. E/CN.4/Sub.2/RES/2001/21 (Aug. 16, 2001).

provides additional flexibilities by way of exceptions to the exclusive rights conferred by a patent. However, these are expressly described as "limited exceptions."[30] Finally, Article 31 sets up a regulatory framework for compulsory licensing that allows governments to issue compulsory licenses in order to permit the generic production of essential medicines without the consent of patent holders.

Generally speaking, the TRIPS Agreement introduces a higher standard of national treatment in relation to its substantive provisions for the creation and enforcement of patent protection.[31] To this end, any derogation from the minimum standards of protection stipulated by the Agreement for purposes of public health will be subject to the proviso of non-discrimination against foreign right holders.[32] By such means, TRIPS recasts the parameters within which decisions about innovation can be made. The rules serve as a restraint[33] on the ability of Members to formulate national law and policy in accordance with their level of economic development. In short, TRIPS constrains imitation as a form of competitive conduct.[34]

The so-called flexibilities of the TRIPS Agreement required reaffirmation. In 2001, at the Ministerial Conference in Doha, Qatar, WTO members adopted the "Declaration on the TRIPS agreement and Public Health." It seeks to clarify that Members are entitled to invoke the flexibilities within TRIPS to foster public health goals. The Declaration reads:

> We agree that the TRIPS agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS agreement, we affirm that the agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.[35]

The declaration does not open up new ways within TRIPS, but reinforced by various instruments of the UN affirming the human right to health,[36] it confirms the legitimacy of measures seeking to invoke the norms already existing in the Agreement. Ostensibly therefore, in relying on these

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[30] TRIPS Agreement, *supra* note 11, at Art. 30.

[31] *See id.* at arts. 2 & 3.

[32] *See id.* at arts. 3 & 8.

[33] Gail E. Evans, Law-Making Under the Trade Constitution 23-24 (2000).

[34] William van Caenegem, Intellectual Property Law and Innovation 1-2 (2007).

[35] World Trade Organization Ministerial Declaration on the TRIPS agreement and Public Health, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002).

[36] *See* International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200A (XXI), U.N. GAOR, 21st Sess., Supp. No. 16, U.N. Doc. A/6316 (Dec. 16, 1966) (explaining that the right to health constitutes a legally binding obligation upon State parties); *see also* Charter of Fundamental Rights Of the European Union, Art. 35, O.J. (C 364/1) (2000) (concerning the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices); Universal Declaration on Human Rights, G.A. Res. 217A, at 25, U.N. GAOR, 3d Sess., 67th plen. mtg., U.N. Doc. A/810 (1948) (endorsing the right to health); Constitution of the World Health Organization, July 22, 1946, 62 Stat. 2679, 14 U.N.T.S. 185 (articulating the first "right to health"). *See also* African Charter on Human and People's Rights, June 27, 1981, OAU Doc. CAB/LEG/67/3 rev.5, 21 I.L.M. 58 (1982); Holger P. Hestermeyer, Human Rights and the WTO: The Case of Patents and Access to Medicines 83-115 (2007).

flexibilities, it should be possible for developing countries to procure medicines either by means of compulsory licensing or parallel importation, or by making exceptions to the rules for patents rights in their countries in order to facilitate the manufacture of generic pharmaceuticals.

However, this has not proven to be the case. First, WTO jurisprudence has shown itself resistant to permitting exceptions to the character of property rights in patents or the extent of their exercise. *Canada Term of Patent Protection*[37] made it clear that developing countries are not entitled to derogation from the stipulated 20 year term of patent protection. *Canada – Pharmaceuticals*[38] further clarified that derogations for generic manufacture may allow regulatory review, but called a halt to the preparatory manufacture of product prior to the expiration of the patent. The WTO panel's interpretation of Article 30 regarding the limited exceptions in respect of patent rights makes it clear that the scope of derogations is narrow. In *Canada-Pharmaceuticals*,[39] Canada argued that limited exceptions in its Patent Act, which were designed to enable the manufacture of generic pharmaceuticals, came within the purview of Article 30 of the TRIPS Agreement. While the Panel was prepared to accept that the regulatory review section,[40] a classic Bolar provision,[41] was a limited exception that did not unreasonably prejudice the legitimate interests of the patentee, the section pertaining to the stockpiling of generic pharmaceuticals[42] was considered inconsistent with the normal exploitation of a patent. Relatively little consideration appears to have been given to the question of whether or not the prejudice was unreasonable - a question which turned on whether the "legitimate interests of third parties" outweighed the patentee's interests in the full enjoyment of its legal rights. In this case, the Complainant European Communities argued that the relevant "third parties" were the competing generic drug producers.

Second, the Article 31*bis* amendment to the compulsory licensing provisions of the TRIPS Agreement, which is designed to facilitate the manufacture and export of medicines to developing countries, has been distinguished only by its lack of acceptance and use.[43] More than four years after WTO members unanimously adopted the Doha Declaration on TRIPS and Public Health, relatively few developing countries have been able or willing to actually implement its provisions. It was not until July 2007 that Rwanda became the first country to notify the WTO that it intended to import generic versions of the HIV/AIDS drug TriAvir, which is manufactured in

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[37] *See* Appellate Body Report, *Canada-Term of Patent Protection*, WT/DS170/AB/R (Sept. 18, 2000).

[38] *See* Panel Report, *Canada – Patent Protection Of Pharmaceutical Products*, WT/DS114/R (Mar. 17, 2000) [hereinafter Panel Report on Canada].

[39] *Id.*

[40] *Id.* at ¶ 7.2.

[41] A Bolar provision permits generic producers to file for regulatory approval prior to the expiration of the patent.

[42] Panel Report on Canada, *supra* note 38, at ¶7.7.

[43] The decision of August 30, 2003 addressed the public health needs of countries with no capacity to manufacture under a compulsory license. The so-called Paragraph 6 Solution created a mechanism for such countries to import cheaper generics made under compulsory licensing elsewhere. A permanent amendment to TRIPS was agreed to on December 6, 2005 in Article 31*bis*: www.wto.org/english/tratop_e/trips_e/wtl641_e.htm.

Canada.[44] Likewise, it was not until 2007 that middle income developing countries found the political will to invoke their compulsory licensing rights under TRIPS. In January 2007, Thailand issued a compulsory license to allow generic manufacture of expensive antiretroviral HIV/AIDS drugs patented by US-based Abbott Laboratories.[45] In May, Brazil followed Thailand's lead, and issued a compulsory license for a lower-cost version of Merck's antiretroviral HIV/AIDS drug.[46] In June 2008, the Philippines introduced the *Universally Accessible Cheaper and Quality Medicines Act* with the aim of making it easier for the government to issue compulsory licenses and lower costs by allowing parallel imports of pharmaceuticals.[47]

When it comes to taking action based on the TRIPS exceptions to patent rights, developing countries are reluctant: first, because WTO case law indicates that these exceptions have a narrow compass and; second, because the US and the EU, via bilateral trade agreements, use their economic and political power to dissuade developing countries from resorting to compulsory licensing. Mindful of foreign direct investment (FDI) and access to the markets of the EU and the US, when negotiating bilateral free trade agreements (FTAs), developing countries have been reluctant to invoke the flexibilities of the TRIPS Agreement as a means of providing access to affordable medicines.

Moreover, most FTAs the US has concluded with developing countries also contain provisions relating to data exclusivity.[48] Data exclusivity refers to protection of clinical test data required to be submitted to a regulatory agency to prove safety and efficacy of a new drug, and prevention of generic drug manufacturers from relying on this data in their own applications. "Data exclusivity" considers that unjustified reliance on this information by competitors to obtain approval for their own version of the same product constitutes an act of unfair competition.[49] Data exclusivity provisions further

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[44] The notification (IP/N/9/RWA/1), filed on 19 July, is the first in several steps that will have to be taken before the affordable drugs reach patients in the African country. Rwanda informed the WTO that it expected over the next two years to import 260,000 packs of the HIV/AIDS drug TriAvir, manufactured in Canada by Apotex, a major generics producer headquartered in Toronto. *Rwanda Becomes First Country to Try to Use WTO Procedure to Import Patented HIV/AIDS Drugs*, 11 BRIDGES WEEKLY TRADE NEWS DIG. (2007), www.ictsd.org/weekly/07-07-25/story2.htm.

[45] Simon Montlake & Elizabeth H. Williams, *Thailand's IP Gamble: Just Say 'No' to Big Pharma*, 170 FAR E. ECON. REV. 39 (2007). In August 2007, Brazil and Thailand signed a bilateral agreement to cooperate on health issues, including generic licensing, which may be a harbinger of more such bilateral and regional health agreements. *Id.*

[46] AIDS Healthcare Foundation, *Profit at What Cost? AIDS Drugs for All* (8 Aug. 2007), at 2, www.aidshealth.org/index2.php?option=com_content&do_pdf=1&id=1124.

[47] *See* Philippines Information Agency, *PGMA to Sign Cheaper Medicines Law* (June 6, 2008), www.pia.gov.ph/?m=12&fi=p080606.htm&no=12.

[48] Jakkrit Kuanpoth, *Patents and Access to Antiretroviral Medicines in Vietnam after World Trade Organization Accession*, 10 J. WORLD INTELL. PROP. Vol. 10 201, 218 (2007) (explaining that because of the data exclusivity provisions under the bilateral Agreement between the United States of America and the Socialist Republic of Vietnam on Trade Relations of 2001, Vietnam cannot rely on the data submitted by the originator company to register generic versions of the same drugs for five years after registration of the originator product).

[49] Article 39.3 of TRIPS provides: "Members, when requiring, as a condition of approving the marketing of pharmaceutical . . . products which utilize new chemical entities, the submission of undisclosed test or other data, . . . shall protect such data against unfair

reduce the policy space available to developing countries to derogate from patent protection in order to facilitate generic manufacture. Conversely, the pharmaceutical companies are obtaining stronger protection for patents and regulatory data, and the reduction or elimination of price controls.[50] Therefore, while TRIPS flexibilities exist, they are uncertain in application, subject to adverse political pressure from the leading powers and relatively little used by developing countries to procure needed medicines.

Recognizing this uncertainty, the Members of the African Union gave voice to the unsatisfactory nature of the situation in the Cairo Declaration. Issued at the ministerial conference in June 2005, it reads:

> We note that the African Group initiated the discussion on the clarification of flexibilities in TRIPS, particularly in relation to patents and public health as well as biodiversity. We call on African countries to take appropriate measures at the national level to make full use of these flexibilities in line with the outcome of the AU Commission Workshop held in March 2005 in Addis Ababa. We call on the EU not to introduce in the EPA [Economic Partnership Agreement] negotiations any TRIPS plus proposals (which go beyond existing TRIPS obligations) which would compromise these flexibilities. If such proposals are advanced, they should be rejected.[51]

The reality is that while TRIPS contains the flexibilities required to allow developing countries to procure medicines, the legislative balance between the rights of the patent holder and the right to public health is not capable of being fully realized — at least not without developing countries engaging in legal battle and withstanding considerable economic and political duress.[52] In the longer term, access to medicines by means of compulsory licensing and derogations from the rights of the patent holder, is neither feasible nor sustainable. As amended, TRIPS Article 31*bis* for the compulsory licensing, manufacture and export of medicines to developing countries took almost five years to accomplish. To date relatively few countries that are capable of

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commercial use." TRIPS Agreement, *supra* note 11, at Art. 39.3. *See also* Frederick M. Abbott & Jerome H. Reichman, *The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions*, 10(4) J.INT'L ECON. L. 921, 963, 2007.

[50] Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT'L L. 317, 357 (2005).

[51] African Union Conference Of Ministers Of Trade, 3rd Ordinary Session, AU's Ministerial Declaration on EPA Negotiations, AU/TI/MIN/DECL. (III) (2005), www.africa-union.org/root/AU/AUC/Departments/TI/EPA/DOC/de/EPA_Decl_Cairo_EN.pdf.

[52] For example, in 2006, Pfizer sued the government of the Philippines for importing its patented hypertension drug Norvasc from Pakistan at a price almost 90% lower than Pfizer's market price for the Philippines. On March 1, 2006, US pharmaceutical company Pfizer sued the Philippine International Trading Corp (PITC) and the Bureau of Food And Drugs (BFAD) before the Regional Trial Court of Makati Branch. It accused them of infringing its patent for its anti-hypertension drug Norvasc (which has the generic name amlodipine besylate), after the PITC imported some samples of a similar drug sold by Pfizer in India (under the brand name Amlogard) and submitted the samples to the BFAD for testing and product registration. Pfizer's Philippine patent expires in June 2007. The PITC filed a Ps1.5 million ($30,000) countersuit against Pfizer, claiming that the US company was attempting to stop the government from importing cheap medicine. Hechanova Bugan & Manila Vilchez, *IP Rights v. Public Health,* MANAGING INTELL. PROP. (2006).

manufacture and supply of pharmaceuticals have implemented the amendment in their patent laws.[53] Given the time to negotiate and adopt derogations from patent rights and the reluctance of Members to implement or adopt them, we must question their longer term feasibility. The current system involves constant tension between patent holder and consumer, mediated through a complex body of rules. This will not provide a long-term, sustainable solution. Rather than temporary waivers of patent rights for the supply of medicines by compulsory licensing and other means of short-term compromise, it is submitted that developing countries must be enabled to render operative their national and regional systems of innovation.

II. THE CENTRAL ROLE OF PUBLIC RESEARCH ORGANIZATIONS IN PROMOTING PHARMACEUTICAL R&D

A. PUBLIC RESEARCH ORGANIZATIONS

In the post-TRIPS dynamic of economic catch-up, research activities at universities and public laboratories will play a central role in promoting the growth of pharmaceutical R&D. Given the policy restrictions imposed by international patent protection, national PROs constitute an important vehicle through which the technologies and organizational forms of the developed countries may be transferred and applied to drug discovery in developing countries. In the area of medical innovations, the existence of indigenous research at national research institutes has long been a particularly important element of catch-up, for which technologies and diagnostics originating from abroad may need to be tailored or revised to suit the national disease profile.[54]

Fortuitously, the restrictions on the policy space available to developing country governments have taken effect at the same time that other trends have pushed or enabled research, industry, and finance to operate on a global plane. Today, a global network of PROs provides an organizing structure for the dissemination and transfer of knowledge by means of information technologies. Moreover, over the last quarter century there has been an increasing transnational exchange of faculty between PROs in developed and developing countries. This transnational flow of scientists has not only been a central mechanism for the training of new faculty for indigenous universities, but also for indigenous firms to acquire access to advanced knowledge and skills.

B. PUBLIC-PRIVATE PARTNERSHIPS

The transnational flow of personnel favors in turn, the creation of the public-private partnerships (PPPs) needed to boost pharmaceutical

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[53] *See* Members Accepting Amendment of the TRIPS Agreement, www.wto.org/english/tratop_e/trips_e/amendment_e.htm (last visited Apr. 12, 2008).

[54] Daniel Lederman & William Maloney, *Research and development (R&D)* 13 (The World Bank, Working Paper Series 3024, 2003) (concluding that one dollar's worth of R&D buys greater increases in productivity for countries far from the technological frontier than for innovating countries who must invent the new technologies that push the frontier forward).

innovation in developing countries. PPPs, consisting of international organizations and academic institutions working in conjunction with small to medium size enterprises (SMEs), have become one of the major sources of new drug development for developing countries.[55] International alliances and partnerships have been proliferating, and will continue to provide important vehicles for firms in developing countries to access advanced know-how. Thus, while the increasing patent law harmonization triggered by the TRIPS Agreement has dramatically reduced the policy space available to offset the concomitant social costs,[56] the transnational networking of skilled personnel has increased the growth of PPPs for pharmaceutical R&D in developing countries.[57]

These partnerships may take various forms, from a small group of institutional partnerships to more complex consortia between public sector organizations and private companies. PPPs normally also include institutions from outside Africa, where it can be demonstrated that they would add significant value to the partnership. Thus, PRO partners in Africa might include a mix of institutions with well-established research activities, and promising institutions that are developing their research potential.[58] For example, 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.[59] This partnership is fully integrated into the KEMRI

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[55] For example, the creation of the United Nations Development Program; World Bank; World Health Organization Special Program for Research and Training in Tropical Diseases (WHO/TDR) enabled the establishment of a partnership-oriented approach to drug discovery and development between public-sector organizations and private companies. This process rapidly accelerated in the late 1990s, when an increase in funding opportunities through national governments and philanthropic institutions, such as the Rockefeller and Gates Foundations, allowed projects to be initiated with million-dollar budgets. Solomon Nwaka & Robert G. Ridley, *Virtual Drug Discovery and Development for Neglected Diseases Through Public–Private Partnerships*, 2 Nature Reviews, Drug Discovery 919, 920 (2003), www.who.int/tdr/topics/discovery_research/files/virtual_drug_discovery.pdf.

[56] *See* Abbot & Reichman, *supra* note 49, at 943; Jerome H. Reichman & Rochelle Cooper Dreyfuss, *Harmonization Without Consensus: Critical Reflections On Drafting A Substantive Patent Law Treaty*, 57 Duke L. J. 85, 98 (2007); Graeme Dinwoodie & Rochelle Dreyfuss, *TRIPS and the Dynamics of Intellectual Property Lawmaking*, 36 Case Western Reserve J. Int'l L 95, 116 (2004).

[57] *See* International Foundation of Pharmaceutical Manufacturers Association, The Pharmaceutical Innovation Platform: Sustaining Better Health Worldwide 49 (2004), www.ifpma.org/documents/NR1916/PIP_final.pdf.*; see also* Sonja Bartsch & Lars Kohlmorgen, *The Role of Southern Actors in Global Governance: the Fight Against HIV/AIDS* 8-9 (German Inst. Global and Area Stud., Working Paper No. 46, 2007); *see generally* Wolfgang Hein & Lars Kohlmorgen, *Global Health Governance*, 8 Global Social Pol'y 80 (2008) (explaining that the new institutional structures in global health governance are characterized by a combination of moral values and material interests that allows some progress in the fight against poverty-related diseases).

[58] The Centre for Health Policy and Strategic Studies in Lagos Nigeria was 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. On the advantages of PPPs see Kevin Outterson, *Access to Global Disease Innovation* 2 (forthcoming) (submitted to WHO IBWG 2006).

[59] 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, www.biocheminc.com/development.php.

research infrastructure. The KEMRI-Wellcome Trust partnership is embedded within Kilifi District Hospital, and builds its research programs around the local medical infrastructure and contributing to healthcare delivery. KEMRI has developed collaborative links with a large number of regional and international institutions including the National Institute of Medical Research in Tanzania and the British Medical Research Council.[60] The KEMRI example confirms a 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.[61] On a global scale, the evidence of increasing levels of PPPs indicates that the university-industry model of innovation is becoming increasingly important to pharmaceutical R&D.

III. THE BAYH-DOLE MODEL OF TECHNOLOGY TRANSFER

The Bayh-Dole Act of 1980[62] established the prevailing model of technology transfer from PRO to the private sector. The Bayh-Dole model of university-industry innovation requires PROs to establish a centralized technology transfer office (TTO) for the commercialization of medical research.[63] In the United States, the Bayh-Dole legislation created a uniform patent policy, under which universities are allowed to retain the rights to government-funded research and license these inventions on a non-exclusive or exclusive basis.[64] By this means, the Bayh-Dole model of technology

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[60] Local and regional collaborators include universities, hospitals, and government agencies. Examples include: 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. *See* Kenya Medical Research Institute: Collaborators, www.kemri.org/International%20and%20Local%20Collaborators.html.

[61] The OECD Science, Technology and Industry Scoreboard 2007, analyzes 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 Co-operation 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 information and communications technology. This is consistent with other observed patterns of science-industry linkages in these fields, such as university spin-offs, industry-university cooperation in R&D, and the tendency for biotechnology companies to cluster around universities. *See* Source OECD: STI 2007, masetto.sourceoecd.org/vl=7460882/cl=15/nw=1/rpsv/sti2007/ (last visited Apr. 12, 2008).

[62] Pub. L. No. 96-517, § 6(a), 94 Stat. 3015, 3019-28 (1980) (codified as amended at 35 U.S.C. §§ 200-212 (2000)).

[63] *See generally* Council on Government Relations, The Bayh-Dole Act: A Guide to the Law and Implementing Regulations (1999), www.cogr.edu/docs/Bayh_Dole.pdf.

[64] "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

transfer enables universities to obtain protection for, and commercially benefit from, the results of research conducted using public funding. This is intended to give the national economy, and potentially the world, the benefit of commercializing the technologies and to give the university the benefit of the financial return on the technology.[65]

The TTOs are charged with evaluating inventions, filing for patent applications on behalf of the university, and licensing patents. The TTO performs patent searches, patent filings and finds a suitable licensee within the business sector. All university-industry cooperation that may involve patents is coordinated by the technology transfer office. Most TTOs therefore conform to a "patent agency" model of operation, where the focus is on selling patentable inventions to industrial adopters. Beyond the United States, the Bayh-Dole model of technology transfer has become a standard institution supported by government innovation policies and infrastructure.[66]

A. EVALUATION OF THE BAYH-DOLE MODEL

There is evidence that the Bayh-Dole Act has exerted a positive effect on pharmaceutical innovation and that it has generated fruitful public-private partnerships for commercial exploitation of academic research.[67] It is credited not only with expanding technology transfer from universities to industry, but also enabling cross-sector R&D collaborations. Typically, university administrators and associations of TTOs, like the US Association of University Technology Managers (AUTM), point to increasing patents, licenses, and revenues as evidence that the model is working, with the implicit assumption that these metrics are related to gains in social welfare.[68] Following the

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promote the collaboration between commercial concerns and nonprofit organizations, including universities." 35 U.S.C.§ 200 (2000).

[65] *See generally* Dominique Guellec and Bruno van Pottelsberghe de la Potterie, *The Internationalisation Of Technology Analysed with Patent Data*, 30(8) RES. POL'Y 1, 9, 10, 13 (2001) *available at* www.ulb.ac.be/cours/solvay/vanpottelsberghe/resources/Pap_ResPol_1.pdf.

[66] In view of the organizational 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 commercialization services to the University. The creation of a research-owning company will also provide medical research departments with the requisite legal capacity to enter into contracts for the development of pharmaceuticals and diagnostics. 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. 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 SCI. & INFO. TECH. 1 (2003) [hereinafter OECD].

[67] *See The Role of Federally-Funded University Research in the Patent System*: *Hearing before the S. Comm. on the Judiciary*, 110th Cong. (2007) (statement of Robert Weissman, Director, Essential Action).

[68] Interest groups, such as the Association of University Technology Managers (AUTM), have formed; and pharmaceutical companies have a vested interest in this model's survival. Much of the data used to support the argument that the Bayh-Dole Act (Patent and Trademark Act Amendments of 1980, Pub. L. No. 96-517, 94 Stat. 3015) is working is based on surveys conducted by AUTM.

evident success of the Bayh-Dole model of university-industry collaboration, nearly all other OECD countries have reformed research funding regulations to allow PROs to file, own, and license the intellectual property they generate.[69]

However, there has been little objective, empirical analysis of the social benefits of the model. The University of California and the Massachusetts Institute of Technology (MIT) were the leading patentees in the US higher education sector between 2002 and 2004. This trend indicates that the Bayh-Dole model for enabling technology transfer works best where you have a PRO with a notable research programme or a network of PROs set up an office to license the technologies to industry.[70] In fact, in most OECD economies, corporate funding of R&D performed in PROs still represents less than 8%.[71] In short, the share of public institutions participating in patent ownership reflects both the strength of their technological research and the legal skills of their technology transfer officers.[72] The statistics suggest that

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[69] OECD, *supra* note 66; *see also* David C. Mowery and Bhaven Sampat, *The Bayh-Dole Act of 1980 and University-Industry Technology Transfer: A Policy Model for Other Governments?*, J. Tech. Transfer 115 (2005).

[70] A similar trend in the UK highlights the success of Cambridge Enterprise, the University of Cambridge's knowledge and technology transfer service company. Jeanette Walker, *Cambridge: Europe's Leading Location For Biotechnology*, 10 Drug Discovery Today 956, 956, 959 (2005). Thomas J. Siepmann remarks that the "two largest licensing/royalty income powerhouses in U.S. academia are Columbia University and the University of California. These two institutions alone brought in $400 million in royalties and licensing deals in 2000, according to the Association of University Technology Managers Licensing Survey." Thomas J. Siepmann, *The Global Exportation of the US Bayh-Dole Act*, 30 U. Dayton L. Rev. 209, 239 (2005) (citing Assn. of U. Tech. Managers, *AUTM Licensing Survey: FY 2000: A Survey Summary of Technology Licensing (and Related Performance for U.S. and Canadian Academic and Nonprofit Institutions and Patent Management Firms)*, 12 (Lori Pressman ed., 10th ed., 2002), *available at* www.provendis.info/home/downs/AUTMFY2000Survey.pdf). Further, the Lambert Review notes that "the US universities that are best at technology transfer also have strong reputations for long-term research." Richard Lambert, HM Treasury, Lambert Review of Business-University Collaboration, Final Report 49 (2003), www.hm-treasury.gov.uk/consultations_and_legislation/lambert/consult_lambert_index.cfm. The indications are that the infrastructure needed to capitalize on research results from universities is not at the level required to make investing worthwhile. Tom Coupé concludes, "those universities that established a technology transfer office, possibly in reaction to Bayh-Dole, do seem to have increased their patenting activity more than those that did not establish such an office." Tom Coupé, *Science Is Golden: Academic R&D and University Patents*, 28 J. Tech. Transfer 31, 43 (2003). *See also* Bhaven N. Sampat & Richard R. Nelson, World Bank, The Emergence and Standardization of University Technology Transfer Offices: A Case Study of Institutional Change 23, 26, 30 (1999), www.isnie.org/ISNIE99/Papers/nelson.pdf.

[71] Around one in ten of all firms in Europe collaborated with a partner for their innovation activities during 2002-04. OECD & Statistical Office of the European Communities, Oslo Manual: Guidelines for Collecting and Interpreting Innovation Data (2005), www.oecd.org/document/23/0,2340,en_2649_37417_35595607_1_1_1_37417, 00.html. Public institutions own 7% of all international patents filed under the Patent Cooperation Treaty (PCT) between 2002 and 2004. More than 10% of patent applications by US residents are owned by public institutions compared to around 4% of patents owned by European residents. Compare Singapore, where almost 40% of all PCT filings are owned either by the government or the higher education sector. Source OECD: STI 2007, masetto.sourceoecd.org/vl=7460882/cl=15/nw=1/rpsv/sti2007/ (last visited Apr. 12, 2008).

[72] Among OECD countries, Ireland has the highest proportion of patenting by universities (9.7% during 2002-04), a noticeable increase over the mid-1990s when

smaller universities without an individual, profitable research base should be cautious in adopting this model, at least as single entities.

Although the TTO has come to characterize university research, the Bayh-Dole model is not without problems.[73] Expected financial returns are likely to be relatively small in the short term. Prior to committing public funds, policymakers should ensure that there exists the critical mass of R&D activity necessary to justify the costs of a fully functioning TTO.[74] Moreover, the model needs a private sector willing and able to obtain and commercialize the technology. The US is a country where entrepreneurs can find venture capital, where there are patent attorneys with the skills to help with patent prosecution, and where university scientists do not own but share the royalties in their inventions with the university.[75] However, in developing economies there may be limited licensing opportunities within the domestic market. Domestic firms will often not have the markets or distribution channels for viable exploitation, and marketing to overseas companies can be difficult without a track record or personal contacts to facilitate necessary linkages.

B. THEORETICAL JUSTIFICATIONS FOR THE PATENTING OF PUBLIC-SPONSORED R&D

The main argument in favor of university patents is that these patents will facilitate technology transfer from universities to private firms. The patent system, which grants the patent holder a 20 year term of protection, allows pharmaceutical companies to charge prices that are higher than the marginal price of manufacturing and distribution, and that are expected to absorb the cost of developing the drug. The major pharmaceutical industry spends huge

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universities owned 3.5%. In Australia, Belgium, China, Spain, the United Kingdom and the United States, the higher education sector accounts for 6% to 8% of all international patent applications. Between 1996-98 and 2002-04, the share of patents filed by universities decreased slightly in Australia, Canada and the United States but increased markedly in Japan and the European Union, notably in France and Germany. This increase resulted directly from policy changes in these countries in the early 2000s: OECD Technology and Industry Scoreboard. *Id.*

[73] *See* Nicholas S. Argyres & Julia Porter Liebeskind, *Privatizing the Intellectual Commons*: *Universities and the Commercialization of Biotechnology*, 35 J. ECON. BEHAV. & ORG 427 (1998) (arguing that since the passage of the Bayh-Dole Act in 1980 a gradual but halting privatization of the intellectual commons has been occurring in US universities).

[74] Some estimates would put this figure within the range of US$100 to $500 million in research expenditures annually. CENTRE FOR MANAGEMENT OF INTELLECTUAL PROPERTY IN HEALTH RESEARCH AND DEVELOPMENT [MIHR], SECTION 6: ESTABLISHING AND OPERATING TECHNOLOGY TRANSFER OFFICES, *in* HANDBOOK OF BEST PRACTICES: EXECUTIVE GUIDE TO HANDBOOK 73, 74, www.iphandbook.org/handbook/ (follow "Establishing and Operating Technology Transfer Offices" hyperlink) (last visited June 7, 2008) [hereinafter MIHR HANDBOOK].

[75] The availability of venture capital, combined with the willingness of Wall Street to support companies with initial public offerings, put the United States as much as five to ten years ahead of Europe and Japan in developing a biotechnology industry. Brigitte Haar, *Venture Capital Funding for Biotech Pharmaceutical Companies in an Integrated Financial Services Market: Regulatory Diversity within the EC*, 2 EUROPEAN BUSINESS ORGANIZATION LAW REVIEW 585, 587 (2001). In contrast, in Sweden and, until recently, in Germany and Japan, university professors have been entitled to own patents resulting from their research. The patents are thus registered as belonging to individuals or businesses rather than to public institutions. Siepmann, *supra* note 70, at 222-23, 225-26. Concerning the effects of Bayh-Dole and royalty sharing see Coupé, *supra* note 70, at 43-44.

sums of money on R&D. While development of a new drug is a costly process, it is relatively easy to copy an existing drug. The harm flowing from lessening competition by means of imitation is said to be outweighed by the advantage flowing from more innovation. Patents are said to constitute an incentive for research and development.[76] However, when it comes to making investments in order to transform university-generated knowledge about neglected diseases into a commercial application, the incentive problem may arise. A firm that endeavors to undertake the additional R&D that is necessary to drug development only considers this a useful undertaking when it has a prospect of deterring imitation by competitors. Only patents for profitable inventions are likely to find an ultimate market. One of the reasons that US universities have done so well in licensing inventions in the biotechnology area is the fact that health-care providers are willing to pay for new technologies and products.[77]

During the last decade, the notion that patent protection would provide a financial incentive to drug firms to invest in research for tropical diseases has not materialized. The redistribution of resources to the private sector accompanied by the introduction of patents alone will not trigger the development of more drugs specifically related to the needs of the poor.[78] Research and development for diseases in developing countries has declined rather than increased.[79] Even the relative boost in research and development for antiretroviral therapy is due to the fact that epidemics also concern developed countries. Low-income countries do not constitute a market capable of inducing patent-driven investment.[80] There is said to be a market failure for medicines in developing countries. Consumption is low.[81] 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.

C. New Pharmaceutical Manufacturers As Potential Business Partners

However, as new pharmaceutical manufacturers enter the market from leading developing countries, such as India, the ability of PROs in Africa and

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[76] William M. Landes & Richard A. Posner, The Economic Structure of Intellectual Property Law 13 (2003).

[77] Patenting statistics at MIT reflect the relationship between patents, markets, and profits. *See* Archive of AUTM licensing reports for 2004-2006, www.autm.net/surveys/index.cfm (last visited Apr. 12, 2008).

[78] Drugs for Neglected Diseases Initiative, Addressing the Lack of Research and Development for Neglected Diseases (2006), www.researchappeal.org/dndi_pdf/RD_Briefing_for_EU_Feb06_final.pdf.

[79] Of the new chemical entities developed between 1975 and 1996, only 11 were for the treatment of tropical diseases. Patrice Trouiller & Pierro Ollario, *Drug Development Output from 1975 to 1996: What Proportion for Tropical Diseases?* 3 Int'l. J. Infectious Diseases 61, 61-63 (1999).

[80] Therefore, only 10% of worldwide research is allocated to tropical diseases affecting 90% of the world population. UK Parliamentary Report, *Fighting Diseases of Developing Countries*, Postnote, June 2005, at 1, www.parliament.uk/documents/upload/POSTpn241.pdf.

[81] *See* World Bank, Africa Development Indicators (2007), siteresources.worldbank.org/INTSTATINAFR/Resources/adi2007_final.pdf.

Asia to find suitable industry partners is likely to increase.[82] 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, and encourage local R&D.[83] 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,[84] supplying drugs for AIDS, asthma, malaria, cancer, cardiac conditions, as well as antibiotics and a variety of other products.[85] The prices are becoming more competitive as more Indian firms establish manufacturing capacities in countries such as Kenya and Zambia.[86] They are also involved in technology transfer agreements with companies in Uganda, Nigeria, Gabon, Egypt, Morocco, and Algeria. Yet other Indian companies,

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[82] The major strengths that 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, ability to manufacture over 50% of the bulk drugs needed for its pharmaceutical production activities locally, the emergence of a promising biotechnology industry, availability of local scientists and R&D personnel of a high scientific quality, and a wide network of organizations performing various aspects of pharmaceutical R&D. Sampath, *supra* note 21, at 700-02.

[83] 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. This division will enable the company to create intellectual property at a faster pace while also positioning Ranbaxy for future expansion. *Ranbaxy to Demerge R&D Unit into a Subsidiary*, ECON. TIMES, Feb 20, 2008, economictimes.indiatimes.com/News/News_By_Industry/Healthcare__Biotech/Ranbaxy_to_demerge_RD_unit_into_a_subsidiary/articleshow/2796824.cms. For more information concerning the capacity of developing countries with innovation capacity to access foreign technology, *see* S. P. Agarwal, Ashwani Gupta & R. Dayal, *Technology Transfer Perspectives in Globalising India (Drugs and Pharmaceuticals and Biotechnology)*, 32 J. TECH. TRANSFER 397, 397-423 (2007); John H. Barton & EJ Emanuel, *The Patents-Based Pharmaceutical Development Process: Rationale, Problems, and Potential Reforms*, 294 JAMA 2075, 2075-82 (2005).

[84] The Indian pharmaceutical company Cipla has a presence in all the 53 markets of Africa. In addition to the AIDS drugs, it supplies medicines for asthma, malaria, cancer, cardiac problems, antibiotics and a variety of other products to African countries. Nandini Patwardhan, *India on African Safari*, EXPRESS PHARMA, www.expresspharmaonline.com/20070630/market01.shtml [hereinafter Patwardhan] (explaining how Indian pharmaceutical companies consider the potential demand for drugs within Africa as an opportunity not to be ignored).

[85] The latest anti-malarials (single and multi-dose combination) and anti-retrovirals (ARVs), as approved by WHO, have experienced a huge demand. India is the preferred country to source pharmaceutical products because of its quality and its competitiveness. *Id.* India's full compliance with the TRIPS Agreement will only affect newer, patented medicines, particularly those that have been patented since 2005. These will be few, 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 antiinfectives (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, *supra* note 21, at 718.

[86] Patwardhan, *supra* note 84. Ranbaxy Laboratories recently acquired Be-Tabs 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-Tabs Buyout in S. Africa*, HINDU BUS. LINE May 9, 2007, www.thehindubusinessline.com/2007/05/09/stories/2007050904010200.htm.

such as Flamingo, have formed joint ventures in African countries, such as Ghana and Uganda, with the aim of exploring the market.[87]

D. RESTRUCTURING OF "BIG PHARMA'S" BUSINESS MODEL

Equally, as the major pharmaceutical industry[88] expands and restructures on a global scale, for companies wishing to conduct research, developing country research institutions are potentially an attractive option.[89] While the business climate for pharmaceutical companies has changed dramatically in the past five years, their pharmaceutical business model has not kept pace. The pharmaceutical business is facing a radical transition because the old model shows diminishing returns.[90] Declining R&D productivity, rising costs of commercialization, increasing payor 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 new business models to restore sound financial results.

PRO-industry partnerships can be related to two of the major building blocks needed to provide a new business model: notably, making use of product and capability partnerships and providing customer-based solutions. For all but the very largest pharmaceutical companies, firms need to find a combination of these building blocks that makes best use of their strengths, improves returns, and manages risk. The search for opportunities in any disease area will require planned experimentation, use of partnerships and, with the entry of competitors from China and India, ultimately a transformation in the way most pharmaceutical companies organize to compete. "Big Pharma" has acknowledged that the prevailing model, largely based on a vertically- or fully-integrated pharmaceutical companies ("FIPCO") model, is incapable of delivering sustainable growth. The industry is likely to transition to greater reliance on partnerships to manage risk and return across both product pipelines and functions.[91] Structural changes in the

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[87] Patwardhan, *supra* note 84 (explaining how Indian pharmaceutical companies consider the potential demand for drugs within Africa as an opportunity not to be ignored). *See generally* PRICEWATERHOUSECOOPERS, GEARING UP FOR A GLOBAL GRAVITY SHIFT: GROWTH, RISK AND LEARNING IN THE ASIA PHARMACEUTICAL MARKET (2007), www.pwchk.com/webmedia/doc/633153381934174976_pharm_gb_gravityshift_may2007.pdf

[88] 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-I, *available at* www.publications.parliament.uk/pa/cm200405/cmselect/cmhealth/42/4205.htm.

[89] Kazuhiro Asakawa & Ashok Som, *Internationalization of R&D in China and India: Conventional Wisdom Versus Reality*, ASIA PAC. J. MGMT (2008) (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 Asia *see* PRICEWATERHOUSECOOPERS, *supra* note 87, at 24-27.

[90] Joanna Von Braun & Meir P. Pugatch, *The Changing Face of the Pharmaceutical Industry and Intellectual Property Rights*, 8 J. WORLD INTELL. PROP. 599 (2005) (discussing the need for change, based on the instability of the revenue stream for the development and marketing of innovative products).

[91] James Gilbert, Preston Henske & Ashish Singh, REBUILDING BIG PHARMA'S BUSINESS MODEL 1-10 (2003), www.bain.com/bainweb/publications (explaining that the

pharmaceutical industry portend a more favorable climate for PROs in leading developing countries to negotiate the terms of patent ownership and licensing.

E. FEASIBILITY OF PATENT OWNERSHIP BY PROS IN DEVELOPING COUNTRIES

The main focus of the legal and policy changes pursuant to the Bayh-Dole model of technology transfer has been to transfer title from governments or individual researchers to PROs, and to give academic inventors a share of royalty revenue in exchange.[92] The rationale is that ownership by PROs, as opposed to individual researchers, provides greater legal certainty, lowers transaction costs, and fosters more efficient channels for technology transfer.[93] That logic needs to be examined in each case. 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. If the firm that is to develop the invention is assigned and owns the invention, the developing country PRO is in a far weaker position to negotiate an ongoing share in the profits from the invention. However, assuming the developing country PRO can obtain the funding from philanthropic foundations to apply for patent protection,[94] it will be in a far stronger position to negotiate the kinds of restrictions and reservations needed to promote ongoing R&D for drug discovery.

IV. THE CASE FOR NEGOTIATING RESTRICTIONS AND RESERVATIONS

A. CONFLICTING INTERESTS: PURE RESEARCH AND COMMERCIALIZATION

Under the Bayh-Dole model of technology transfer, we have noted that policies promoting the downstream application of university research tend to conflict with policies favoring full and open access to research data.[95] Contrary to the evident need for compromise, in the pharmaceutical industry, exclusive licenses are often required because they offer more protection for the necessary development to be undertaken before a university invention can become a marketed product. Concerns have been 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

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blockbuster business model that underpinned the major pharmaceutical companies' success is irreparably broken).

[92] Nonetheless, generating revenue for universities was not the actual goal of the Bayh-Dole Act, which requires that the profits accruing to the beneficiary nonprofit organizations "be utilized for the support of scientific research or education." 35 U.S.C. § 202(c)(7) (2000).

[93] COUNCIL ON GOVERNMENTAL RELATIONS, THE BAYH-DOLE ACT: A GUIDE TO THE LAW AND IMPLEMENTING REGULATIONS 1-4 (1999), www.cogr.edu/docs/Bayh_Dole.pdf.

[94] Bart Verspagen, *University Research, Intellectual Property Rights and European Innovation Systems*, (Eindhoven Centre for Innovation Studies, Working Paper 06.05, March 2006).

[95] J.H. Reichman & Paul Uhlir, *A Contractually Reconstructed Research Commons For Scientific Data In A Highly Protectionist Intellectual Property Environment*, 66 LAW & CONTEMP. PROBS. 315, 320 (2003).

science. Concerns about maintaining open access and dissemination include the impact of patenting on the academic goals of pure research, the effect on the direction of public research, the costs and benefits of patenting, the effects on the diffusion of, and access to, publicly funded research results.

The commercial currency of patents, often to the detriment of their quality, may make it more difficult for researchers to access certain types of basic science.[96] By definition, patent holders are granted the right to restrict others from using their inventions. In the biological sciences in particular, restricted access may have negative effects on upstream research. Patents over research tools may increase the difficulty of obtaining the necessary tools and materials for basic research and increase its cost.[97] For example, medical research increasingly utilizes genetic material, which is provided under material transfer or confidentiality agreements that restrict the uses of that material. As a result, research may be difficult to commence or, in the worse case, even abandoned, due to need for access to proprietary biological material. Negotiation of rights for commercial use may simply prove too time-consuming or complicated to pursue, or the terms offered might be prohibitory. Transaction costs simply become prohibitive.

Nevertheless, 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.[98] Innovation studies tell us that open dissemination of science and technology best facilitates technological progress, "if the findings of publicly funded university research are placed in the public domain, or are inexpensively licensed to anyone who wants to use them competition alone may stimulate their widespread application."[99] In light of the considerable evidence that developing economies benefit from more open models of innovation, PROs have a responsibility to generate and transmit knowledge as widely as possible. By this means, research collaborations between PROs in developed and developing countries can help address unmet needs, such as those of underserved patient populations and neglected diseases.

With the aim of reasserting their traditional commitment to open access and dissemination in the advancement of scientific research,[100] PROs should begin by setting out these core values in a mission statement. For example,

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[96] Ian Ayres & Gideon Parchomovsky, *Tradable Patent Rights: A New Approach to Innovation* (Yale Law School, Public Law Working Paper No. 145), papers.ssrn.com/sol3/papers.cfm?abstract_id=1020276#PaperDownload.

[97] There is also some concern about the quality and breadth of patents issued by patent offices, notably some DNA patents. Some believe that in a number of cases the criteria of novelty and inventive step are not being met, and that broad patents are issued that could give the patent holders an overly-strong negotiating position vis-à-vis possible licensees. *See generally* NUFFIELD COUNCIL ON BIOETHICS, ANNUAL REPORT (2002), www.nuffieldbioethics.org/fileLibrary/pdf/nuffield_annual_report_2002.pdf.

[98] *See generally* Paul A. David, David Mowery, & W. Edward Steinmueller, *Analysing the Economic Payoffs from Basic Research*, 2 ECON. OF INNOVATION AND NEW TECH. 73 (1992); Partha Dasgupta and Paul A. David, *Toward a New Economics Of Science*, 23 POL'Y RES. 487 (1994), *available at* www.compilerpress.atfreeweb.com.

[99] David C. Mowery et al., *The Growth Of Patenting And Licensing by U.S. Universities: An Assessment Of The Effects Of The Bayh–Dole Act of 1980*, 30 RESEARCH POLICY 99, 103 (2001).

[100] *See* NATIONAL INSTITUTES OF HEALTH, REPORT OF THE NATIONAL INSTITUTES OF HEALTH (1998), www.nih.gov/news/researchtools/index.htm; *see also* Centre for Science in the Public Interest, www.cspinet.org/about/mission.html (last visited Apr. 12, 2008).

the University of Cambridge's mission and core values speak specifically about the contribution the University can make to society through the pursuit, dissemination, and application of knowledge. The mission statement also addresses the University's place within the broader academic and local community, facilitating the creation of opportunities for innovative partnerships with business, charitable foundations, and healthcare.[101] These common values can form the basis of research collaboration to boost innovation, even where other features of a modern innovation infrastructure may be lacking.

Consequently, in the commercialization of research for drug development, the core values of the PRO should be maintained to the fullest extent possible in patent licensing contracts for technology transfer. TTOs should aim to safeguard the public mission of universities to disseminate knowledge and to manage the deployment of resulting therapeutics and diagnostics for the public benefit. The mission of the PRO is not something that should be bargained away in negotiations with business partners or dissipated by contact with for-profit values, but instead should be protected by setting up separate entities for the property transfer and commercialization arms of the organization. Due to tensions inherent in the transfer of technology from PRO to business with the norms of open science, it is necessary to have a clear statement of the mission, values and objectives of the PRO in the preamble to the licensing contract. Thereafter, a tailored approach to licensing can help developing country PROs avoid the infringement of intellectual property rights.

B. OFFSETTING STRONG INTELLECTUAL PROPERTY RIGHTS WITH FREEDOM OF CONTRACT

The patent licensing contract offers PROs the potential to reclaim the space for public health policy that has been eroded by the strength of international patent law. In addition to the negative rights to exclude unauthorized uses under TRIPS Article 28, the patentee also possesses the positive right "to assign....the patent and to conclude licensing contracts." A license provides a party with permission to do an act that would otherwise be prohibited. In contrast with an assignment, no proprietary interest is passed under a license.[102] 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 generally signed between two parties, specifying the terms and scope of their agreement. 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

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[101] University of Cambridge Mission and Core Values, www.admin.cam.ac.uk/univ/mission.html (last visited Apr. 12, 2008).

[102] Patents Act, 1977, c. 37, § 30 (Eng.) [hereinafter U.K. Patents Act]; *see also* Phillip B.C. Jones, *Violation of a Patent License Restriction: Breach Of Contract Or Patent Infringement?*, 33 IDEA: J. OF LAW &TECH. 225 (1993).

values on probabilities of future outcomes. It requires a duty of good faith and fair dealing in negotiating the terms of the contract.[103]

Of course, the final terms of the contract depend on the negotiating power the parties bring to the table. While developing country PROs may not have the financial advantage of their business partners, recent developments within international intellectual property law can bring the authority of law to the negotiating table. A flexible approach to licensing contracts for the transfer of technology finds support in the TRIPS Agreement. On the one hand, the objectives in support of public health that are found in Article 8 of the Agreement are conditioned upon any derogation from the exclusive rights of the patentee being consistent with the provisions of the Agreement. On the other hand, Article 7 of the TRIPS Agreement, concerning the transfer of technology, echoes the International Covenant on Economic, Social and Cultural Rights,[104] insofar as transfer and dissemination should be done "in a manner conducive to social and economic welfare," free of conditions, and to the mutual advantage of producers and users of technological knowledge.[105]

When a University, as an independent public research organization, negotiates with a private pharmaceutical manufacturer for the development of a drug, the dynamics of the situation are dramatically changed. The freedom to contract and draft the terms of the agreement provide a vehicle for addressing the conflict between the interests of the PRO in the broad dissemination of knowledge, and those of the business partner in recouping the costs of development and manufacture. First, 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

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[103] See Lorelei Ritchie de Larena, *License to Sue?* (FSU College of Law, Public Law Research Paper No. 279, Oct. 2, 2007), *available at* ssrn.com/abstract=1018715 (discussing the intersection of normative values between intellectual property and contract law).

[104] Article 2(1) in the International Covenant on Economic, Social and Cultural Rights 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), Jan. 3 1976, *available at* www.unhchr.ch/html/menu3/b/a_cescr.htm. Additionally, Article 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." *Id.* at Art. 23. Reaffirming this obligation in respect of Least-Developed Country Members (LDCs), the TRIPS Agreement states that "[d]eveloped country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base." TRIPS Agreement, *supra* note 11, at Art. 66(2).

[105] 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." U.N. Sub-Commission on Human Rights Res. 2007/7, ¶ 2, U.N. Doc. E/CN.4/Sub.2/2000/L.20 (Aug. 17, 2000), *available at* www.unhchr.ch/Huridocda/Huridoca.nsf/0/c462b62cf8a07b13c12569700046704e?Opendocument.

the dominant factor in negotiations. Instead, the business deal becomes the dominant factor of negotiation. Whereas the property right is structured to provide an incentive to the investor, the licensing contract is designed to meet the expectations of the parties.

The contract provides a structure against which the core values of PROs in promoting research may be brought to bear on the bargain. The greater flexibility of the licensing contract means that a developing country PRO has the opportunity to draft provisions that allow it to reserve rights of access and use. These rights are important for the dissemination and competitive commercialization of drugs and diagnostics tools. When negotiating reservation clauses, the flexibilities of the TRIPS Agreement, affirmed by the Doha Declaration on TRIPS and Public Health, provide a margin of maneuver to draft terms that favor the use and dissemination of pharmaceutical research. By exploring business models that contain alternative arrangements, private and public partners can experiment with alternative solutions to access problems. By this means, they might agree to place certain inventions in the public domain, or alternatively, to create mechanisms for sharing the results and exploitation of research.

Likewise, the commercial aspects of the licensing transaction can be tailored to suit local market conditions. Licensing approaches, even for comparable technologies, can vary considerably from case to case and from institution to institution, based on circumstances particular to each specific invention, business opportunity, licensee, and university. The licensing contract allows the parties the freedom to craft a mutually acceptable commercial arrangement. The absolute nature of the rights conferred on the patent holder may be organized 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 permits. The licensor can regain the patent easily by not renewing the license at the end of its term.

The flexibility of the licensing contract offers developing country PROs considerable advantages, not least the potential to control production and distribution in time and geographic area. The PRO as licensor has the potential to control the extent and manner in which the invention is exploited. Once a suitable business partner is found, the licensor can apportion particular uses of the patent. For instance, the licensor can divide use of the patent by territory and by the number of licensees. The parties may test their expectations by inserting performance milestones.

The patentee can obtain ownership or license to any improvements made by the licensee if a suitable right to improvements can be negotiated by the patentee in the license. If a developing country PRO can be financially assisted to file for a patent, the costs of maintaining the intellectual property can be offset against the grant of the license to develop the invention. An exclusive licensee might be required to maintain the patent and to be directly responsible for invalidity and infringement issues.

A licensing contract offers not only a chance to share exploitation but also to learn. While patent law does not provide for licensing intellectual property such as know-how or confidential information, it is often included in a license agreement to facilitate the licensee's practice of the invention. Technical information such as formulae, techniques and operating procedures,

commercial information - such as customer lists and sales data, marketing, professional and management procedures - may be the subject of such protection.

In summary, contract and property share related characteristics, but differ in certain critical areas and in their dimensions. Those differences and the reigning principle of freedom of contract give rise to the possibility of the parties, via their negotiations, shaping the property rights to suit the purposes of strengthening developing country research institutions, including universities in the early stage of developing research potential. The licensing of patented technologies can provide financial rewards to inventors while encouraging the dissemination and use of inventions by others.

V. UTILIZING A MIX OF EXCLUSIVE AND NON-EXCLUSIVE LICENSES TO PROMOTE R&D

A. EXCLUSIVE LICENSES

The capacity of licensing to accommodate the commercial exploitation of the patent and the dissemination of basic research, two ostensibly disparate sets of interests, lies in the dual nature of its character. A patent license is a hybrid creature: it is not only a legal document, but also a way of doing business. Exclusive licenses grant exclusive rights to produce and sell certain products in certain territories and markets during the term of the license. An exclusive license permits only the licensee and persons authorized by the licensee to exploit the invention. Exclusive licenses may exempt the licensor, either explicitly or implicitly. Insofar as an exclusive license means that the licensor itself cannot use the rights and only one license can be created, the grant of an exclusive license is very similar to an assignment, since an exclusive license confers powers on the licensee that are equivalent to those of the proprietor.[106] In the pharmaceutical industry, given the high cost of innovation, an industry partner will normally seek an exclusive patent license.[107] Generally, pharmaceutical innovation needs one company to invest heavily to commercialize the product, including investment in performing clinical trials. A potential licensee, unwilling to face competition from other licensees, will usually insist on obtaining an exclusive license.

In the ongoing evaluation of the Bayh-Dole model, there has been considerable debate about whether PROs should grant exclusive licenses to the private sector for discoveries that have benefited from public funds. PROs should certainly be aware of the potential impact that the exclusive license

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[106] A license provides a party with permission to do an act that would otherwise be prohibited. Licenses may be made: orally or in writing; may be express or implied by the court for business efficacy: U.K. Patents Act, *supra* note 102, at § 67. For example, an exclusive licensee can sue infringers in their own right. As with other licenses, an exclusive license may be made orally (there is no statutory requirement for the license to be made in writing) and may be express or implied. Morton-Norwich v. Intercen & United Chemicals [1981] FSR 337.

[107] Exclusivity is also very 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 22 (2004), www.oecd.org/dataoecd/48/12/24508541.pdf.

might have on further research, unanticipated uses, future commercialization efforts and markets. Special consideration should be given to the impact of an exclusive license on uses of a technology that may not be appreciated at the time of initial licensing. By definition, exclusive licenses 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 licenses to others. Technology transfer officers therefore need to be mindful of the impact of granting overly broad exclusive rights. Officers should strive to ensure that the license agreement specifies the efforts that the licensee will have to expend and that it grants only those rights necessary to encourage the development of a particular technology. They should utilize approaches that balance a licensee's legitimate commercial needs against the university's goals, taking account of the university's educational and charitable mission and the public interest of ensuring a broad practical application of the fruits of its research programs.

B. NON-EXCLUSIVE LICENSES

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

Alternatively, "co-exclusive" licenses may be granted to a small, limited number of licensees. Such a licensing strategy has the advantage of permitting competitive product optimization 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.[108] 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 license, where a failure to develop the product will require the licensor to terminate the license, negotiate a new license, and recommence product development.[109]

C. HYBRID LICENSES

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 license grants can expand the range of creative possibilities for defining an exclusive licensee's rights.[110] The ability of the licensing contract to accommodate a variety of business models is reflected in the Lambert Model Contracts that were

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[108] ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS (AUTM), IN THE PUBLIC INTEREST: NINE POINTS TO CONSIDER IN LICENSING UNIVERSITY TECHNOLOGY 12 (2007), www.autm.net/aboutTT/Points_to_Consider.pdf [hereinafter AUTM].

[109] *Id.*

[110] *Id* at 13.

drafted for the use of PROs by university, business, and industry stakeholders in the United Kingdom.[111] Each model contract represents a different approach to the management of intellectual property rights.

"Convertible exclusive" licenses permit the licensor to grant an exclusive license 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.[112] 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.[113] If triggered, defeasance may take a variety of forms, including the conversion of the entire license grant from exclusive to non-exclusive; or the clawing-back of certain products or inventions from the exclusive license grant, to either non-exclusive status, or total exclusion from the license grant.[114] In particular, a claw-back clause is normally used to remedy the licensee's failure to meet minimum net sales requirements.[115] 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" license grant might begin with the classic non-exclusive language, but also undertakes not to grant to third parties the right to sell like products if the licensee complies with all the terms and conditions of the license agreement.[116] 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.[117] Licensees are likely to favor a "non-exclusive exclusive" grant over a standard non-exclusive grant, because the former holds some degree of protection against competition.[118]

Another variant within the hybrid license 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.[119] 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

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[111] 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) www.innovation.gov.uk/lambertagreements/index.asp?lvl1=2&lvl2=0&lvl3=0&lvl4=0.

[112] AUTM , *supra* note 108, at 12.

[113] Oliver Herzfeld & Richard Bergovoy, *Trademark Licensing Made Easy (Part I)*, MANAGING INTELLECTUAL PROPERTY, July 2007, www.managingip.com/Article.aspx?ArticleID=1393888.

[114] *Id.*

[115] *Id.*

[116] *Id.*

[117] *Id.*

[118] *Id.*

[119] *Id.*

manufacture or sell, directly or indirectly, in its territory. A possible variation is the "convertible non-exclusive" license, where if additional expressions of interest are not received within a defined period of time, then a non-exclusive license converts to exclusivity, at least within a particular territory or field of use.[120]

With the promotion of PRO research in mind, time-limited clauses may be used 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.[121] Following this arrangement, the grant may convert to a non-exclusive license, allowing competitors access to the market.[122] 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.[123]

VI. DRAFTING RESTRICTION CLAUSES

We have identified the core values of the PRO and its mandate for research. 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. If the PRO negotiates with a business partner for the ownership or assignment of the patent with broad restrictions on further use by the PRO, this may reduce the potential economic benefits of the research. We have noted the narrow derogations from the exclusive rights of use and sale conferred upon the patentee. Within contract on the other hand, we have found that it is possible to define a space in which basic research inquiries could be free of overly burdensome patent restrictions. In order to address both the interests of the PRO in ongoing research and those of the industry partner in minimizing the financial risks involved in developing and marketing the product, the parties may negotiate restrictions as to territory, mandatory sublicensing, diligence requirements, and milestone clauses.

A. RESTRICTIONS ON FIELD OF USE, TERRITORY AND TERM

PROs 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 license 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 licenses under the patents of other territories. Field-restricted licenses therefore enable the grant of rights that cover only the particular products that a licensee can and will accept a solid 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

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120 AUTM , *supra* note 108, at 12.
121 *Id.* at 13.
122 *Id.*
123 *Id.*

in the field of the exclusive license grant, to undertake product development.[124] A license 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.[125]

B. Territorial Restrictions and their Interface with European Community Competition Law

If the PRO gives the licensee the security of exclusivity, it is normally on condition that it will respect the territorial exclusivity of others, either licensor or exclusive licensee.[126] 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.[127] For its part, the licensee will be interested in ensuring protection of the investment that it will have to make: on the supply side, the equipment that it must install and the labour that it must employ; on the sales side, the distribution chains that it may have to set up, the advertising that it may have to do and the servicing that it may have to provide.[128] 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.[129] 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 license to export to other countries where parallel patents exist.[130]

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 afoul of competition law. The European Commission opposes restrictions as to territory, because it considers that the objective of creating a common market justifies treating a license to manufacture in one country of the Community as a license to sell in all.[131] The Community principle of the free movement of goods derives from Article 30 of the foundational Treaty of Rome,[132] which prohibits quantitative restrictions on imports and all measures having an equivalent effect thereto

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[124] AUTM, *supra* note 108, at 12.

[125] *Id.* at 2.

[126] William Cornish & David Llewelyn, Intellectual Property: Patents, Copyrights, Trademarks and Allied Rights 284 (2007) [hereinafter Cornish & Llewelyn].

[127] *Id.*

[128] *Id.*

[129] *Id.*

[130] *Id.*

[131] *Id.* at 292.

[132] Consolidated Version of the Treaty Establishing the European Community, Art. 28, 2002 O.J. (C 325), *available at* www.interreg3c.net/sixcms/media.php/5/EC+Treaty.6806.pdf [hereinafter Treaty Establishing the European Community].

between member states of the European Community (EC).[133] The exercise of a patent to block imports is considered a "measure having an equivalent effect." Article 36 provides that Article 30 shall not prevent the protection of intellectual property. However, the exclusion of 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."[134]

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 (unauthorized 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, where the product has been put onto the market in that Member State with the consent of the patentee.[135]

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 license fall within the scope of the Technology Transfer Block Exemption (TTBE).[136] However, it is not possible for a licensor to impose an obligation on its licensee, in the nature of an exclusive license 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*,[137] the European Court of Justice (ECJ) ruled against an indiscriminate application of Article 81 of the Treaty Establishing the European Community, which prohibits agreements that have as their object the restriction of competition within the common market.[138] *Nungesser* concerned a license 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 license to cultivate and

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[133] *See generally* David T. Keeling, *Intellectual Property Rights in* EU Law: Free Movement and Competition Law 6-7 (2003).

[134] Treaty Establishing the European Community, *supra* note 132, at Art. 30.

[135] In Case 15/74, Centrafarm B.V. v Sterling Drug, 1974 E.C.R. 1147, the European Court of Justice (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 onto the market in the U.K. with its consent under the protection of its U.K. patent in Case 187/80, Merck Inc. v. Stephar BV, 1981 E.C.R 2063. Regarding trademarked pharmaceuticals, *see* Case C-348/04, Boehringer Ingelheim KG and Boehringer Ingelheim Pharma GmbH & Co. KG v Swingward, *available at* oami.europa.eu/en/mark/aspects/pdf/JJ040348.pdf. The ECJ said that rules allowing trademark owners to object to parallel imported pharmaceuticals within the European Economic Area (EEA) apply to re-labelled, as well as re-boxed, products.

[136] The TTBE (Commission Regulation 772/2004, 2004 O.J. (L 127) (EC)) provides a block exemption that creates a safe harbor. 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 O.J. (L 304) (EC).

[137] Case 258/78 L.C. Nungesser KG & Kurt Eisele v. Commission of the European Communities, 1982 E.C.R. 2015.

[138] Treaty Establishing the European Community, *supra* note 132, at Art. 28.

sell in the German market four varieties of its hybrid maize seeds. By way of exclusivity, INRA agreed that it would not grant further licenses 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 afoul of Article 81(1) and could not be saved by the exemption in Article 81(3).[139] On the other hand, because the agreement was in the nature of an open license, 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 Article 81(1).[140] 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.[141] Such an outcome would be prejudicial to the dissemination of knowledge and techniques in the Community.[142]

Following the decision in *Nungesser*, the EC Technology Transfer Block Exemption (TTBE) takes account of whether the parties are competitors and whether the license constitutes a reciprocal or non-reciprocal agreement.[143] With regard to geographical limitations on production, these will be considered unacceptable divisions of markets where competitors enter into reciprocal agreements.[144] At the other end of the spectrum, if non-competitors are involved in a non-reciprocal agreement, the license is normally acceptable.[145] At the mid-point of the spectrum, the agreement is likely to

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[139] CORNISH & LLEWELYN, *supra* note 126, at 292-3. *See also* Sergio Baches Opi, *The Approaches Of The European Commission and The U.S. Antitrust Agencies Towards Exclusivity Clauses in Licensing Agreements*, B.C. INT'L & COMP. LAW REV. 85, 102-03 (2000). Art. 81(3) of the EC Treaty 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." EC Treaty, *supra* note 18, at Art. 81(3).

[140] CORNISH & LLEWELYN, *supra* note 126, at 292-3. *See also* Opi, *supra* note 139, at 102-03.

[141] Case 258/78 L.C. Nungesser KG & Kurt Eisele v. Commission of the European Communities, 1982 at para. 57, eur-lex.europa.eu.

[142] *Id.*

[143] 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* TRIPS Agreement, *supra* note 11, at 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 id.* at arts. l(c)-(d).

[144] CORNISH & LLEWELYN, *supra* note 126, at 293.

[145] *Id.*

benefit from the block exemption, especially if the license is other than exclusive.[146]

Likewise, restrictions on the sale of products are not permitted between competitors where the licensing arrangements are reciprocal.[147] 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.[148] Nevertheless, in different Member States, the parties are free to engage in passive sales in the territories of other exclusive licensees.[149] 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.[150]

C. IMPROVEMENT CLAUSES

Reservations regarding the PRO's patent rights in any improvements may seem like a stipulation that is consistent with the PRO's core values to promote ongoing research.[151] However, rights to improvements can prove problematic with respect to competition law.[152] 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 license 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 one party acquires additional patent rights, the other party is likely to consider that it is entitled to no less than a non-exclusive license to the improvement.[153] Sub-licensing is a further area where improvements are likely to be patentable or otherwise

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[146] *Id.* 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 O.J. (C 101) (EU) [hereinafter Article 81 Guidelines].

[147] CORNISH & LLEWELYN, *supra* note 126, at 293.

[148] *Id.* 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 Verticle Restraints, para. 50, 2000 O.J. (C 291) (EC) (2000).

[149] *E.g.*, Article 81 Guidelines, *supra* note 146, at paras. 63, 64, 77.

[150] Case 258/78 L.C. Nungesser KG & Kurt Eisele v. Commission of the European Communities, 1982 E.C.R. 2015, para. 44.

[151] The standard improvement clause in a patent license 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." MARK ANDERSON, TECHNOLOGY TRANSFER; LAW, PRACTICE AND PRECEDENTS 42 (2d ed. 2003).

[152] TERRELL ON PATENTS 10-52, (16th ed. 2005). *See also* Richard Binns & Bryan Driscoll, *Intellectual Property Issues in R&D Contracts*, 1 PHARM. SCI. & TECH.TODAY 95, 99 (1998).

[153] PHILIP MENDES, INTERNATIONAL TRADE CENTER, *Licensing and Technology Transfer in the Pharmaceutical Industry*, *in* EXPORTING PHARMACEUTICALS: A GUIDE FOR SMALL AND MEDIUM-SIZED EXPORTERS 17 (2005), *available at* www.wipo.int/sme/en/documents/pharma_licensing.html.

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-license to other 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 licenses, territory by territory.[154] 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 license follow-on patents and rights to know-how acquired by the licensee.[155] 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 unwilling to discover improvements. In this situation, without a clear direction as to duration and termination of the license, there may be difficulties about the obligations concerning improvements which one side owes to the other at the date of termination.[156]

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.[157] 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.[158] 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 on new models, it is crucial that the contract define the nature of an improvement and, thereby, what is covered by the license and what constitutes a new, independently

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[154] *See generally* Cornish & Llewelyn, *supra* note 126, at Ch. 7: Property Rights and Exploitation.

[155] *Id. See also* Donald M. Cameron & Rowena Borenstein, Ogilvy Renault LLP, Key Aspects of IP License Agreements 22 (2003), www.jurisdiction.com/lic101.pdf.

[156] *See generally* National Broach v Churchill Gear [1965] R.P.C. 61.

[157] AUTM, *supra* note 108, at 4.

[158] *Id.*

patentable technology.[159] The latter case, depending on the national law, may necessitate a new license agreement.[160]

Given the potential to reduce 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.[161] 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.[162] In addition, an improvements clause should be restricted to inventions that are owned and under the control of the licensor PRO.[163]

D. 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. Article 5 TTBE 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.[164]

Article 5(1) provides that the Article 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 license 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;

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[159] 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, LexisNexis, *Ch. 6A: Government, University and Biotechnology Licensing*, *in* PATENT LICENSING TRANSACTIONS § 6A.03[c] (1968), www.lexisnexis.com/practiceareas/ip/pdfs/531CH6A.pdf.

[160] In the U.S.A, if the licensee participated in the improvement enough to qualify as a named inventor, he will have the right of use regardless of the existence of a license. *See* 35 U.S.C. § 262 (2001).

[161] AUTM, *supra* note 108, at 4. 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, *supra* note 25, at Art. 4.

[162] AUTM, *supra* note 108, at 4.

[163] *Id.*

[164] *See* TTBE, *supra* note 18, at Art. 5 and recital (14).

- 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, Article 5(2) further provides that the Article 2 exemption shall not apply to any direct or indirect obligation limiting the licensee's 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.[165] Best practice is therefore to ensure that there is no license term that may be considered incompatible with EC Article 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.[166]

VII. DRAFTING RESERVATION CLAUSES

Drafting appropriate reservation clauses is crucial for dealing with future R&D.[167] In order to address both the interests of the PRO in the continued conduct and dissemination of research and those of the industry partner in minimizing the financial risks involved in developing and putting the invention on the market, PRO licensors in developing countries should negotiate provisions in the licensing contract concerning the reservation of rights to use, research exemptions, and publication.

An area of much debate concerns the use of the so-called exemption for research use that has been invoked by universities in both the United States and EU, either formally or informally. Traditionally, universities have been exempted from paying fees for patented inventions they use in their own research. The rationale is that universities fulfill a public mission. For example, the UK Patents Act creates two general exceptions for private use

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[165] The Commission may withdraw the benefit of the block exemption pursuant to Article 29(1) of Regulation (EC) 1/2003 (the Modernisation Regulation) where it finds in a particular case that a technology transfer agreement to which the exemption provided for in Article 2 applies, nevertheless has certain effects which are incompatible with the conditions laid down in Article 81(3) of the EC Treaty. Council Regulation 1/2003, of 16 December 2002 on the Implementation of the Rules on Competition Laid Down in Articles 81 and 82 of the Treaty, 2003 O.J. (L 1) 1 (EC). *See also* TTBE, *supra* note 18, at Art. 6 and recital (16).

[166] Intel Technologies v. Via Technologies Inc. & Anor, [2002] EWCA (Civ) 1905, [72] (Eng.), *available at* www.bailii.org/ew/cases/EWCA/Civ/2002/1905.html.

[167] 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: SECTION 2: SPECIFIC STRATEGIES AND MECHANISMS FOR FACILITATING ACCESS TO INNOVATION, *in* MIHR HANDBOOK, *supra* note 74, at 35, 41, www.iphandbook.org/handbook/ (follow "Specific Strategies and Mechanisms for Facilitating Access to Innovation" hyperlink) (last visited June 7, 2008).

and for experimental use.[168] As more public research is carried out with business and generates monetary rewards, the rationale for the exemptions has become less clear. The extent and status of this exemption differs across countries and is often ill-defined.

The issue is given further importance due to the currently uncertain position regarding exemptions for research and experimental use in patent laws. The scope of the research exemption has been the subject of considerable policy debate and litigation. Recent court decisions in the United States have tended to restrict its meaning. The concern is that the present patchwork of national research exemptions is both ill-defined and being gradually eroded by legal challenge.

This being the case, it is crucial that PROs and their industry partners negotiate and clarify their position regarding research exemptions for private and experimental use. Technology transfer officers should make express provision within the licensing contract as to the scope of research exemptions. More precise research exemptions, inserted within the terms of the licensing contract, should aim to permit limited use of patented technologies, while offering adequate protection for the PRO's invention and the industry partner's need to reduce the risk of investment.

A. RIGHTS TO USE

PROs should reserve the right to practice licensed inventions with a view to ensuring that 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.[169] 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.[170] Such a general reservation should clearly articulate the scope of reserved rights: to practice 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

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[168] U.K. Patents Act, *supra* note 102, at § 60(5)(a). Note: although both Article 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/EEC, Relating to Community Patents, 1-27, 1989 O.J. (L 401)), 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 O.J. (C 337 E) (EU).

[169] AUTM, *supra* note 108, at 2.

[170] *Id.*

sectors.[171] For example, such a reservation clause should include a definition of non-commercial use, to read:

> The PRO 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;
>
> each solely for Non-Commercial Research Purposes.
>
> 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."[172]

B. EXPERIMENTAL USE

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,[173] the exemption has proven increasingly controversial.[174] 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*,[175] Aldous LJ said the subject matter of the invention must be ascertained from the patent as a whole. For example, if a genetic testing tool is needed to help navigate genetic sequences related to an inherited disease and that tool is patented, then a license for its use will be necessary. This also means that a third party who wishes to test a cure for cancer using a genetically modified mouse cannot rely on the defense of experimental use against a claim by the patentee of the mouse.[176] A researcher wishing to use diagnostic kits containing patented processes or products to test other subject matter, therefore needs to obtain a license.

Recent developments within Contracting States to the European Patent Convention (EPO)[177] indicate that the exception may also apply to research

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[171] *Id. See, e.g.*, Gene Service, *Material Transfer Agreements for the Supply of Biological Matter*, www.geneservice.co.uk/products/mtas/Tomlinson_IJ_MTA_NIH_02_05_07.pdf (last visited Apr. 12, 2008).

[172] AUTM, *supra* note 108, at 2.

[173] *See, e.g.*, Indian Patents Act, *supra* note 12, at §60(5)(b).

[174] CORNISH & LLEWELYN, *supra* note 126 at 254-55.

[175] [1999] R.P.C. 397 (A.C).

[176] Lionel Bentley & Brad Sherman, INTELLECTUAL PROPERTY LAW 545 (2002).

[177] Article 64 (3) of the EPC provides that any infringement of a European patent shall be dealt with by national law. European Patent Convention, Art. 64(3), Oct. 5, 1973, www.epo.org/patents/law/legal-texts/html/epc/1973/e/ma1.html. Therefore no provision regarding defenses to infringement is found in the EPC. Concerning the membership of the EPC, *see* Member States of the European Patent Organisation, www.epo.org/about-us/epo/member-states.html#contracting (last visited May 8, 2008).

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.[178] 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 defense is unlikely to cover trials examining whether a third party can commercially produce the patented product. The UK courts have on occasion, been willing to entertain a broad interpretation of "experimental."[179] 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, seeks to exploit and sell its technology to third parties.[180] In this respect, English law seems to have recently moved somewhat closer to the experimental use exception as it is applied in the US.

In *John M.J. Madey v. Duke University*,[181] 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 and student education should be limited to strictly philosophical inquiry.[182] As a 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.

Notwithstanding the attempt in *Madey* to distinguish between a PRO'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.[183] 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.[184] For example, in *Monsanto v. Stauffer*,[185] Stauffer had developed a market variant of Monsanto's successful patented weed-killer "Roundup" for which Staffer established tests both inside

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[178] Most Members of the EPO have introduced a uniform, general non-industry specific experimental use exception in their patent statutes. For example, section 60(5)(a) and (b) of the U.K. 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." The U.K. Patents Act, *supra* note 102, at § 60(5)(a), (b). *See also* CORNISH & LLEWELYN, *supra* note 126, at 254

[179] See Monsanto v. Stauffer Chem. Co. [1985] R.P.C 515 (A.C.); Smith Kline & French Laboratories Ltd. v. Evans Medical Ltd. [1989] F.S.R 513. 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."

[180] Inhale Therapeutic Systems Inc v Quadrant Healthcare Plc [2002] R.P.C. 21.

[181] 307 F.3d 1351 (Fed. Cir. 2003), *cert. denied*, 123 S. Ct. 2639 (2003).

[182] 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).

[183] CORNISH & LLEWELYN, *supra* note 126, at 254.

[184] *Id.*

[185] Monsanto Co v Stauffer Chemical Co [1985] RPC 515, (A.C.).

and outside their 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 the 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.

Second, 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.[186] 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.[187] It is the accepted view that the purpose of Article 10(6) of the Medicinal Products for Human Use Directive[188] 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 addition, there is further uncertainty regarding the application of the experimental use exception in Article 10(6): the 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 authorization for that new drug.

Similarly, in the US, there is now considerably less scope for PROs to avail themselves of the defense of experimental use. For example, in *Merck KGaA*

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[186] CORNISH & LLEWELYN, *supra* note 126, at 255.

[187] The Hatch-Waxman Act is also known as the Drug Price Competition and Patent Term Restoration Act of 1984. 35 U.S.C. §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 years exclusivity granted by the issuance of a patent.

[188] "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/EC, of 31 March 2004 Amending Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use, Art. 10, 2004 O.J. (L 136) 6 (EC). 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." The U.K. Patents Act, *supra* note 102, at § 60(5). Note the trade-off is that 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."

v. Integra Lifesciences Ltd[189] the Supreme Court decreased protection for academic institutions generating data in support of FDA filings. Generally speaking, academic research was considered too remote from the regulatory filing process to fall within the scope of the exemption.[190] For this reason, when licensing technology, it is crucial for developing country PROs to seek to reserve all those rights that will enable academic research to proceed unimpeded.

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.[191] It is important that this science, so vital to diagnostics and drug discovery, should remain open to experimentation and further progress.[192] The *Gowers Review of Intellectual Property* suggested that, in terms of a dividing line, the exception should only operate in those cases where licenses of the existing patent are unlikely to be given — such as where a patentee is seeking to monopolize further experimentation.[193]

Consequently, it is advisable to prepare for the worst case, by considering the definitions of non-commercial use in light of *Madey*.[194] Licensing contracts should seek to ensure that PROs 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.[195] 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 may be licensed or otherwise transferred, either directly or indirectly, to third parties; and

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[189] Merck KGaA, Petitioner v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005).

[190] Drug Price Competition and Patent Term Restoration Act of 1984, 35 U.S.C. §271(e)(1) (2006). This safe harbor provision of the Hatch-Waxman Act exempts from patent infringement the use of a patented invention "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." The scope of protection under the safe harbor provision has been the subject of considerable uncertainty and controversy.

[191] CORNISH & LLEWELYN, *supra* note 126, at 255.

[192] 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 Suppport of Petition for Writ of Certiorari, 307 F.3d 1351 (Fed. Cir. 2003).

[193] ANDREW GOWERS, GOWERS REVIEW OF INTELLECTUAL PROPERTY 45-76 (2006), www.hm-treasury.gov.uk/media/6/E/pbr06_gowers_report_755.pdf

[194] 307 F.3d 1351, 1362 (Fed. Cir. 2002).

[195] AUTM, *supra* note 108, at 11.

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.[196]

In summary, in drafting reservation of rights clauses and associated definitions, it is important to keep both the *Madey* and *Merck* decisions in mind. Even beyond the EU and US jurisdictions, the influence of such authoritative decisions is likely to have an impact on patent law.

C. ACCESS RIGHTS TO RESEARCH RESULTS

In our previous discussion of the core values of PROs, we identified the way in which the global network of PROs shares a responsibility in helping to advance medical knowledge. One of the ways in which they can do this is by preserving open access to the results of scientific research. Since PROs began patenting the results of research, access to the research results connected with the subject matter of the patent has become a controversial issue. Licensing to an industry-partner founded by university inventors raises the potential for conflicts of interest. Pre-grant, as soon as the technology is identified for protection, the confidentiality needed to preserve the art in the invention comes into conflict with the PRO's goal of the dissemination of research. Post grant, the patentee will desire to maintain its monopoly over the use of the invention.

Patenting of basic research and patenting by PROs raises new issues regarding the conditions of access to the outcome of that research, particularly in developing countries where systems of finance and innovation are immature. When buying technology, instances and threats of restricted access (for example, for genetic testing) to proprietary research tools create the risk of slowing research and raising costs in developing countries.[197] When disseminating technology, clauses for promoting the use of public domain knowledge and information need to be made more systematic in order to provide the appropriate conditions and incentives for public knowledge to actually be accessible to science.[198]

Too precipitous and rapid commercialization of publicly funded research could upset the necessary and most appropriate balance between protection and diffusion. A failure to support the broad diffusion of basic research could potentially slow the rate of innovation and economic development. It may lead to a loss of expertise and information among other researchers. One notorious example is the monopoly Myriad acquired on BRCA1 and 2 genes.

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[196] *Id.*

[197] Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 621, 626 (1988).

[198] *See* J. Barton, *Patents and the Transfer of Technology to Developing Countries*, *in* OECD, PATENTS AND INNOVATION: TRENDS AND POLICY CHALLENGES 26, 26 (2004), *available at* www.oecd.org/dataoecd/48/12/24508541.pdf.

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.[199] 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 monopolize the data collection, analysis and price of the genetic tests in that country.[200]

Proponents of the patenting of genes argue that researchers and corporations deserve to be rewarded for their investment of time, labor and capital in genetic research. They also argue that, once a patent has been filed, research is forced more rapidly into new areas and that secrecy is reduced as all researchers have access to the discovery. However, this access to proprietary research tools and diagnostic tests often comes at a high cost in terms of license fees and royalties, thus creating potential barriers to further important research and potentially severely limiting the timely development of new knowledge and new therapies. The American College of Medical Genetics has declared its concern that such monopolies limit the accessibility of competitively priced genetic testing services, hinder the development of quality assurance programs and limit the number of knowledgeable individuals to assist in patient care.[201]

More broadly, the patenting of genetic inventions by PROs highlights the potentially serious implications that such patents can have in light of the mission of Universities to disseminate knowledge throughout the broader academic and local community. A university might license a research tool exclusively to a company to optimize and sell licensed products and services for research, diagnostic, or other end uses. Insofar as commercial innovations may be considered a by-product of publicly funded research, there is considerable debate about whether PROs should grant exclusive licenses to the private sector for discoveries that have benefited from public money. By definition, exclusive licenses limit the diffusion of medical technologies. In order to manage the potential conflict relating to the dissemination of knowledge and the commercialization of research, technology transfer officers should consider including clauses in license agreements to protect access to

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[199] Benjamin Coriat & Fabienne Orsi, *Are "Strong Patents" Beneficial to Innovative Activities? Lessons from the Genetic Testing for Breast Cancer Controversies*, 14 INDUS. & CORP. CHANGE 1205, 1212-13 (2005)

[200] *Id.* at 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.

[201] Jonathan F. Tait & The Intellectual Property Subcommittee of the Economics Committee, *Points to Consider in Preparing License Agreements for Patented Genetic Tests* 1-2 (2004), *available at* www.acmg.net/AM/Template.cfm?Section=Search2&section=Products1&template=/CM/ContentDisplay.cfm&ContentFileID=66.

the research tools for future research and discovery. The drafting of such an exclusive license should specify that the license is exclusive for the sale, but not use, of such products and services. By such means, the PRO should seek to ensure that it is free to license non-exclusively to others the right to use the patented technology.[202]

Further, recall 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:

- 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.[203]
- Making a provisional filing of the patents on improvement with a one-year option for possible future filing, where the patent office allows.[204]

The provisional patent application permits an option 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,[205] 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.[206] A further advantage is that an international patent

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[202] AUTM, *supra* note 108, at 5.

[203] *See, e.g.,* Conditions for Patentability; Novelty and Loss of Right to Patent, 35 U.S.C § 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.

[204] *See, e.g.,* South African Institute of Intellectual Property Law, Copyright Information, www.saiipl.org.za/introductio-patents.htm (explaining that in South Africa it is possible to file a provisional patent application, a complete patent application, or a Patent Co-operation Treaty (PCT) International Patent Application which also designates South Africa). If the idea has not been finalized 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. *Id.*

[205] Paris Convention, *supra* note 25, at Art. 4.

[206] *See* World Intellectual Property Organization, Patent Cooperation Treaty, (Jun. 19, 1970), *available at* www.wipo.int/pct/en/texts/articles/atoc.htm. Currently, 124 countries in the world are members of the PCT, with South Africa having joined in 2000. WORLD

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.

D. PUBLICATION RIGHTS

The Bayh-Dole model of commercialization, and its accompanying rules for the patenting of inventions and confidentiality, potentially conflicts with academic goals of publication and pure research. The core values of the PRO confirm its traditional mandate as an institution that is dedicated to pure scientific research that is immediately published and placed in the public arena where it may be freely applied in the public interest. PROs traditionally encourage the wide dissemination of publications. In order to publish research results, scientists must agree to make unique resources — including antibodies, cell lines and chemical compounds — available to others for verification of their published data and conclusions. However, patenting requires that the results of that research remain confidential. Premature publication in articles, research papers and at conferences and meetings may destroy the novelty of a patentable invention.[207] As a result, patenting requirements that necessitate the restriction of access to ideas and information tend to conflict with the values of open access and the dissemination of knowledge.

Notwithstanding, it would be unreasonable for PROs to have an unfettered right to publish research outcomes, if to do so would result in the industry partner losing any competitive advantage arising from investing in the development of the technology. Hence, addressing this conflict of interest is a key task of the licensing contract.The contract should reflect the necessary trade-off between the potential for future patent protection and the ability to freely publish the results of research. These competing interests can be the source of conflict during negotiations. Ideally, a company that is fully funding a research project will have the right to approve any proposed publication, but this is not always commercially achievable.

By way of compromise, the competing interests of the parties will typically be addressed by specifying withholding periods for publication, providing the industry partner with the opportunity to review any proposed publication without the right to prohibit publication, and specifying how post-graduate dissertations will be treated. A delay before publication will enable patent applications to be filed in relation to project outcomes if desirable and, at the very least, will provide the industry partner with a period of exclusive access to the project outcomes.

INTELLECTUAL PROPERTY ORGANIZATION, PCT: ONE MILLION AND COUNTING 2 (2004), www.wipo.int/export/sites/www/pct/en/million/leaflet.pdf. The cost of filing a PCT application typically ranges from R20,000 to R45,000. 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.

[207] *See* Massachusetts Institute of Technology v. AB Fortia, 774 F.2d 1104 (Fed. Cir. 1985). *See also* Ann L. Monotti, The Legal Issues: Patenting & Technology Transfer, users.ox.ac.uk/~edip/Monotti_paper.doc (last visited June 17, 2008).

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.[208]

Apart from the problem of jeopardizing 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.[209] 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.[210]

VIII. SAFEGUARDING THE BENEFITS OF THE LICENSING TRANSACTION

A. NO-CHALLENGE CLAUSES

While the underlying thesis of this paper is based upon the advantages of the patent licensing contract in opening some further policy space for public research exemptions, the asymmetrical relationship between property and contract can also hold considerable risk for the licensor. No more so than when the licensor's interest is in protecting its intellectual property against internal attack from a licensee who is able to challenge the validity of the patent.

Let us assume that, the PRO has been successful in negotiating a range of reservation clauses in favour of research and dissemination of knowledge. In order to protect that bargain, and to gain some immunity from an infringement suit by its licensee, the PRO licensor decides to insert a "no-challenge" clause in the contract. Under such a clause, the licensee promises, in consideration of its license, that while it holds the license or after it has

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[208] AUTM, *supra* note 108, at 10.

[209] *See* European Patent Office, DG3: DBA case G 0003/93 EBA (Aug. 16, 1994), *available at* legal.european-patent-office.org/dg3/biblio/g930003ep1.htm (regarding the underlying legal principles EPO Enlarged Board of Appeals).

[210] *See* European Patent Organisation, The Patent Process, www.epo.org/about-us/office/annual-reports/2005/business-report/patent-process.html (paying filing fee during 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).

terminated the license, it will not attack the validity of the licensed property; in other words, that it will not bite the hand that feeds it.

As a matter of common law, even without an express no-challenge covenant, the common law disapproves of a person who seeks to approbate and reprobate at one and the same time. A licensee, when sued for royalties in respect of a licensed patent, for example, cannot respond by trying to show that the patent is invalid in order to avoid its contractual liability. The licensee estoppel rule in English law was outlined by the court in *Fuel Economy Company Ltd v. Murray*:

> A licensee cannot challenge the validity of a patent in an action under the license, the license being admitted by the licensee, because the title is not in issue. But in an action for infringement a different set of circumstances arises altogether. It is not an action under the license at all, and in such a case, so far as my judgment goes, no estoppel arises.[211]

In the US, however, as a result of the *MedImmune v. Genentech* decision,[212] the possibilities of challenging licensed rights widened. The Supreme Court found that respondents could not rely on "the common-law rule that a party to a contract cannot at one and the same time challenge its validity and continue to reap its benefits."[213] In 1997, Genentech entered into a patent license with MedImmune to pay royalties on sales of "Licensed Products." The license covered Genentech's patent for the production of chimeric antibodies. Some years later, Genentech informed MedImmune that one of MedImmune's pharmaceutical products, Synagis, was covered by the patent, and asked hat MedImmune pay royalties in accordance with the license. MedImmune responded that no royalties were due because the patent was invalid. Nevertheless, MedImmune agreed to pay royalties, although subsequently it decided to ask the court for a declaration that the patent was indeed invalid and therefore unenforceable. Genentech argued that because MedImmune had entered into a patent license agreement and could not be sued for patent infringement of the licensed patent, MedImmune could not file a declaratory judgment action without first stopping its royalty payments.[214] MedImmune countered that it did not want to terminate the license because of the risk that it might be found liable for treble damages.

The Court held that a licensee is not required to breach or terminate a license agreement as a prerequisite for filing an action to challenge the

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[211] Fuel Economy Co Ltd v Murray (1930) 47 R.P.C. 346, 353; Matthew Jones, *Licensee Estoppel: An Overview Of The Position Under English And European Law*, 2 J. INTELL. PROP. L. & PRAC. 750-55 (2007).

[212] MedImmune, Inc. v. Genentech, Inc., 127 S. Ct. 764 (2007).

[213] *Id.* at 776.

[214] *See id.* at 766. Genentech's legal argument was that the suit did not involve a "case or controversy" (required by the Constitution and the Declaratory Judgment Act) because there was no real legal dispute between the parties as long as there was a license. The question presented to the Supreme Court was: Does Article III's grant of jurisdiction of "all Cases . . . arising under . . . the Laws of the United States" implemented in the "actual controversy" requirement of the Declaratory Judgment Act, 28 U.S.C. § 2201(a), require that a patent licensee refuse to pay royalties and materially breach the license agreement before the licensee can sue to have a court declare the patent invalid, unenforceable or not infringed?

validity, enforceability, or non-infringement of a licensed patent.[215] In short, a licensee may maintain the benefit of the license while at the same time challenging the patents covered in the license by seeking a declaration of patent invalidity. The Court stated that MedImmune was not repudiating the license while continuing to reap its benefits. Instead, the license, properly interpreted, did not prevent Medimmune from challenging the patents and did not require the payment of royalties, because the patents did not cover MedImmune's products and were invalid.[216] Thus, the Court held that MedImmune was not required to break or terminate its license agreement before seeking a declaratory judgment.

As a result of *MedImmune*, licensees may view entering into a license agreement as a situation which will allow them the freedom to challenge a patent's validity at any time without a risk of losing the license. The *MedImmune* decision allows licensees the ability to challenge the infringement, scope, or validity of a licensed patent while continuing to pay royalties. The decision has important implications for the relationship between licensor and licensee that go beyond the US jurisdiction.

In light of the *Medimmune* decision and its influence, licensors need to consider drafting a clause to indicate that the licensee had an opportunity to review the patent and decided to enter into the license agreement. In fact, the Supreme Court suggested that licensors might be permitted to require, as a condition of granting the license, that the licensee promise not to seek a holding that the licensed patents are invalid, and that the contract might prevent the licensee from challenging the patents.[217]

Nevertheless, if *MedImmune* means that post-agreement challenges cannot be ruled out, then licensors may wish to include a contractual provision indicating that, if the license is unsuccessfully challenged, then attorney's fees and costs for the declaratory judgment action must be paid by the licensee.[218] Alternatively, licensors may consider adding a clause to provide for termination of the license upon the challenge of the underlying patented technology. In such an event, the licensee would no longer be in a position to reap the benefits of the license and the licensor could immediately look for another licensee.[219] 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

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[215] *Id* at 777.

[216] *Id* at 776.

[217] *See id.* ("Promising to pay royalties on patents that have not been held invalid does not amount to a promise not to seek a holding of their invalidity.").

[218] Of course, such arguments may be less persuasive where, as in *MedImmune*, the license covers pending applications that later issue as challenged patents (*i.e.*, the licensee never had the opportunity to analyze the claims of the licensed patents), and a dispute develops over the validity and/or infringement of the new patents. *But see* Gen-Probe Inc. v. Vysis, Inc., 359 F.3d 1376 (Fed. Cir. 2004) (holding that unless a licensee breaches the license by refusing to pay royalties, there is no actual controversy and the federal courts lack jurisdiction.).

[219] *See* Lear v. Adkins, 395 U.S. 653 (1969) (regarding the enforceability of such a provision).

give the licensor the opportunity to renegotiate the agreement or evaluate the strength of the licensee's claim.[220]

In any event, the *MedImmune* decision may give European Lawmakers reason to rethink the European competition rules concerning no-challenge clauses contained in the Technology Transfer Block Exemption Regulation. Article 5 of the Regulation states that the block exemption applies to no-challenge clauses in which the licensor may terminate the license agreement in cases where the licensee challenges the validity of the licensed intellectual property.[221] When assessing an agreement containing a no-challenge clause that does not benefit from the exemption, for example one where the parties' market shares exceed the thresholds, it is evident that the licensor needs to consider whether it is inconsistent with the prohibition in Article 81 of the EC Treaty against undertakings that tend to restrict competition. The strong reasoning in *MedImmune v. Genentech* may suggest the contrary.

CONCLUSION

The foregoing analysis has shown how patent licensing may offer a self-regulatory solution to the potential conflict of interest associated with strong intellectual property protection and the dissemination of publicly funded medical research. While many inventions do not merit the expense of filing for patent protection, those that do depend on technology transfer officers utilizing an appropriate mix of licenses and drafting terms that promote pharmaceutical R&D for the greater welfare of under-served patient populations.

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[220] *See, e.g.*, The Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. §301 (1984), which provides for a notification process similar to that by Generic Drug Manufacturers under paragraph IV of Section 505(j) of the Drug Price Competition and Patent Term Restoration Act of 1984.

[221] Article 5(1)(c) of the TTBE 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." *See* TTBE, *supra* note 18, at Art. 5(1)(c).