

**A NEW GLOBAL PATENT REGIME FOR DISEASES:
U.S. AND INTERNATIONAL LEGAL ISSUES**

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TABLE OF CONTENTS

I. INTRODUCTION.....	86
II. THE MECHANISM.....	91
<i>A. The Declaration</i>	91
<i>B. Basic Outline of Why It Works</i>	92
<i>C. More Complex Settings</i>	94
III. CRUCIAL ELEMENTS OF THE MECHANISM.....	96
<i>A. Foreign Filing License Obligation</i>	97
1. Discrimination.....	97
2. Justification.....	98
3. Takings.....	99
4. Declaration.....	99
5. Requires No Additional Security Assessment.....	100
6. Coverage.....	100
7. Foreign Filing License Prior to Domestic Filing.....	101

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8. Time Limits and Patent Cooperation Treaty	
Applications.....	101
9. Procedure to Determine Content of the Declaration	102
10. Data Issues.....	104
<i>B. Enforcement</i>	106
1. Form of Punishment.....	106
2. When Filing License Precedes Domestic Filing.....	108
3. Procedures to Identify When the Declaration Has Been Falsified	108
4. Equitable Estoppel.....	110
IV. INTERNATIONAL COVERAGE	110
<i>A. Effect of Non-Implementing Countries</i>	111
<i>B. Effectiveness of the Mechanism in Small Countries</i>	112
<i>C. European Patent Office Applications</i>	113
V. IMPLEMENTATION — SELECTED COUNTRIES	113
<i>A. United Kingdom</i>	114
<i>B. France</i>	116
<i>C. Germany</i>	118
<i>D. Canada</i>	119
<i>E. Japan</i>	120
VI. OTHER POLICY OPTIONS	120
VII. CONCLUDING COMMENTS.....	123

I. INTRODUCTION

Starting with the fight over the inclusion of intellectual property in the Uruguay round of the General Agreement on Tariffs and Trade (“GATT”) negotiations in the 1980s, re-kindled with the spread of HIV/AIDS and the discovery of expensive drug treatments, there has been intense disagreement over the global reach and desirable form of patent protection. Currently, there is widespread dissatisfaction with the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPs”), the international framework for patent rights agreed to in the mid-1990s, as it applies to pharmaceuticals.¹ The dissatisfaction is strongest in the developing world, where new patent laws will have the most effect, but the potential implications of the new regime for health in these countries have also raised concern elsewhere.

1. Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS-RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPs], available at http://www.wto.org/english/docs_e/legal_e/final_e.htm (last visited Oct. 11, 2002).

The fact that the TRIPs-based global architecture has generated such resistance has damaging implications. Until we find a more broadly accepted structure, incremental changes to the system of patent rights and drug prices will be forced, the result of pressure built up by a coalition of diverse parties. Such pressure has been brought to bear on legal proceedings and on companies deciding the prices of products that have attracted particular attention. This is a very costly process of change. It consumes the time and energy of firms, governments, international organizations, and civil society — valuable resources that could be used productively elsewhere. It is also a process that is extremely random in effect, with outcomes depending on the vagaries of public attention and the demands made by other issues. The uncertainty this creates about future markets and pricing opportunities is itself a strong deterrent to private sector involvement in drug research for the developing world. Risk is costly and firms require a higher return to invest in an uncertain environment.

Dissatisfaction with the patent system in the realm of health will also be damaging if it spills over into a distrust of the system more generally. This possibility should concern anyone who considers patents to be an important stimulus to innovative effort. In rich countries, a skeptical public will be less willing to support strong intellectual property rights and their extension to new areas such as biotechnology. In poorer countries, even assuming that treaties are signed and laws are enacted, effective enforcement will need to be developed and encouraged. A reliable and consistent patent system can only be established with local support. It is not easily imposed from the outside. A global patent framework that shows respect for the evolving development level of countries and for the variation in markets for different drugs could be put forward as a basis for building this support in the developing world.

The debate over this issue has become very polarized, which makes finding an acceptable framework difficult. Positions tend towards two endpoints. At one endpoint are those who argue that all countries should have the same form of protection as is currently in place in developed countries.² They argue that patents will encourage researchers in the developing world and will stimulate efforts to discover new products of particular interest to consumers in those markets. Adherents of this position largely prevailed in the TRIPs negotiations. At the other endpoint are those who view the higher prices supported by pharmaceutical patents as too burdensome in poor countries and advocate either no patents for drugs in the developing world

2. See, e.g., Pharmaceutical Research & Manufacturers of America (PhRMA), *Health Care in the Developing World* (explaining the position of PhRMA, the industry group representing the U.S. pharmaceutical industry), at <http://www.phrma.org> (last visited Oct. 24, 2002).

or expansive compulsory licensing and other provisions.³ This Article goes back to the original justification of the patent system to devise a framework that is arguably preferable to either of these alternatives and that could perhaps serve as a meeting point simply by virtue of not being either of those alternatives.

The proposal starts from the recognition that granting inventors intellectual property rights always entails a tradeoff. The higher prices supported by patents finance the search for new innovations, but higher prices also mean that fewer consumers can purchase goods incorporating those innovations.⁴ Whether poor countries should grant firms patent rights on pharmaceutical products depends importantly upon the extent to which the prospect of greater profits leads firms to increase research investment and the degree to which each additional dollar of investment results in beneficial innovation.⁵ These both decline at higher levels of research and development (“R&D”) investment. As a result, one can expect relatively more benefit from increasing protection where incentives are initially low. The optimal geographic extent of protection thus *differs* across innovations, and there is no single best patent treatment.

From this perspective, the key point is that there are two very different and identifiable types of drug markets. Some diseases are specific to the developing world, for example, malaria. Since markets for drugs treating these diseases are almost entirely in the developing world, there has been almost no investment in these markets by the for-profit sector. Without protection in the developing world, there

3. See OXFAM, FATAL SIDE EFFECTS: MEDICINE PATENTS UNDER THE MICROSCOPE (2001), available at <http://www.oxfam.org.uk/cutthecost/downloads/policy3.rtf> (last visited Oct. 24, 2002); see also Frederick M. Abbott, Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WTO After the Doha Declaration on Public Health (2002), available at <http://www.geneva.quino.info> (last visited Oct. 11, 2002). Issues concerning compulsory licensing include, for example, whether national emergency situations allow the override of advance licensing negotiations with the rights holder; whether production under compulsory license can be for export; whether the compulsory license of two national patents to allow exports requires separate compensation be paid to the patentee, and so on. See *id.*

4. See Jean O. Lanjouw, The Introduction of Pharmaceutical Product Patents in India: “Heartless Exploitation of the Poor and Suffering?” (Nat’l Bureau of Econ. Research, Working Paper No. 6366, 1998) (discussing other costs and benefits of granting intellectual property rights for pharmaceuticals in developing countries), available at <http://papers.nber.org/papers/W6366> (last visited Oct. 24, 2002).

5. An analysis of extending protection to additional countries is very closely analogous to that of granting protection for more years. See WILLIAM D. NORDHAUS, INVENTION, GROWTH, AND WELFARE: A THEORETICAL TREATMENT OF TECHNOLOGICAL CHANGE (1969) (providing an economic analysis of the length of a patent term); Alan V. Deardorff, *Welfare Effects of Global Patent Protection*, 59 *ECONOMICA* 35 (1992) (providing an economic analysis of the extension of patent protection to additional countries).

has been little prospect of profit anywhere and therefore little interest on the part of firms to invest in therapies for these diseases.⁶

Consider, however, global diseases, those that are widespread in poor countries but *also* in rich countries. Although they have received less attention in development debates over intellectual property because they are not specific to developing countries, global diseases are an important cause of disability and mortality amongst the poor.⁷ At the same time, almost all of the potential market for global diseases is found in the West. Table 1 (p. 90) ranks selected developing countries by their 1998 purchasing power parity adjusted per-capita gross domestic product (“GDP”).⁸ We see each country’s share of total worldwide drug expenditure and an estimate of their individual shares of total worldwide spending on drugs for cardiovascular disease. These numbers are remarkably small. In particular, the table indicates that about 46% of the world’s population is found in countries representing less than 2% of total expenditure on drugs for cardiovascular disease. As another example, countries with GDP per capita less than \$2,500 together contributed less than 0.5% to global spending on anti-retroviral drugs in 1999.⁹

6. *But see* Jean O. Lanjouw & Iain M. Cockburn, *New Pills for Poor People? Empirical Evidence After GATT*, 29 *WORLD DEVELOPMENT* 265 (2001) (explaining that even with effective patent systems the group of developing country markets may not, by itself, be very attractive given the prices that it can support). The goal of one set of recent policy initiatives is to put more money into poor country markets via a dedicated fund or tax credit to subsidize purchases of specified products. *See* Michael Kremer, *Creating Markets for New Vaccines — Part 1: Rationale*, in 1 *INNOVATION POLICY AND THE ECONOMY* 35; Michael Kremer, *Creating Markets for New Vaccines — Part 2: Design Issues*, in 1 *INNOVATION POLICY AND THE ECONOMY* 73 (2001); Martha Ainsworth et al., *Accelerating an AIDS Vaccine for Developing Countries: Recommendations for the World Bank* (2000), available at <http://www.worldbank.org/aids-econ/vacc/index.htm> (last visited Oct 31, 2002).

7. One-hundred thousand children die each year in poor countries from treatable cancer. *See* REUTERS, *Children Dying Needlessly of Cancer, Experts Say* (Jan. 14, 2002), available at <http://www.huntsmanccancer.org/content/reuters/2002/01/14/20020114publ002.html> (last visited Oct. 11, 2002). I say this only to emphasize that global diseases are important in poor countries. An industry representative pointed out that none of the treatments needed for cancer are currently under patent protection. This may well be true, but the proposed framework does not concern current treatments. Indeed, it would not affect any products on the market at the time of implementation. It would set up a new structure for future products. Given that the industry reported 402 cancer medicines in the pipeline last year, at least a few new and useful products in this class should be arriving soon. *See* Press Release, PhRMA, *PhRMA Survey Finds 402 Medicines in the Pipeline for Cancer* (Mar. 29, 2001), available at <http://www.phrma.org/mediaroom/press/releases/29.03.2001.203.cfm> (last visited Oct. 20, 2002).

8. The included countries have major drug markets.

9. For further evidence, see Jean O. Lanjouw, *A Patent Proposal for Global Diseases*, in *THE ANNUAL WORLD BANK CONFERENCE ON DEVELOPMENT ECONOMICS* 189–219 (Boris Pleskovic & Nicholas Sterns eds., World Bank 2002).

Table 1: Income, Size, and Drug Expenditures Across Countries					
Country/ Group	Purchasing Power Parity (dollars) ^a	Population (millions) ^b	Population (percent of worldwide)	Country Drug Ex- penditure (percent of worldwide) ^c	Cardiovascular Drug Expendi- ture (percent of worldwide) ^d
Pakistan	1715	131.6	2.2	0.30	0.12
India	2077	979.7	16.7	1.13	0.47
Indonesia	2651	203.7	3.5	0.27	0.11
Egypt	3041	61.4	1.0	0.30	0.13
China	3105	1239.0	21.1	2.07	0.86
Philippines	3555	75.1	1.3	0.39	0.16
Total			45.8	4.0	1.85

Notes

- Purchasing power parity is GDP per capita in 1998 converted to U.S. dollars using a constant purchasing power parity index. Data are from World Bank, 2000.
- Population is for the year 1998. Data are from World Bank, 2000.
- Expenditure is for the year 1999. "Worldwide" refers to sales in 70 countries, which cover all major drug markets. Data are from IMS HEALTH Global Services and personal communications with Anne Calbazanna of IMS HEALTH.
- The estimated percent of all cardiovascular expenditure represented by a given country is its percent of total expenditure multiplied by the ratio of cardiovascular to total expenditure for Mexico, 0.41. Data of Mexico's cardiovascular expenditures are from IMS HEALTH Global Services and personal communications with Anne Calbazanna of IMS HEALTH.

The empirical evidence demonstrates that for therapies for global diseases, the profit derived from having a monopoly over sales in poor countries makes only a marginal contribution to the total worldwide profit of pharmaceutical firms and therefore only marginally increases their incentive to invest in research. At the same time, in a poor country even a small price increase due to such a monopoly can greatly reduce the number of people able to purchase patented drugs and the welfare of those who do. This is particularly so since drug purchases in developing countries are largely paid for directly by consumers, without the benefit of insurance.

In this Article, I propose a new global patent framework ("the Mechanism") that would allow protection to continue increasing worldwide in most areas of pharmaceutical innovation as envisioned in TRIPs. At the same time, it would effectively limit protection in situations where an increase in profits is less likely to generate new innovation. To do this, the policy requires that if a patented product is for a global disease, inventors must choose either protection in the

rich countries or in the poor countries but not in both. Because the profit potential offered by rich country markets is far greater, firms will naturally relinquish those in poor countries. Unlike any of the current alternatives under discussion, the framework outlined here would *automatically* adapt to the evolution of markets for different diseases and expand coverage as a country developed.

Economists and policy makers have been reluctant to differentiate protection across types of innovation despite the fact that there is a strong theoretical basis for doing so. Article 27 of the TRIPs Agreement, for example, explicitly requires non-discrimination.¹⁰ There are good reasons for this reluctance. The information needed to decide how best to differentiate is limited, and any differentiation must be based on features both easily identified and hard to change or resources will be wasted as everyone tries to fit into the better class.¹¹

Section II outlines the Mechanism, which provides a feasible way to present patentees with the desired choice between protection in either rich or poor country markets in the limited situations where their patents relate to products for specific global diseases. Section III discusses in detail the crucial elements of the Mechanism with a focus on U.S. laws and procedures. Although the Mechanism can be adopted unilaterally, Section IV considers the potential benefit of international coordination and the feasibility of comprehensive coverage. Section V outlines the relevant law in the United Kingdom, France, Germany, Japan, and Canada. Section VI briefly contrasts the Mechanism described here with other policy options. The final section concludes.

II. THE MECHANISM

We begin by considering the Mechanism as if implemented by the United States. Extensions to other countries are considered below.

A. The Declaration

To explain how the Mechanism would work, assume that there are two countries: the United States, a developed country, and India, a

10. TRIPs, *supra* note 3, art. 27.

11. "Orphan" drugs are an example. The U.S. Orphan Drug Act gives tax benefits and exclusive marketing privileges to applicants for new drug approvals related to products that would otherwise be uneconomic to discover and bring to market. *See* Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 409 (1983). It identifies qualifying products as those with expected patient populations of less than 200,000. *See id.* By defining diseases very narrowly, the industry has obtained orphan drug designations on many treatments for cancer, AIDS, asthma, and other diseases one would not expect to find under that heading. *See* Anticompetitive Abuse of the Orphan Drug Act: Invitation to High Prices, Hearing before the Senate Comm. on the Judiciary, 102d Cong. (Jan. 21, 1992) (testimony of James Love), *available at* <http://www.cptech.org/ip/health/orphan/orphan92.html> (last visited Oct. 24, 2002).

developing country. Further assume there are two diseases: “Cancer” representing global diseases and “Malaria” representing all others. Finally, there are three companies: PharmaUS, a multinational pharmaceutical firm, CiplaIndia, a developing country firm, and US-Generic, a generic drug manufacturer.

The basis of the Mechanism is the obligation in U.S. law that the inventor must apply *first* for a U.S. patent when an innovation is made in the United States. To make subsequent applications abroad, the inventor must obtain a “foreign filing license” from the U.S. Patent and Trademark Office (“PTO”). Specifically, U.S. law provides that “[e]xcept when authorized by a license obtained from the Commissioner of Patents a person shall not file or cause or authorize to be filed in any foreign country prior to six months after filing in the United States an application for patent or for the registration of a utility model, industrial design, or model in respect of an invention made in this country.”¹² This domestic filing requirement is in place for the purpose of national security. Failure to obtain the license before a foreign filing renders the U.S. patent invalid.¹³

The proposed Mechanism requires that when a patentee petitions for a foreign filing license, he must make a Declaration to the U.S. PTO similar to the following:

I, the undersigned, request a license to make foreign patent filings covering the invention described in U.S. patent application No. X, with the understanding that this permission will not be used to restrict the sale or manufacture of drugs for Cancer in India by suing for patent infringement in India.

B. Basic Outline of Why It Works

Consider the simplest situation. PharmaUS has a Cancer product protected by identical patents in the U.S. and in India. The company obtains marketing approval in both countries and sells the product. Now CiplaIndia or USGeneric enters the Indian market with its own version of the same product. PharmaUS can choose one of three strategies. First, it may continue to sell the product. Making this choice, it would need to lower its price to remain competitive with the new entrants. PharmaUS would then obtain no benefit from its Indian patent. This is a strategy that multinationals have followed for decades in countries not offering protection.

Second, PharmaUS may choose to withdraw from the Indian market altogether. It might be uncomfortable selling at prices low

12. 35 U.S.C. § 184 (2000).

13. *Id.* § 185 (2000).

enough to be competitive in India — perhaps because of international price comparisons. This is also a strategy that multinationals have followed for decades. With this choice, PharmaUS would continue to exercise its rights in the U.S. market, and the Indian market would be served either by generic drug manufacturers or developing country firms. The latter have shown themselves to be adept at rapid imitation. Over the past two decades, for example, copies of major patented drugs typically arrived on the Indian market within seven years of their world launch — often much earlier — and the speed may be increasing.¹⁴ For ten drugs launched in the United States after 1985, there was an average time lag to availability in India of just two years.¹⁵

PharmaUS could, however, make a third choice. The company may sue CiplaIndia for infringement because it has a valid patent in India. Nothing prevents the company from choosing to protect its rights in India based on its patent there in exactly the same way that it would without the Mechanism. But what happens then? At this point, either CiplaIndia or, more likely, USGeneric, can enter the U.S. market. If sued for infringement in the United States by PharmaUS, the firm can defend itself on the basis that PharmaUS rendered its U.S. patent unenforceable. This is so because, by filing the infringement suit in India, PharmaUS falsified the Declaration it made to the U.S. PTO to obtain the foreign filing license. Patentees have a duty to deal with the patent office in good faith and failure in this regard is grounds for rendering a patent unenforceable.¹⁶

Suppose now that the innovation had been for a Malaria product. Again PharmaUS could choose either to compete or to exit the market upon entry by CiplaIndia. Again its third option is to sue for infringement. Now, however, the suit would not render the U.S. patent unenforceable. The Declaration made by PharmaUS to obtain its foreign filing license says nothing about Malaria.

So what is our result? In the case of a patent for a Cancer product, PharmaUS's two choices are effectively between protecting its profits in the United States or in India, but not both, just as desired. The key point is that the firm will not sue *in India* for infringements of Cancer product patents because it will not want to jeopardize its U.S. patents. Knowing this, CiplaIndia will enter the market and prices in India will

14. For a discussion of other costs and benefits in this particular context, see Lanjouw, *supra* note 6; see also Jayashree Watal, *Pharmaceutical Patents, Prices and Welfare Losses: Policy Options for India Under the WTO TRIPS Agreement*, 23 *WORLD ECON.* 733 (2002).

15. See *id.* The Indian experience over the past two decades also suggests that patent-owning firms will not contract with potential entrants to prevent entry as an alternative to exercising their patent rights. See Lanjouw, *supra* note 6.

16. See *Molins PLC v. Textron*, 48 F.3d 1172, 1178 (Fed. Cir. 1995) (“Applicants for patents are required to prosecute patent applications in the PTO with candor, good faith, and honesty.”).

fall. In the case of a patent for a Malaria product, PharmaUS will prosecute infringements in India and therefore has effective protection in both the United States and India. Thus, incentives for investment in Malaria products are maintained.

Note that the Mechanism is triggered by a lawsuit filed in India by the patent holder. One important reason for this feature is that when an infringement suit is filed to prevent the sale of a *product*, it is on the basis of a set of *patents*. In order to be successful in prosecuting his suit, the patent owning firm has an incentive to correctly announce which patents it believes best protect the product in question. This resolves the otherwise intractable problem of how to identify the use of innovations described in particular patents.¹⁷

C. More Complex Settings

In reality, patenting is considerably more complex than the simple situation just described with a single patent protecting a product. In most cases a number of patents will contribute to protecting a given product. Clearly the most obvious way to try and go around the Mechanism is to try and write patents in such a way that separate sets of patents are each effective in protecting the same basic innovation. Succeeding in this, in our example, PharmaUS could sue on the basis of one set in India and use the remaining patents to protect its market in the United States.

I will explain in a moment why it is very unlikely that PharmaUS would circumvent the Mechanism in this way. But first let me emphasize that, if PharmaUS were to do so, it would simply mean that, for the product in question, the Mechanism would have no effect. No damage would be done. If every once in a while the particular constellation of patents on a product made avoidance feasible, the Mechanism would be 99% effective rather than 100%.

Direct “double patenting” of inventions is forbidden. Applications may be rejected for “statutory” double patenting on the basis of Section 101, which states in the singular that an inventor “may obtain a patent” for an invention.¹⁸ The doctrine of “non-statutory” double patenting prohibits “claims in a second patent not patentably distinguish[able] from claims in a first patent.”¹⁹ However, protection that reinforces basic compound patents covering a product is frequently obtained through patents on new formulations and patents on new uses of the product. Firms can strategically time their submission of

17. For example, new uses for a molecule may be discovered years after the patent on the molecule has been granted.

18. 35 U.S.C. § 101 (2000) (emphasis added).

19. U.S. PTO, U.S. DEP'T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 804 (1999).

applications for formulation and use patents to retain at least partial control of a patented product beyond the expiration of the initial compound patents — a procedure labeled “evergreening” by its critics.

Suppose that the Cancer product is covered by a basic compound patent and also formulation or use patents, and there is some possibility that PharmaUS might sue in India on the basis of one or the other of them. In this case, CiplaIndia or USGeneric would probably choose to purchase some of PharmaUS’s Cancer product in the United States and initially infringe the Indian patent owned by PharmaUS by importing the product into India. This would force PharmaUS to reveal its intentions,²⁰ while being almost costless to the infringing firm.²¹ If PharmaUS chose not to respond to the infringement, CiplaIndia or USGeneric could safely begin production in reliance on this choice.

Consider the various ways in which PharmaUS might respond to the infringing imports. It could defend its rights in India on the basis of one of the following:

The compound patent. This would be effective in India but would leave the firm vulnerable in the United States. A competitor could enter the U.S. market upon finding any new formulation or use for the product. Patent counsel at PharmaUS would be in a very uncomfortable position if this were to occur. Such a response is therefore highly unlikely.

Formulation patents. This would not protect PharmaUS against sales of the original compound in India. Other firms would also be able to sell any new formulations using the compound that they could devise. At the same time, by giving up its formulation patents in the United States, PharmaUS would forgo the opportunity to extend its protection beyond the life of the compound patent.

Use patents. There are two issues that would arise if use patents were made the basis of protection in India. First, it is not obvious that the courts in developing countries will enforce use patents. They are not explicitly required by TRIPs and the patentability of new uses has been controversial. As yet there is little case law on this point. Second, use patents are not infringed by CiplaIndia when the firm imports the product. Rather, infringing acts are performed by individual doctors who prescribe, or patients who ingest, the product for indications covered by the patents. It would be a public relations disaster for a firm to sue its customers. Therefore, for a defense on the basis of use patents to be feasible, PharmaUS must be able to establish, in an In-

20. See *infra* § III.C.4 (discussing equitable estoppel).

21. While the smallest Indian firms might be intimidated into inaction by cease and desist letters from PharmaUS, the process described would be well within the capabilities of many developing country manufacturers and certainly within those of developed country generic drug producers.

dian court, a cause of action on the basis of indirect infringement.²² These two considerations together suggest that it is quite likely that PharmaUS would fail to win such a suit in India. It would also be a prolonged and complex case. In addition, PharmaUS would lose its ability to enforce its U.S. use patents.

None of these options looks very appealing so one would not expect them to be used to dilute the effect of the Mechanism very frequently. Again, if they were used upon occasion, the only effect would be to keep the status quo in those instances.

Finally, consider a last form of patent, those on research tools. These are innovations used in the process of doing research, such as a method for inserting genetic material into cells. Because there is no product associated with the use of these innovations, the patents on research tools would not fall directly within the scope of the Mechanism. Protection would be available in both rich and poor country markets. However, the licensing fees that tool owners can charge depend, at least indirectly, on the size of the profits that those who use the tools can obtain on resulting products.²³ Where patented research tools are important, the outcomes described above simply move back a step to those investing in the creation of new tools.

III. CRUCIAL ELEMENTS OF THE MECHANISM

This Section explores the two key legal elements of the Mechanism: (1) a foreign filing license obligation, and (2) invalidity or unenforceability as the remedy for either failing to obtain a license or falsifying the Declaration made therein. It discusses issues associated with each and the importance of specific features. Again particular attention is given to U.S. laws and procedures. Understanding these elements is important when considering how the Mechanism could be extended to other legal settings in Section IV.

Careful attention to details such as those discussed here can make it difficult for an inventor to evade the Mechanism. However, as with multiple patenting, there will remain ways in which an inventor can try to do so. What is important to note is that, here again, failure in such an attempt will often jeopardize his intellectual property or restrict his ability to market products in his most valuable markets. Thus, even if he were to have a reasonable chance of success, with little to gain from the poor country markets and much at stake, it is

22. In the United States, for example, this would be facilitating infringement by another through specific acts of contributory infringement or acts of inducement of infringement. *See, e.g., Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844, 860 (1982).

23. With "reach-through" royalty contracts that give the tool owner a percentage of final product sales, this relationship is direct.

unlikely that an attempt to circumvent the Mechanism will look attractive.

A. Foreign Filing License Obligation

1. Discrimination

TRIPs requires that “patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.”²⁴ Any policy that directly differentiates legal treatment across diseases is in certain conflict with TRIPs. The Declaration required for a foreign filing license avoids this conflict because it is required of all those patentees wishing to file abroad. If you have an innovation for a drug, you must sign the Declaration; if you have an innovation for a toaster oven you must sign the Declaration. Thus, the Mechanism is, *de jure*, non-discriminatory.

That said, the Mechanism certainly implies *de facto* discrimination, since that is the intention. There are two reasons for thinking that this will not pose a problem. First, it is not clear whether the discriminatory effect of the Mechanism would be interpreted as “discrimination” under TRIPs. A recent World Trade Organization (“WTO”) dispute panel decision concerns *de facto* discrimination in patent laws as to the field of technology under Article 27.1 of the TRIPs Agreement.²⁵ There, it is emphasized that the interpretation of discrimination had not yet been resolved:

The Panel recalled that various claims of discrimination, *de jure* and *de facto*, have been the subject of legal rulings under GATT or the WTO As the Appellate Body has repeatedly made clear, each of these rulings has necessarily been based on the precise legal text in issue, so that it is not possible to treat them as applications of a general concept of discrimination.²⁶

Further, that panel did not rule on the issue: “On the record before the Panel, there was no occasion to consider the question raised by certain third parties — whether measures that are limited to a particular area

24. TRIPs, *supra* note 3, art. 27.1.

25. WTO Secretariat, *Canada-Patent Protection of Pharmaceutical Products*, WT/DS114/R at ¶¶ 4.16–4.18 (Mar. 17, 2000), at http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf (last visited Oct. 20, 2002).

26. *Id.* at ¶ 7.98.

of technology — *de jure* or *de facto* — are necessarily ‘discriminatory’ by virtue of that fact alone”²⁷

The WTO Doha Ministerial Conference issued a “Declaration on the TRIPS Agreement and Public Health” in November 2002.²⁸ In this, the Ministers clearly discriminate between pharmaceuticals and other areas of innovation. For example, the time period under which the least developed countries must complete their implementation of TRIPS requirements is extended to January 1, 2016, but only with respect to pharmaceutical product patents.

More importantly, perhaps, it is not obvious who would have an interest in bringing a dispute over the Mechanism to the WTO. Disputes must be brought by national governments. Implementing countries would not raise the issue against themselves; beneficiary countries would have no reason to do so, nor would the countries not involved. Outside of the pharmaceutical industry, other industry groups would have no incentive to lobby against the Mechanism because their behavior would not be constrained by the Mechanism. Further, because they have an interest in strong intellectual property protection, they would actually benefit from the Mechanism if it dampened the negative publicity concerning patents caused by the current policy debate over TRIPS. Even the pharmaceutical industry would be better off without too close a look being taken at *de facto* discrimination. There is now considerable evidence that pharmaceutical inventors obtain substantially more benefit from the patent system than do inventors in other areas.²⁹

2. Justification

Imposing a foreign filing license obligation on inventors requires a justification. Where licensing rules are currently in force, they were established to enhance national security. The basis of the license requirement could remain national security if security is construed broadly enough to encompass global health concerns.³⁰ Otherwise, a

27. *Id.* at ¶ 7.105, n. 439.

28. WTO Ministerial Conference, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 14, 2001), available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf (last visited Oct. 6, 2002).

29. See Wesley M. Cohen et al., Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not) (Nat’l Bureau of Econ. Research, Working Paper No. 7552, 2000), available at <http://papers.nber.org/papers/w7552.v5.pdf> (last visited Oct. 20, 2002). For an example of the many surveys indicating the importance of patents in the pharmaceutical industry based on patent application and renewal patterns, see Jean O. Lanjouw et al., *How to Count Patents and Value Intellectual Property: Uses of Patent Renewal and Application Data*, 46 J. INDUS. ECON. 405 (1998).

30. This has been suggested by the title of the INSTITUTE OF MEDICINE, AMERICA’S VITAL INTEREST IN GLOBAL HEALTH: PROTECTING OUR PEOPLE, ENHANCING OUR ECONOMY, AND ADVANCING OUR INTERNATIONAL INTERESTS (1997), available at <http://www.nap.edu/readingroom/books/avi> (last visited Oct. 24, 2002). This link has been

more general national interest as opposed to a security justification would be needed.

3. Takings

The proposed Mechanism raises a potential legal takings issue, however, not as it typically arises in association with the foreign filing license. In the normal situation, a potential taking occurs when a foreign filing license is denied and the patent is put under a secrecy order. Then, the patent holder can sue the government department or agency that requested the secrecy order to recover damages.³¹ But a foreign filing license is *never* denied as a result of the Mechanism.

Would implementation of the Mechanism itself be a taking by virtue of having limited a patentee's ability to benefit from patent protection abroad? Property is defined by government and can be changed to further societal goals. Virtually all laws and regulations burden someone's private property in some manner. Thus, what will be considered a "takings" from a legal perspective is a matter of degree. The Supreme Court has identified three factors to guide a determination: (1) "the economic impact of the regulation on the claimant"; (2) "the extent to which the regulation has interfered with distinct investment-backed expectations"; and (3) "the character of the government action."³² What is important here is that the takings in question are *prospective* — the property rights in question do not yet exist. Therefore, their loss entails no specific economic impact, and implementation of the Mechanism does not affect investor expectations. It is known that certain rights will be (*de facto*) circumscribed when investments in R&D are made. Other changes in patent policy, such as the extension of the statutory term of utility patents to twenty years from the date of application³³ or the change to eighteen months for the time of publication of patent applications,³⁴ are analogous.

4. Declaration

Current U.S. law provides that "[f]iling an application for a patent for inventions made in the United States will be considered to include a petition for [a foreign filing] license"³⁵ Implementing the Mechanism would require enabling legislation to allow the U.S. PTO

made often in relation to the AIDS pandemic. See Sheryl Gay Stolberg, AIDS Fund Falls Short of Goal And U.S. Is Given Some Blame, N.Y. TIMES, Feb. 13, 2002 at A12 ("If the [AIDS] epidemic is not turned around, [U.S. Senator Biden] said, 'We will have much more than a health problem, we will have a security problem'").

31. 35 U.S.C. § 183 (2002).

32. Penn Central Transp. Co. v. City of New York, 438 U.S. 104, 124 (1978).

33. See 35 U.S.C. § 154(a)(2) (2001).

34. See 37 C.F.R. § 1.211 (2001).

to require the Declaration as part of obtaining this license. The Declaration could be added to those already made by all patent applicants with respect to inventorship, disclosure, and so forth.³⁶

5. Requires No Additional Security Assessment

The Mechanism requires a system in which all applicants filing abroad must first request a foreign filing license. However, no foreign filing license requests are ever denied for reasons due to the Mechanism. If a country had a foreign filing license requirement initially for other reasons, after implementation of the Mechanism, permission would be granted or denied on the same grounds as before. For countries not already having a foreign filing license requirement, after implementation of the Mechanism, approval of foreign filing license requests could be automatic and simply assumed by a patent applicant signing the Declaration. There would be no additional administrative burden.

6. Coverage

U.S. law states that the foreign filing license obligation applies “in respect of an invention *made* in [the United States].”³⁷ Thus, the requirement for a license applies to all types of inventions even though secrecy orders will only be placed on inventions related to national security. Coverage of all technology areas, not just those related to security, is crucial for the Mechanism to be effective.³⁸

The scope of the U.S. requirement is also explicitly defined with reference to the geographical location of where the invention was made. In other countries, coverage may be determined by the residence, domicile, or nationality of an inventor or corporate body. National differences in foreign filing license obligations would require consideration when trying to build global coverage through international coordination.

When a patent will be granted or assigned to a firm with research locations in multiple countries and with employees of many nationalities, an important part of ensuring the effectiveness of the Mechanism is the identification of all true inventors. If firms are allowed to choose inventors, they could simply say that all inventions were made

35. *Id.* § 5.12 (2001).

36. *See infra* § III.B.3.

37. 35 U.S.C. § 184 (2002). The term “made” has been interpreted as “conceived” and not necessarily “reduced to practice.” *See* *Burroughs Wellcome Co. v. Barr Lab., Inc.*, 40 F.3d 1223, 1227–28 (Fed. Cir. 1994).

38. At any point in time, inventors in all technology areas would sign the same Declaration relating *only to* diseases. Thus, inventors in most technology areas would simply be unaffected by having made the Declaration.

by employees not under an obligation to make a foreign filing license declaration. The correct identification of inventors is, however, an important part of patent law, as it establishes ownership rights to the intellectual property represented by the patent. In the United States, the Code of Federal Regulations states, “Joint inventors must apply for a patent jointly . . . ; neither of them alone, *nor less than the entire number*, can apply for an innovation invented by them jointly, except as provided in Section 1.47.”³⁹ As part of the patent application, each inventor must make an oath or declaration to the effect that he and all other listed inventors are, in fact, the original inventors.⁴⁰ The declaration also states the applicants’ awareness that “willful false statements may jeopardize the validity of the application and any patent issued thereon.”⁴¹

Note that, if a foreign filing license obligation that includes a declaration falls on any one of a set of joint inventors, the invention is effectively covered by the Mechanism.

7. Foreign Filing License Prior to Domestic Filing

A license is required for foreign patent filings regarding U.S. inventions even if no application has been filed for a U.S. patent. The inventor requests the license from the Commissioner of Patents and Trademarks, and the petition must include a description of the invention.⁴² In this case, the Declaration would refer to “the material for which the license is being sought” rather than “the invention described in U.S. patent application no. X.” Inventors of global disease products of any importance will surely wish to patent in the United States so this should rarely arise.

8. Time Limits and Patent Cooperation Treaty Applications

The obligation to obtain an explicit license to file abroad is typically time-limited. Currently, Section 184 indicates that a foreign filing license can be assumed to have been given after a *six-month* period following the application for a U.S. patent.⁴³ This limits the delay that the security section of the U.S. PTO can impose on applicants. Thus, under current rules, a patentee can easily circumvent the need to request a license by delaying his foreign applications for six months

39. 37 C.F.R. § 1.45 (2001) (emphasis added). Section 1.47 requires the absence of an inventor to be explained. *Id.* § 1.47.

40. *See id.* § 1.63.

41. U.S. Patent and Trademark Office, U.S. Department of Commerce, Declaration for Utility or Design Patent Application (2001), available at <http://www.uspto.gov/web/forms/sb0001.pdf> (last visited Nov. 1, 2002).

42. *See* 37 C.F.R. § 5.13 (2000).

43. 35 U.S.C. § 184 (2000).

after the initial U.S. filing. He can do this because national entry in Patent Cooperation Treaty (“PCT”) countries can be postponed without loss of priority for twelve months, and use of an international PCT application extends this period to thirty months — sometimes even longer.⁴⁴ The only cost of deferring is some restriction on the inventor’s ability to obtain injunctions and damages during that period. Effective implementation of the Mechanism would require that the six-month limit on the foreign filing license obligation indicated in Section 184 be extended beyond thirty months or removed altogether. Protection against PTO delay could be retained with a statement that applicants can assume approval of the license if not told otherwise within the six-month period following its request.

9. Procedure to Determine Content of the Declaration

In Section II we assumed that there is a single poor country, India, and a single disease with a predominantly rich country market, Cancer. The Declaration would, in fact, specify lists of countries and lists of diseases. A straightforward, transparent, and objective procedure is needed to determine these lists. The patent office would update the Declaration periodically — say every two years — following the stated procedure. The patent office would not need to make any judgments of its own about the content of the Declaration.

Before discussing how to specify these sets, it is important to emphasize why we would not want to simply apply the Mechanism to *all* diseases. If we were to do so, the design of the Mechanism would ensure that firms’ own choices would automatically keep incentives roughly in order. For products where potential profits were greater in the United States, patent holders would refrain from enforcing Indian patents. For products more valuable in India, they would choose to prosecute infringements there and give up the U.S. market. Thus, responding on the basis of their knowledge of global market opportunities, firms’ behavior would reflect the relative demand for new products, as one would want. The problem is that, when a product has a market that is fairly evenly spread across the two countries, allowing the inventor protection in just one country or the other would have a substantial effect on his profits. Thus, to maintain research incentives, the Mechanism should be limited to diseases with markets that are

44. “[T]he filing of an international application in a country other than the United States on the invention made in this country shall be considered to constitute the filing of an application in a foreign country” *Id.* § 368 (2000). However, an inventor may file a PCT application without a license if the U.S. PTO acts as the receiving office. *See id.* § 361 (2000).

concentrated in the rich countries. A procedure is needed to determine which diseases these are.⁴⁵

Starting with a group of poor countries, the goal is to identify those diseases where the potential profit coming from sales in that group of countries is less than, say, 2% of global profits. The one requirement is that a sufficient number of countries be included in the poorest set of countries to cover the fixed costs of launching imitative products. This is not a particularly stringent condition given that the largest fixed cost in this industry, the expense of discovery R&D and large-scale clinical trials, is not borne by imitating entrants. For example, the vibrant and competitive pharmaceutical industry in India developed entirely under such conditions.⁴⁶ A practical approach would be to set up a procedure with two steps. First, identify increasingly broad groups of poor countries. Second, identify appropriate diseases for each group of countries. An example would be the following:

Step 1: Ask countries with GDP less than \$3,000 per capita whether they object to being included in the Declaration.⁴⁷ Place remaining countries with GDP per capita less than \$500 in group A; those with GDP per capita less than \$1,500 in group B; and those with GDP per capita less than \$3,000 in group C. The GDP figures to be used are the United Nations annual statistics. Note that the countries in group A are also in groups B and C, and the countries in group B are also in group C.

Step 2: Using data on pharmaceutical sales by disease class, calculate total world sales by disease class. Then, calculate total sales for each of the country groups A, B, and C by disease class. Include on disease list A all classes where the sales for country group A are less than 2% of world sales. Include on disease list B all classes where the

45. The fact that firms choose the better market, rich or poor, when a disease is included in the Mechanism makes it self-correcting against large mistakes. Suppose, for example, that there is a rare form of cancer only found in Africa. If this type of cancer were not separately classified, then products treating it would be included along with all other cancer products under the Mechanism. However, for products treating this form of cancer, patentees would choose to protect their patents in Africa and any available profits would be realized.

46. See Lanjouw, *supra* note 6. Another factor to consider is the ability of patentees to prevent patent infringing imports into the different countries. If India was included, for example, and Brazil was not, can we expect Brazilian patent owners to be successful in preventing imports from India? If barriers are likely to be weak, it would point in the direction of including a larger set of countries and correspondingly fewer diseases.

47. Domestic pharmaceutical firms in poor countries may wish to engage in cooperative ventures with multinational companies. If the latter makes the availability of domestic patent rights a prerequisite to such interaction, and if a poor country's government views its industry's concerns as more pressing than its consumers' interests, it might prefer not to be on the list. Inclusion in the Declaration should not be forced upon any country.

sales for country group B are less than 2%, and similarly for disease list C.

For the poorest of poor countries of group A, probably all disease classes would qualify, and, effectively, no protection would be afforded pharmaceuticals in those countries. Moving to B, the group gets larger and also somewhat richer. Some disease classes may no longer qualify, and patent protection would be available on those. For the largest group C, even fewer diseases would qualify, and the scope of protection would widen further. Once a country attained a GDP per capita greater than \$3,000, protection would be available for all products.

This example illustrates *only* how the procedure could be structured. Other GDP cutoffs and more country groups could be chosen. Similarly, a number other than 2% might be appropriate. Increasing its value would allow the Mechanism to encompass a larger number of diseases and confer greater price benefits on the poor, but doing so would more significantly dampen research incentives. Structured in this way, the procedure combines certainty with flexibility. The effective patent rights available to a firm with respect to a particular innovation are determined by the content of the Declaration when it is signed at the time of patent application. The patent rights remain the same throughout the life of the patent, and the firm can make its marketing decisions accordingly.⁴⁸ At the same time, the content of the Declaration evolves to reflect changes in pharmaceutical markets and the development of countries. A country starting out in group B, for instance, would move to group C as it grew richer and eventually would not be included in the Declaration at all.

10. Data Issues

Ideally, one would like information on profits, as it is profits rather than gross sales that represent the incentive to invest in research. However, there is no consistent and comprehensive source of profit figures, while sales data are available for disaggregated therapy classes and across seventy countries from IMS HEALTH Global Services ("IMS"), a private database vender. The countries in this database encompass 94.4% of 1998 world GDP measured in purchasing

48. One could have the Declaration refer to lists maintained by the PTO, rather than specifically-named countries and diseases. The content of the lists could then change over the life of a patent. However, the lists are unlikely to change very rapidly so the benefits of such a list would be small. At the same time, this approach would introduce an uncertainty as to the contents of the list that is costly to both the patent-owning firm and those considering an infringing entry.

power parity terms.⁴⁹ The value of sales across countries for a particular type of disease gives a reasonable picture of the importance of different markets.

Incidence of disease is another obvious contender for determining the size of potential drug markets. But because countries differ to a surprising extent in their use of drug therapies relative to other medical treatments, cross-country statistics on disease incidence give a very imprecise indication of the relative size of potential drug markets. There are two other problems with disease incidence and mortality figures. First, they can be strongly affected by current drug consumption. Thus, the larger the pharmaceuticals market, the lower may be the incidence and mortality. HIV/AIDS provides a good example. Second, like profits, these data do not exist in anything like the comprehensive and consistent form necessary.

That said, gross sales figures differ from what we would like in that they reflect a combination of costs and a profit margin. Since the price-cost margins are typically much higher in richer countries, looking at gross sale values will understate the importance of rich country markets as a source of profit. This is particularly true when profit is a small component of total sales, as it would be for drugs no longer under patent protection. In all countries, many sales in any given disease category are of drugs whose patents have expired, and these drug products are not easily distinguished in the data from those still protected by patents.⁵⁰ Being sold under competitive conditions, sales figures relating to generic products cannot reflect the potential monopoly profits available in different markets. As a result, we would conservatively allow too few diseases to qualify for any specified group of poor countries. An alternative would be to use sales data adjusted by an estimate of the relative price-cost margins in rich and poor countries.

A related issue arises for those products still under patent protection in the West. We want to know the relative profit that could be obtained from the sales of drugs in rich and poor countries, assuming that the seller has a monopoly in each country. But many poor countries are only now beginning to offer patent protection and have had very competitive pharmaceutical markets. As a result, for products still under patent, sales figures in the rich countries include a monopoly profit margin, while those in the poor countries often do not. The lack of mark-up would tend to make the poor country markets look

49. If possible, veterinary uses of pharmaceuticals should be included in the determination of the potential size of country markets (e.g., products for parasitic and worm diseases). Whether the marketing data on veterinary sales and U.S. Food and Drug Administration treatment of such products would allow them to be incorporated in a simple way is something to be determined.

50. Recall that this is precisely the reason that we are using infringement actions to make the link between products and patents.

less important than they would if the owner had a patent everywhere. However, the opposite may also be true. Competitive prices mean more output is sold so that gross sales can actually be larger under competition than with a monopoly despite the lack of mark-up.

Note that if prices in a country are relatively low due to price controls rather than competition, it is not a concern for us. Price controls are not restricted by any treaty agreements, and many rich countries have both strong patent systems and extensive regulation of pharmaceutical prices. The same will be true in many of the developing countries that are now implementing new patent systems. Any assessment of the profits that a patentee could potentially obtain in each country, whether rich or poor, should take its price control regime into account. The fact that sales data reflect the operation of price controls is thus an advantage rather than a drawback.⁵¹

B. Enforcement

1. Form of Punishment

Punishment for failure to obtain the license or for falsifying the Declaration should be invalidity or unenforceability of the domestic patent. Existing U.S. law already provides these remedies. First, the failure to obtain a license prior to filing abroad prevents issuance of a U.S. patent or invalidates an issued U.S. patent.⁵² Second, falsifying a license declaration results in unenforceability of the U.S. patent. In the United States “[e]ach individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office,”⁵³ and rendering a patent unenforceable is the standard remedy for false statements. This remedy has been put into effect, for example, in cases where a patentee knowingly misrepresented prior art to the patent office.⁵⁴ If it is not sufficiently clear that the same remedy would apply for falsifying the foreign filing license declaration, then the implementing legislation should make this remedy explicit.

51. The move to a regime where patent owners have the right to prevent sales of a product in a country gives them a stronger bargaining position in negotiations with price regulators. Thus, price controls may not constrain the future profits of patentees to the extent reflected in current sales data. If important, the relative profit to be gained from patent protection in poor countries would be greater than suggested by these data. One might worry that the Mechanism might push a developing country government to implement stricter price controls in order to get more diseases to qualify. This would be limited by the strength of its own domestic producer interests and the fact that tighter price controls in a single country would have only a marginal effect on overall sales for the group of poor countries.

52. 35 U.S.C. § 185 (2000).

53. 37 C.F.R. § 1.56 (2000).

54. MARTIN J. ADELMAN ET AL., CASES AND MATERIALS ON PATENT LAW § 12.3 (1998).

This form of punishment is important both to ensure that the Mechanism affects the right products, and to make the threat credible and therefore effective in altering behavior. It is only when the domestic patent is threatened that those owning patents on global disease products must choose to protect either the rich or the poor country markets. With any other remedy they can retain protection in both markets. Forcing them to confront this choice best reaches the objective of dissuading patentees from bringing suits in poor countries when the market for a product is small there and large elsewhere. When the loss of protection in a rich country market is the remedy for bringing a suit, the force of the dissuasion grows as the rich country market size grows. With fines or imprisonment, the remedy for falsifying the Declaration stays the same size irrespective of the importance of the rich country market. We lose some of the sensitivity of the Mechanism to differences in relative market sizes for products within the broad categories defined on the Declaration.

A second reason why loss of protection in the domestic country is the preferred remedy is that, regardless of form, no remedy will be required of a badly behaving patentee unless an interested party is prepared to present a case to the patent office or court. A fine only harms the patentee and does not directly benefit competing firms or consumers. With invalidity or unenforceability, other firms and consumers stand to gain and thus have an interest in activating the process. Further, these interested parties will often be domestic constituents with experience navigating the domestic political and legal landscape. Returning to our earlier example, USGeneric would have both the desire and the experience to pursue a case to render unenforceable a PharmaUS patent on a global disease product.⁵⁵ The alternative would be to rely on CiplaIndia to persuade a U.S. court to jail an executive of PharmaUS or levy a fine — at no gain to the Indian firm. It seems clear that the prospect of the first scenario would be far more worrisome to PharmaUS and therefore more likely to encourage desirable behavior.

55. USGeneric might only be a third party to the suit in India. However, it could obtain standing in the United States to seek a declaratory judgment against PharmaUS by importing CiplaIndia's product into the United States.

2. When Filing License Precedes Domestic Filing

In Section III.B, it was noted that a request to file abroad could be made in the absence of a domestic filing. In this case, the Declaration would refer to “the material for which the license is being sought.” For the reasons just given, the remedy for falsifying the Declaration is also to render unenforceable any ensuing U.S. patents on the material covered in the license.

3. Procedures to Identify When the Declaration Has Been Falsified

Two steps are needed to determine whether a particular filing implies that the patentee has falsified a foreign filing license declaration. To return to our example, suppose CiplaIndia or USGeneric introduces a drug in India, and PharmaUS brings an infringement suit there.

First, there must be a clear procedure for determining whether the Indian product treats a particular disease. CiplaIndia or USGeneric will always have an incentive to claim that the product is for Cancer in order to render the U.S. patent of PharmaUS unenforceable. On the other side, PharmaUS will claim the product is for Malaria.

To resolve disputes of this nature, I suggest the following: to render a U.S. patent unenforceable, a challenger must take the accused product and apply to the U.S. Food and Drug Administration (“FDA”) for an abbreviated new drug approval (“ANDA”). Pharmaceutical products are granted approval by the FDA for marketing against specific indications.⁵⁶ Because firms are constrained in their ability to promote products for uses that are not approved, they have an interest in obtaining approval for any indications that are likely to have significant markets.⁵⁷ This procedure is already followed for any generic

56. Until October 2000, products were assigned by the FDA to one or more detailed therapeutic classes. See The National Drug Code Directory, at <http://www.fda.gov/cder/ndc> (last modified Oct. 3, 2002). This coding has been stopped for budgetary reasons but may resume in the future and would clearly be most useful for our purpose. Telephone interview with Robert Reinwald, Information Management Team, FDA (Dec. 2001). Diseases listed on the Declaration could correspond to the classification used by the FDA. Other countries' health authorities also code products. For example, an applicant for marketing approval in the United Kingdom must indicate the Anatomical Therapeutic Class (“ATC”) code assigned to the product. See Licence Application Forms: Marketing Authorisation Application Form Instructions, available at <http://www.mca.gov.uk/inforesources/infolicapps/licapp/forms/mktauthform.htm> (last modified Feb. 4, 2001). Thus, there may be scope for making use of their systems as an additional method of identification. If so, the relationship between the ATC classification also used by IMS HEALTH Global Services to code products and the FDA system of defining indications would need to be understood.

57. A firm having a product useful for Cancer and Malaria could decide not to obtain approval for the Cancer indication in the U.S. just to keep the product from falling under the Mechanism. There are examples of products used without FDA approval. *The Economist* reports that Botox has been used for a decade to remove wrinkles without having FDA approval. See *Smooth face, big Botox*, THE ECONOMIST, Feb. 16, 2002, at 60. However,

drug on the expiration of a patent, so generic drug producers are well versed in the administrative procedure. In this case, to render unenforceable PharmaUS's U.S. patent, USGeneric must take the Indian product and apply to the FDA for an ANDA. It will claim that the Indian product is equivalent to a product already marketed in the U.S. with a Cancer indication. If the FDA bioequivalence review is favorable, the case that the Indian product is for Cancer is made, and the U.S. patent is rendered unenforceable.

At this point, USGeneric or CiplaIndia can, and will, request final marketing approval from the FDA, since obtaining access to the U.S. market was the reason for causing PharmaUS's patent to be rendered unenforceable. The bioequivalence report is a major component of that approval. Thus, there is no net increase in resources expended by either the companies or the government as a result of using the ANDA process for our purpose. It also means that the FDA has a serious interest in the quality of the bioequivalence report as it has direct implications for the integrity of the U.S. system of safety regulation.⁵⁸

The second step is to link the Indian patents supporting PharmaUS's infringement claims to their U.S. counterparts. Fortunately, this is a standard output of international patent procedures. Having first filed in the United States, a subsequent Indian application typically refers back to the U.S. application to establish the owner's global priority over the innovation and the time limit for related foreign filings. The global links between patents covering the same innovation that are exposed by this process are publicly available at national patent offices or online.⁵⁹ If the applicant happens to choose not to make use of his U.S. priority, however, the equivalence of particular U.S. patents would need to be shown.

pharmaceutical firms advertise heavily, and it is highly unlikely that a firm would choose to limit itself in this way just to preserve patent protection in a set of poor countries. In the same article, *The Economist* notes that "[a]pproval [of Botox], likely next month, will enable Botox's maker . . . to advertise its cosmetic benefits direct to doctors and consumers in America, and could turn Botox into a billion-dollar lifestyle drug to rival Viagra and Prilosec." *Id.*

58. The current rules concerning ANDA applications may require a minor alteration to allow the procedure described. For our purpose, a firm must be allowed to file an ANDA and the FDA allowed to issue a statement of bioequivalence while a patent protecting the product is still valid and in force. The FDA must also be allowed to grant final approval when the patent is either unenforceable or invalid.

59. The U.S. PTO provides information on prior foreign applications for U.S. patents at its website. See Patent Full-Text and Full-Image Databases, at <http://www.uspto.gov/patft/index.html> (last modified Oct. 31, 2002). The private company Derwent Information has compiled global filing information for patents in their proprietary database Derwent World Patent Index ("WPI"). See <http://www.derwent.com> (last visited Nov. 1, 2002).

4. Equitable Estoppel

The Mechanism has just one legal requirement of the poor countries. Their law must recognize the doctrine of equitable estoppel. If a patentee knows or has to reason to know of potentially infringing acts and the patentee does not object, then the patentee is estopped from asserting infringement later. Why is this important? Suppose the patentee could sue at any time. Then, PharmaUS could watch CiplaIndia invest substantial sums in building manufacturing capacity, getting regulatory approval, and marketing its version of the product. PharmaUS could then sue for infringement, and CiplaIndia would lose its investment if found infringing. PharmaUS might also allow CiplaIndia to sell its product for some time and only later sue for damages. If PharmaUS could succeed with such a strategy, it would effectively destroy CiplaIndia's incentives to enter the market in the first place and render the Mechanism largely ineffective. An equitable estoppel defense would protect CiplaIndia against delayed lawsuits.⁶⁰

IV. INTERNATIONAL COVERAGE

The Mechanism described above could be implemented by any country acting alone. The U.S. government, for example, could implement the Mechanism on its own. However, inventions made by scientists working outside the United States would not be affected, limiting the Mechanism's effectiveness and making it unlikely to be politically tenable. Thus, we should think in terms of the Mechanism being implemented by all countries that have an innovative pharmaceutical industry.

Pharmaceutical firms tend to concentrate their research in a limited number of centers located in developed countries. Table 2 (p. 111) suggests that over 99% of all R&D spending by U.S.-owned firms is in the United States, Western Europe, Canada, and Japan. Table 3 (p. 112) gives the nationality breakdown of inventors of U.S. pharmaceutical patents.⁶¹ It shows that R&D output is likewise highly concentrated in the United States and in relatively few other countries. Thus, by far, the preponderance of activity could be covered by the

60. In the United States, acquiescence to infringing acts by failing to object is not always a strong basis for an equitable estoppel defense. *See A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020, 1041-43 (Fed. Cir. 1992). However, in this situation it is the Indian court assessing the case.

61. Data on patenting in the United States should indicate the full range of sources of all significant innovations since those of any importance would almost surely be patented there. While the share statistics will be tilted towards U.S. inventors, who will also patent less important innovations at home, we are only concerned here with knowing the set of locations, not their relative importance.

Mechanism with coordination among a limited number of governments.

Table 2: R&D Expenditures by U.S.-owned Research-based Pharmaceutical Firms, 1999	
Location of R&D	Expenditure (percent of worldwide)
United States	78.1
Western Europe (European Community, European Free Trade Association, Switzerland)	16.0
Japan	3.2
Canada	2.0
Other	0.7
Source: Pharmaceutical Research and Manufacturers of America, PhRMA Annual Survey, 2001.	

The following Section outlines relevant laws in the United Kingdom, France, Germany, Japan, and Canada. These countries are major producers of innovations, and the consideration of their laws gives some idea of the range of current practice.⁶² In this Section, we first consider some general issues.

A. Effect of Non-Implementing Countries

Table 3 (p. 112) suggests that just eight countries would need to implement the Mechanism for it to cover over 90% of all pharmaceutical patents. If these countries were to do so, however, it does raise the question of whether firms would respond by moving the location of their research centers to non-implementing countries. In part, the answer to this question is similar to the comment made at the beginning of Section III. Firms choose their research locations for a variety of reasons and R&D, unlike manufacturing, tends to be done at a few centers. The international reorganization of their research activities would be costly for firms.⁶³ Since the gains from avoiding the Mecha-

62. Other high income PCT member countries that already have in their patent law some form of domestic filing requirement for residents include at least Greece, Italy, Portugal, Singapore, Spain, Vietnam, Belgium, Denmark, Finland, Luxembourg, the Russian Federation, and Sweden. For the first six, the requirement covers all innovations. For the rest, it covers only security-related innovations. WIPO, PCT Applicant's Guide, at <http://www.wipo.int/pct/guide/en/> (last updated Sept. 19, 2002).

63. However, it might be relatively easy to shift activities from the United States to Canada, which is one reason that Canada should be an implementing country.

nism are small, it seems unlikely that implementation by a small

Nationality ^b	First-named Inventor		Listed Inventor	
	Percentage	Cumulative %	Percentage	Cumulative %
U.S.	50.68	50.68	42.75	42.75
Japan	11.36	62.04	17.54	60.29
Germany	9.21	71.25	12.49	72.78
U.K.	6.94	78.19	5.86	78.64
France	5.86	84.05	6.03	84.67
Switzerland	2.79	86.84	1.99	86.66
Italy	2.56	89.40	2.69	89.35
Canada	2.00	91.40	1.67	91.02
Sweden	0.96	92.36	0.91	91.93
Belgium	0.82	93.18	0.74	92.67
Netherlands	0.78	93.96	0.56	93.23
Denmark	0.77	94.73	0.70	93.93
Israel	0.70	95.43	0.56	94.49
Hungary	0.64	96.07	1.76	96.25
Australia ^c	0.55	96.62	0.41	96.66

Notes

- a. Calculations by Jeffrey Furman, from U.S. PTO Technology and Assessment Forecasting division data, 2001. It includes all U.S. pharmaceutical patents applied for during the period 1985-95.
- b. Nationality refers to country of residence.
- c. The table only includes nationalities that comprise at least 0.5% of total first-named inventors or at least 0.5% of total listed inventors.

group of countries would cause firms to move their research laboratories elsewhere. Statistics such as those in Tables 2 (p. 111) and 3 would show any change in R&D patterns in response to the Mechanism.⁶⁴ If the statistics show that research became important in additional countries, they too could be encouraged to implement the Mechanism. Regardless, wider coordination initially — say, among the United States, members of the EU, Switzerland, Japan, and Canada — would be desirable.

64. Changes in R&D patterns across countries could happen over time even if not in response to the Mechanism.

B. Effectiveness of the Mechanism in Small Countries

Since it is the domestic patent that is put at risk by falsifying the Declaration, one might argue that the Mechanism would not be effective if implemented by a small country, even if it were wealthy. For instance, an inventor of a Cancer product in Luxembourg might be willing to give up protection there in order to keep protection in India. While there is no doubt that the threat of losing a U.S. patent would have a greater effect on incentives than the threat of losing a Luxembourg patent, more may be at risk than profits in Luxembourg. Competitive generic sales in a rich world market during the time of patent coverage may have implications for prices elsewhere. Further, the small country would become a location where others could freely use the patented product in research⁶⁵ and where generic drug companies could manufacture and stockpile before patent expiration in other countries.

C. European Patent Office Applications

No special implementation issues are raised by the availability of European patent applications. The European patent application does, however, present a possible opportunity. Suppose that the Declaration were required of all residents of European Patent Office (“EPO”) member countries when submitting a European patent application (i.e., a security provision at the regional level). Member countries would state in their laws that falsifying the Declaration would render any ensuing national patent invalid. Then protection in the entire EPO area, as opposed to protection in just the home market, would be jeopardized by undesirable behavior.⁶⁶ This would increase the effectiveness of the Mechanism for inventions made in smaller countries. It would not, however, be a good option if it simply encouraged inventors to avoid the EPO in favor of a series of national patent applications.

V. IMPLEMENTATION — SELECTED COUNTRIES

This Section describes features of the current laws in five countries. These laws are relevant to implementation of the Mechanism. There are two important elements common to all countries. First, all

65. There is an “experimental use” defense to patent infringement, but it is limited. See ROBERT P. MERGES ET AL., *INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE* 295–97 (2d ed. 2000) (for the United States); William R. Cornish, *Experimental Use of Patent Inventions in European Community States*, 29 *INT. REV. OF INDUS. PROP. & COPYRIGHT* 735 (July 1998).

66. However, invalidity proceedings would need to be pursued in each country separately.

of the countries have some form of national security-related provisions regarding the treatment of patent applications. Thus the law acknowledges that national interests may limit the actions of patentees — in particular their ability to disclose information. Second, the law in all of the countries discussed below recognizes the basic principle that patent rights are a privilege granted by society and that patent rights may be retracted if a patentee does not fulfill requirements designed to further social goals. This is evident in that patents may be invalidated on the grounds of insufficient disclosure.⁶⁷

There is an additional element lacking in all five countries. In none of the countries is there a general duty to deal in good faith with the patent office.⁶⁸ Therefore, even more so than in the United States, it may be necessary to amend the laws to make invalidation and unenforceability the explicit remedies for falsifying a declaration to the patent office.

Beyond these basic elements, the countries differ substantially. The United Kingdom has foreign filing obligations and procedures very like those described above for the United States; Canada and Japan have no restrictions on filing abroad; France and Germany have obligations that apply in more limited circumstances.

A. United Kingdom

The United Kingdom has a foreign filing license requirement. Its justification is national security: to control information “prejudicial to the defense of the realm”⁶⁹ or “to the safety of the public.”⁷⁰ The security provisions state that:

no person resident in the United Kingdom shall, without written authority granted by the comptroller, file or cause to be filed outside the United Kingdom an application for a patent for invention unless . . . an application for a patent for the same invention has been filed in the Patent Office . . . not less than six weeks before the application outside the United Kingdom.⁷¹

67. Disclosure requires that the invention be described sufficiently clearly and completely to enable one skilled in the art to practice the invention. See 35 U.S.C. § 112 (2002).

68. However, good faith may be required in some specific circumstances. See, e.g., *infra* § V.A.

69. Patents Act, 1977, § 22(1) (Eng.), available at <http://clea.wipo.int> (last visited Oct. 3, 2002) (search term GB100EN).

70. *Id.* § 22(2).

71. *Id.* § 23(1).

In the United Kingdom, firms may apply for patents: “[t]he term ‘person’ includes one or more individuals or a corporate body.”⁷²

As in the United States, the license obligation applies to all types of inventions. Coverage differs, however, in that the obligation is limited to inventions made by a resident of the United Kingdom, rather than to all inventions made in the United Kingdom.⁷³ The question of exactly who would be considered a resident from the point of view of the license obligation has not been tested in the courts and is somewhat unclear. It is the opinion of the U.K. Patent Office that an individual’s residency would be established very quickly — in a matter of weeks — for the purpose of the country’s security provisions. It gives the example of a U.K. national working in France during the week and living in the United Kingdom on the weekends. Inventions made at home would fall under the U.K. security provisions but not those made during the week in France, during which time he would be considered a resident of France. With this interpretation of residency, the “residency” standard converges with the “location of invention” standard used in the United States. However, the “residency” standard is also broader since “[a]ny United Kingdom resident temporarily traveling abroad is considered to be bound by [the security provisions] during his travels.”⁷⁴

The obligation remains if the inventor is one of several joint inventors: “when a United Kingdom resident is a joint inventor with a foreign resident or seeks to be a joint applicant therewith in relation to a foreign application, the [security provisions] should be complied with.”⁷⁵ All inventors must be listed within sixteen months after application.⁷⁶ However, failure to do so is not grounds for invalidity.⁷⁷

There are two ways to request the license, as in the United States. A request is assumed upon the application for a U.K. patent at the U.K. Patent Office or by submitting a PCT or EPO application with the U.K. Patent Office acting as the receiving office.⁷⁸ Alternatively,

72. U.K. PATENT OFFICE, MANUAL OF PATENT PRACTICE § 7.02 (4th ed. 1999), available at www.patent.gov.uk/patent/reference/mpp/index.htm (last updated July 8, 2002).

73. See Patents Act § 23(1). The phrase “cause to be filed” means that a U.S. firm with U.K. resident inventors cannot avoid the security provision by applying for patents in the name of the U.S. home office. This is because the inventor is considered to have “caused” the filing. Letter from James Porter, Legal Adviser, UK Patent Office, to author (Feb. 2002) (on file with author). A U.K. patent attorney filing for, say, a German company is also technically in breach of the security provision unless permission is sought. *Id.* Since this is a “technical” breach, the U.K. Patent Office has resolved it by giving attorneys under contract to foreign firms special general permits to cover applications filed in this way whenever the technologies involved are not defense-related. *Id.*

74. U.K. PATENT OFFICE, *supra* note 72, § 23.01.

75. *Id.*

76. *Id.*

77. Letter from James Porter, Legal Adviser, UK Patent Office, to author (Nov. 20, 2001) (on file with author).

78. *Id.*

permission may be requested directly from the Comptroller.⁷⁹ An explicit foreign filing license is only required for a limited time after the patent application — six weeks rather than the six-month limit in the United States.⁸⁰

A person who fails to comply with the security provisions has committed a criminal offense. He is liable “(a) on summary conviction, to a fine not exceeding the prescribed sum; or (b) on conviction on indictment before the court, to imprisonment for a term not exceeding two years or a fine, or both.”⁸¹ The maximum fine under (a) is currently 5,000 pounds.⁸²

Turning to the remedy for falsifying the Declaration made to the U.K. Patent Office, as noted there is no general provision explicitly stating that patentees are required to deal with the U.K. Patent Office in good faith. However, in some cases a failure to do so can lead to restricted rights. The Patents Act states that, if a patent specification is amended for any reason, “no damages shall be awarded in proceedings for an infringement of the patent committed before the decision to allow the amendment unless the court or the comptroller is satisfied that the specification of the patent as published was framed *in good faith* and with reasonable skill and knowledge.”⁸³ Further, patent applications can be refused or issued patents can be invalidated for insufficient disclosure of the invention.⁸⁴

B. France

France also has a foreign filing license requirement. When an inventor would like to submit an EPO or PCT application, the obligation is very similar to that of the United Kingdom. All “natural or legal persons having their place of residence or business in France” wishing to submit PCT or EPO applications *must* file the documents with the National Institute of Industrial Property (“INPI”) of France as the receiving office, unless claiming priority from an earlier filing in France or elsewhere.⁸⁵ Since it is not explicitly limited, the obligation presumably applies to innovations in all technology areas. Authorization is automatic after a period of five months after filing, so an explicit license is not required once this period has passed.⁸⁶ The penalty

79. Patents Act 1977, § 23(1) (Eng.).

80. *Id.* § 23(1)(a).

81. *Id.* § 22(9).

82. Criminal Justice Act, 1991, c. 53, § 17(2)(c) (Eng.), available at http://www.legislation.hmso.gov.uk/acts/acts1991/Ukpga_19910053_en_2.htm (last visited Oct. 3, 2002).

83. Patents Act § 62(3) (emphasis added).

84. Letter from James Porter, Legal Adviser, UK Patent Office, to author (Nov. 20, 2001) (on file with author).

85. CODE PROPRIÉTÉ INTELLECTUELLE [C. PROP. INTELL.] arts. L. 614-2 to 614-18 (Fr.), available at <http://clea.wipo.int> (last visited Oct. 3, 2002) (search term FR065EN).

86. *Id.* art. L. 612-9.

for a failure to comply with this regulation is between 3,000 and 40,000 French Francs (“FF”) and, if damage is caused to national defense, there can be a jail sentence of one to five years.⁸⁷

When an invention is related to one of “the essential elements of [the French nation’s] scientific and economic potential,” there is an obligation in the Penal Code for both French citizens and residents to obtain permission to display the information to the benefit of a foreign body, which could include filing a patent abroad.⁸⁸ This obligation applies to French citizens irrespective of their length of residence elsewhere and to residents of France even if recently arrived.⁸⁹ In this respect the French foreign filing obligation is more strict than both the U.K. and U.S. foreign filing obligations. However, if an application is made at the French Patent Office, it can be used to demonstrate that the inventor did not have an intention to go against the provisions contained in the Penal Code.⁹⁰ Nevertheless, unlike the dual avenues allowed by the United States and the United Kingdom, in the most recent revision of the Penal Code, no provision was made for obtaining permission to file abroad other than with a national filing.⁹¹ “Inventions which are the subject of patent applications may not be disclosed or freely worked until an authorization to that effect has been granted.”⁹² As with the EPO and PCT applications, unless the prohibition is extended, “[a]uthorization shall be automatic on expiry of a period of five months from the filing date of the patent application.”⁹³ The applicant may request permission to file abroad before the end of the five-month period. It is the inventor’s responsibility to decide whether his invention falls into the category of technologies that require permission for filing abroad.⁹⁴ There is no official interpretation of what is covered under the heading “essential elements of the scientific and technical potential” and it is broader than just inventions related to national defense.⁹⁵ Failure to file first in France on a relevant invention is considered treason if the inventor is a national and espionage if the inventor is a foreigner.⁹⁶ Filing abroad without a license

87. *Id.* arts. L. 615-15 to 615-16.

88. C. PÉN. arts. 410-1, 411-1, 411-6 (Fr.), translated in EDWARD A. TOMLINSON, THE FRENCH PENAL CODE OF 1994: AS AMENDED AS OF JANUARY 1, 1999, at 199–201 (1999).

89. Letter from Marion Guth, Senior Legal Adviser, INPI, to author (Mar. 5, 2001) (on file with author) [hereinafter Guth letter].

90. *See id.*

91. A legal advisor of the INPI suggests that this was an oversight since there was such a procedure in the Penal Code prior to 1994. Guth letter, *supra* note 89. In practice, permission to file abroad first is sought from the Bureau of IP Matters within the Ministry of National Defense. However, they do not have the legal authority to decide on these issues. *See id.*

92. C. PROP. INTELL. art. L. 612-9.

93. *Id.*

94. Guth letter, *supra* note 89.

95. *Id.*

96. *Id.*

after having filed in France carries a penalty of 30,000 FF and, if national defense is prejudiced, may also include imprisonment for five years.⁹⁷

Again, as in the United Kingdom, there is no general duty to deal with the French Patent Office in good faith. However, the French Intellectual Property Code does state that a “patent shall be revoked by court decision . . . if it does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.”⁹⁸

C. Germany

Germany has a foreign filing obligation very similar to that of France in that it applies only to technologies constituting state secrets. “A patent application containing a State secret (Section 93 of the Penal Code) may only be filed, outside the territory to which this Law applies, with the written consent of the competent supreme federal authority.”⁹⁹ This obligation is narrower than that imposed by France in that the equivalent provisions for PCT and EPO applications are also limited to state secrets.¹⁰⁰ Furthermore, German state secrets are defined as facts and knowledge accessible to a limited number of people whose revelation would damage the external security of the German nation.¹⁰¹ Thus, the foreign filing obligation relates expressly to security inventions only. According to the German Patent Office, 90% of military-related inventions would fall under this heading, but so too would some others.¹⁰² They give inventions related to the printing of the new Euro currency as a recent example.¹⁰³ Regardless of the type of application, national or international, it is up to the inventor to decide whether he has an invention that falls under the secrecy provisions. Who might have a German state secret is not clearly defined either by geographic location or citizenship.

As in the United Kingdom and France, PCT and EPO applications must be filed with the German Patent Office acting as the receiving

97. See C. PROP. INTELL art. L. 615-13.

98. *Id.* art. L. 613-25.

99. Patentgesetz (Patent Law) § 52(1), v. 25.10.1994 (BGB1. I S.2278) (Ger.), available at <http://clea.wipo.int> (last visited Oct. 7, 2002) (search term DE017EN).

100. Gesetz zu dem Übereinkommen (Law on International Patent Treaties), v. 21.6.1976 (BGB1. II S.649, 658), available at <http://clea.wipo.int> (last visited Oct. 7, 2002) (search term DE082EN).

101. § 93 Nr. 1 STRAFGESETZBUCH [StGB] (Ger.), translated in JOSEPH J. DARBY, THE PENAL CODE OF THE FEDERAL REPUBLIC OF GERMANY 118 (1987).

102. Letter from Hans Georg Bartels, Referent für Patentrecht, Gebrauchsmusterrecht und Geschmacksmusterrecht, Richter am Amertgericht, to author (Feb. 28, 2002) (on file with author).

103. *Id.*

office whenever the secrecy provision applies.¹⁰⁴ In all cases, a request for permission to file abroad is assumed when a patent application is filed.¹⁰⁵ If no secrecy order is served during a period of four months after application, permission can be assumed and the inventor can proceed with foreign filings.¹⁰⁶ A person who files abroad without permission is subject to imprisonment not to exceed five years or to a fine.¹⁰⁷

As in the other countries, a “patent shall be revoked if it transpires that . . . the patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.”¹⁰⁸

D. Canada

Canada does not limit an inventor’s ability to file abroad first. However, if a patent is applied for in Canada, restrictions on the use of the information may be imposed:

The Governor in Council, if satisfied that an invention relating to any instrument or munition of war, described in any specified application for patent . . . is vital to the defence of Canada and that the publication of a patent therefor should be prevented in order to preserve the safety of the State [may place the invention under secrecy orders].¹⁰⁹

Communication of the information is then an offense under the Official Secrets Act.¹¹⁰

Patentees have an explicit obligation to deal with the Canadian Patent and Trademark Office in good faith during the application process: “An application for a patent in Canada shall be deemed to be abandoned if the applicant does not . . . reply in good faith to any requisition made by an examiner in connection with an examination . . .”¹¹¹ As elsewhere, Canadian law requires that the patent specification must “correctly and fully describe the invention and its operation

104. Law on International Patent Treaties, art. II § 4.2, art. III § 2.1.

105. Letter from Hans Georg Bartels, Referent für Patentrecht, Gebrauchsmusterrecht und Geschmacksmusterrecht, Richter am Amertgericht, to author (Jan. 28, 2002) (on file with author).

106. Patent Law § 52(1).

107. *Id.* §§ 53(1), 52(2).

108. *Id.* § 21(1).

109. Patent Act, R.S.C., ch. P-4, § 20(17) (1985) (Can.), available at <http://clea.wipo.int> (last visited Oct. 6, 2002) (search term CA007EN).

110. See Official Secrets Act, R.S.C., ch. O-5, § 4(1)(a) (1985) (Can.).

111. Patent Act § 73(1), amended by ch. 15, § 52 (1993) (Can.).

or use as contemplated by the inventor.”¹¹² It is not explicitly stated that failure in this regard would invalidate a patent. However, according to the Canadian PTO, it would do so on the indirect grounds that the patent “lacked utility” as a result of its being poorly described.¹¹³

All inventors must be identified. Canadian law states that, where an invention is made by two or more inventors, a subset of the inventors may make an application only “on satisfying the Commissioner that the joint inventor has refused to make application or that his whereabouts cannot be ascertained after diligent inquiry.”¹¹⁴ However, failure to identify inventors is not grounds to invalidate a patent.¹¹⁵

E. Japan

Like Canada, Japan does not have a foreign filing license obligation, and there is also no provision for secrecy in the patent law itself. However, there is a special agreement between the United States and Japan to allow patent applications related to national security not to be published.¹¹⁶

There is no general duty to deal with the Japanese Patent Office in good faith. However, if a patentee is found to have misrepresented the inventors or the assignee of his patent, the patent can be invalidated by the Japanese Patent Office.¹¹⁷

As in the United States, a failure to sufficiently disclose the invention is grounds for invalidation.¹¹⁸

VI. OTHER POLICY OPTIONS

One response to the proposal outlined here is to ask, “Would it not be simpler for the developing countries to use existing provisions in TRIPs to lower their prices?” Most countries, rich and poor, control the prices of pharmaceuticals. Such control is not restricted by treaty. In addition to price controls, TRIPs allows countries to issue compulsory licenses to attain public health goals.¹¹⁹ These are non-exclusive

112. *Id.* § 34(1)(a).

113. Telephone interview with David Cillis, Special Advisor, Patent Branch, Canadian Intellectual Property Office (Feb.15, 2002).

114. Patent Act § 31(1).

115. Telephone interview with David Cillis, Special Advisor, Patent Branch, Canadian Intellectual Property Office (Feb.15, 2002).

116. *See* Interchange of Patent Rights and Technical Information for Defense Purposes, Mar. 22, 1956, U.S.-Japan, art. III, 7 U.S.T. 1021.

117. Letter from Masayuki Koyanagi, Director Washington Office, Institute of Intellectual Property, Japan, to author (Jan. 28, 2002) (on file with author).

118. Tokkyō Hō [Patent Law], Law No. 121 of 1959, art. 123, no. 1–4 (Jpn.), available at <http://clea.wipo.int> (last visited Oct. 24, 2002) (search term JP006EN).

119. TRIPs, *supra* note 3, art. 31(b).

licenses granted to domestic producers that allow them to use a protected innovation. Reasonable royalty payments must be paid to the patentee.¹²⁰

If the only goal were to attain lower prices on products developed for rich country markets, then either price control or compulsory licensing *might* be adequate. The drawback of price controls is that patentees would retain control over sales in the poor country market, and a firm could simply keep its patented product off the market altogether if the controlled price were viewed as too low. Compulsory licensing avoids this problem by allowing domestic producers to sell a patented product. However, compulsory licensing only helps in countries with some R&D and manufacturing capacity. There would no source of imports because no one can produce under a compulsory license for export under current rules.¹²¹ Because of procedural conditions, reliance on a compulsory license system could also substantially delay the arrival of new drugs to the market.¹²²

More importantly, neither price control nor compulsory licensing offers what the proposal here was designed to provide: a feasible way to allow competitive entry in some areas while keeping in place incentives for private firms to invest in research on diseases specific to poor countries. Private firms do little research on products for the developing world.¹²³ With the extension of patent protection across developing countries and in conjunction with other policies, this may change. Although how responsive firms will be is hard to predict, it seems certain that compulsory licensing or stringent price control regimes that limit the returns to companies that discover new products specifically designed to treat poor countries' health problems would prevent any beneficial redirection of research.

Could compulsory licensing or price control regimes be structured so as to constrain most tightly the prices of products for global diseases while allowing higher profit margins for inventors of products for diseases specific to developing countries? A number of considerations suggest that the answer is probably no. As noted above, compulsory licensing is only meaningful if it can be done quickly. Firms considering competitive entry will not even begin the process of investment that entry requires until they know that they will be able

120. *Id.* art. 31(h).

121. *See id.* art. 31(f). This feature is under review at the TRIPs Council.

122. The recent Doha Declaration on Public Health by the WTO Ministerial states that a country may override these procedural requirements in circumstances of national emergency including public health crises. *See* WTO Ministerial Conference, Declaration on the TRIPs Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 14, 2001), available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf (last visited Oct. 6, 2002). It is too early to tell how broadly this exception will be interpreted.

123. *See* Jean O. Lanjouw & Iain M. Cockburn, *New Pills for Poor People? Empirical Evidence After GATT*, 29 *WORLD DEVELOPMENT* 265 (2001).

to proceed with production and sales. For this reason, Scherer and Watal, in a discussion of compulsory licensing experience, commend the approach taken by Canada, which set 4% as the reasonable royalty payment for all such licenses.¹²⁴ By doing this, the licensing board avoided having to investigate R&D costs and market conditions before setting each fee. The average licensing approval time of only ten months was possible precisely because no attempt was made to differentiate across products.¹²⁵

In order to differentiate effectively, a country would need to define categories of products according to different royalty or pricing treatments and then have a quick method for identifying into which category a particular product or set of patents should fall. This directly leads to the difficult identification problems addressed above. Further, unlike the proposal outlined here — under which firms would rarely trigger an event making it necessary to classify a product — there is no self-enforcement under compulsory licensing. Under a differentiated compulsory licensing or pricing scheme, the correct allocation of every patented product would have to be determined. Firms have every incentive to make this as hard as possible. Such a regime would create clear opportunities for lobbying and produce confrontations unlikely to contribute in a helpful way to the already acrimonious discussions in this area between countries.

Beyond the informational problem, the more difficult aspect of discriminating between products for different types of diseases might well be political. Having seen a compulsory license granted for a global disease product with a “reasonable royalty” of 1%, those suffering from diseases like malaria might well object to a “reasonable royalty” rate of 30% or 50%, regardless of the sound economic logic. Domestic political pressures might make differentiation along the lines required by efficiency — i.e. higher rates on patents for developing country-specific diseases — untenable and result in a structure of incentives far from those desired.

Under my proposal and for the specified set of global products, firms effectively obtain either full protection in the poor countries or no returns at all — a 0% royalty — depending on their choices. A variant would be to reformulate the Declaration so as to enable firms to preserve monopoly rights in the rich countries and at the same time

124. F.M. Scherer & Jayashree Watal, *Post-TRIPS Options for Access to Patented Medicines in Developing Countries* (2001), available at http://www.cmhealth.org/docs/wg4_paper1.pdf (last visited Nov. 4, 2002).

125. The Canadian approach may not even be an option as it may not be TRIPs compliant. For example, according to TRIPs, in the event a compulsory license is granted, the remuneration must “tak[e] into account the economic value of the authorization.” TRIPs, *supra* note 3, art. 31(h). Moreover, the authorization of a compulsory license must be “considered on its individual merits.” *Id.* art. 31(a). Thus, an across the board figure of 4% for all technologies is not consistent with the TRIPs standard of a case-by-case analysis.

obtain some return from the poor countries. For example, they might declare that they “will not prevent the manufacture or sale of drugs for Cancer unless they obtain less than a 5% royalty.” Although this appears, on the face of it, to be preferable in the sense of striking some type of middle ground, it is not. With a 5% royalty, either more diseases or more countries should qualify for inclusion in the Declaration — just to the point where firms would be indifferent to the choice between my proposal and this variant. Although being able to include more countries might be attractive on political grounds, the positive royalty is not necessary because one can increase the number of countries as much as one wants to by narrowing the set of diseases.

Further, it would be considerably more difficult to demonstrate that a declaration with a royalty requirement had been falsified. This is for two reasons. First, establishing real royalty payments requires verifiable sales information. PharmaUS might insist that any payment from CiplaIndia represented a royalty below 5% because CiplaIndia’s sales were at some high level, while CiplaIndia would assert the opposite. Second, payments from the licensee to the patent holder may come in a variety of forms, not all linked as a share of sales. These other payments would need to be converted into an estimated royalty payment to ascertain if the Declaration was being falsified. For both reasons there would be great scope for delaying tactics. By contrast, the Mechanism described here simply requires a finding that a suit has been filed.

VII. CONCLUDING COMMENTS

This Article has outlined a new mechanism for reconciling the two goals of an intellectual property system. It allows the research incentives of pharmaceutical firms to increase with the extension of patent protection to poor countries when added incentives may have some benefit. At the same time, it preserves the access of poor consumers to important classes of drugs. The lowest possible prices are encouraged by allowing competition in the poorer countries for global disease products — those whose research can be supported by profitable markets elsewhere. Aspects of patent law, such as the foreign filing license requirement, equitable estoppel, and priority procedures; features of litigation and the drug approval process; as well as available data sources are all used in ways not originally intended to arrive at a mechanism that serves our purpose. The new rules would give firms new incentives, and in responding to these rules, firms would choose not to suppress competition in markets where potential monopoly profits are small. Rarely would the procedure to render a patent unenforceable occur because firms would alter their behavior to avoid this outcome. An outside body would not be required to make

the difficult judgment about what disease a patented invention treats because established FDA procedures would be used in the rare situations when the Mechanism is triggered in the event of an infringement suit. The Mechanism requires no changes in international treaties and only minor changes to the legal codes of implementing countries. As a result, it would be straightforward to implement. Because it uses existing institutions and procedures, is largely self-monitoring, and does not require the collection of information for each patent, the Mechanism would cost very little to administer and enforce. Thus, the Mechanism need not be seen as an alternative to other policies within the constraints of fixed health or development budgets.