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Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options

Jerome H. Reichman

I. How Compulsory Licensing Survived the TRIPS Agreement of 1994

Few topics in international intellectual property law have been as controversial in recent years as the one we are about to examine. In the 1980s and early 1990s, a Diplomatic Conference attempted to revise the oldest international convention providing some protection for patented inventions outside of the domestic laws.¹ Those efforts broke down, largely because developed and developing countries could not agree on the powers that governments should retain to issue compulsory licenses or on the grounds for which these powers could be exercised.² The failure of this Conference, held under the auspices of the World Intellectual Property Organization (WIPO), persuaded the technology-exporting countries to link future negotiations concerning international intellectual property protection to the Multilateral Trade Negotiations, known as the Uruguay Round, which got underway in 1986.³ The end result was Annex IC of the Agreement Establishing the World Trade Organization of 1994, which incorporated a new, comprehensive and relatively elevated set of international minimum standards of patent protection into the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).⁴

A. What the TRIPS Agreement Did Not Give the Pharmaceutical Sector

Taken together, the TRIPS Agreement's standards amounted to a veritable revolution in international intellectual property law from which the research-based pharmaceutical industry emerged as one of the biggest winners. Faced with a "take it or leave it decision," all developing-country Members of the WTO, including those with growing pharmaceutical production capabilities, such as India, Brazil, and eventually China, agreed to respect relatively stringent worldwide norms of patent protection no later than 2005.⁵ In return, these countries were given greater access to developed markets for traditional manufactured goods plus a commitment of the developed countries to stop imposing unilateral trade sanctions for allegedly inadequate protection of foreign intellectual property rights (IPRs).⁶

Ironically, if the developing countries lost the war, in the sense that their generic pharmaceutical industries could no longer freely reverse-engineer the costly products of foreign research and development under the shield of domestic laws that ignored pharmaceuti-

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cal patents, then they won a great battle with specific regard to the question of compulsory licenses,⁷ which had triggered the drive for the TRIPS Agreement in the first place. Thanks largely to the fortitude and analytical skills of the Indian delegation,⁸ the right of governments to grant compulsory licenses on virtually any ground — including public interest, abuse or anti-competitive conduct, or for noncommercial government use, among others — issued stronger and clearer from the TRIPS Agreement than had previously been the case under the Paris Convention.⁹

The TRIPS Agreement did subject the exercise of this power to certain preconditions, including a duty to notify and negotiate with the affected patentees under ordinary circumstances; but these specific conditions, among others, are waived in the case of “national emergency or other circumstances of extreme urgency or in cases of public noncommercial [i.e., government] use.”¹⁰ Moreover, the very existence of these conditions only magnified the legitimacy of every complying government’s right to resort to compulsory licensing whenever its domestic self-interest so required.¹¹

Historians may wish to note that, while international minimum standards of patent protection have gradually and progressively risen over time, in keeping with the expressed goals of the Paris Union,¹² every attempt to limit or constrain a state’s power to issue compulsory licenses has invariably resulted in a strengthening of that same power at the international level.¹³ Policymakers and scholars should also note that two European Union (E.U.) countries, France and Belgium, recently adopted new and sweeping powers to grant compulsory licenses of patented pharmaceutical inventions for public health purposes.¹⁴

1. THE DOHA MINISTERIAL DECLARATION ON TRIPS AND PUBLIC HEALTH

The developing countries’ victory in this regard — modest as it otherwise seems in the overall context of burdensome TRIPS obligations — was destined to bear even greater fruits with specific regard to pharmaceuticals. The worldwide patent standards adopted by the TRIPS Agreement threatened to disrupt future supplies of patented medicines at prices people in poor countries could afford by elevating the prices patentees would charge affluent patients in these countries.¹⁵ In principle, developing country governments needing drugs at prices lower than those of the patentees could issue compulsory licenses under article 31 of the TRIPS Agreement. In reality, most of these countries lacked the capacity to manufacture the drugs in ques-

tion, or otherwise to obtain the key active ingredients, in which case the granting of a compulsory license could amount to an empty gesture for lack of access to non-infringing generic substitutes.

Of course, Good Samaritan countries that possessed manufacturing capacity might be willing to assist a needy country by issuing compulsory licenses of their own, with a view to exporting supplies of the drug in question for this purpose. But that type of assistance was limited by article 31(f) of the TRIPS Agreement, which expressly required products manufactured under a compulsory license to serve “predominantly for the supply of the domestic market” (thus limiting such exports literally to 49.9 per cent of the total output). Moreover, even middle-income countries with growing manufacturing capacity, such as India and

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Brazil, might themselves need a drug that they could not manufacture locally, in order to temper a patentee’s prices. In that case, any willing supplier to them — if one could be found in a developed country — would likewise be bound by the limitation on exports that article 31(f) imposed.

The tensions generated by these prospects for rising prices of essential medicines came to a head in the late 1990s, at the very time when the developed countries wanted the developing countries to agree to yet another round of Multilateral Trade Negotiations, to be known as the Doha Round. The latter countries made removal of constraints on their public health authorities under the TRIPS Agreement a *sine qua non* of their participation in that Round. The outcome was a momentous Ministerial Declaration on the TRIPS Agreement and Public Health of 2001, which, in paragraph 4, affirmed that this Agreement “can and should be interpreted and implemented in a manner supportive of WTO Members’ rights to protect public health and, in particular, to promote access to medicines for all.”¹⁶

The Ministerial Declaration expressly reconfirmed many of the key flexibilities set out in the TRIPS Agreement,¹⁷ including the power of WTO Members “to grant compulsory licenses and the freedom to

determine the grounds upon which such licenses are granted,¹⁸ a freedom that the originator pharmaceutical companies had continued to question despite the clarity of the TRIPS language itself. The Declaration then expressly addressed the constraints on exports set out in article 31(f) of TRIPS. In paragraph 6, it provided a mandate for “establishing legal machinery to enable countries lacking the capacity to manufacture generic substitutes for costly patented medicines under domestically issued compulsory licenses to obtain imports from countries able and willing to assist them without interference from the relevant patent holders.”¹⁹

2. THE WAIVER TO, AND PENDING AMENDMENT OF, ARTICLE 31

This solution, which obviously improved the export opportunities for generic producers in Brazil, China, India, and other emerging economies, was to be broadly applied to all “products of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of [the Ministerial Declaration].”²⁰ There were no limitations in that paragraph on the application of the new legal machinery either to cases of national emergency or to specific diseases or medicines.²¹ This machinery would thus enable any country (that had not voluntarily waived the privilege) to issue a compulsory license for a medicine it could not produce and then to seek help from any other country having that capacity that was willing to assist it. If the latter country issued a second compulsory license, and otherwise complied with specified conditions of registration and packaging, it could produce the requested medicines entirely for export and supply the needy country, notwithstanding the language of article 31(f) of the TRIPS Agreement to the contrary.²² While “adequate compensation” must be paid to the patentee,²³ it will be collected once only, in the exporting country, based on conditions in the importing country.²⁴

In other words, the scheme ultimately negotiated under the auspices of paragraph 6 of the Doha Ministerial Declaration envisioned a process of back-to-back compulsory licenses that would enable any country needing medicines at lower prices than those charged by local patentees to seek assistance from other countries able and willing to produce the drugs for export purposes, without interference from the patentee in either country. After protracted and difficult negotiations, this solution was initially embodied in a Waiver, known as the Decision of 30 August 2003.²⁵ If all goes as planned, this Waiver would be rendered permanent by virtue of a pending Amendment to the TRIPS Agreement, known as article

31*bis*.²⁶ The Waiver remains in effect while governments take steps to ratify the Amendment,²⁷ as the European Union recently did after the European Parliament endorsed the Amendment and issued instructions for its wholehearted implementation.²⁸ As of 2009, the Waiver process had only been used once due in part to the cumbersome procedures put in place by some governments, in addition to the core WTO process.²⁹

Meanwhile, the originator pharmaceutical industry did not accept this further defeat without countervailing initiatives of its own. Besides flooding the world with misleading and self-serving interpretations of the relevant legal instruments, which continue to influence incautious government officials and even some scholars to this day, the industry persuaded the United States Trade Representative (USTR) to recapture some of the lost ground by means of Bilateral or Regional Free Trade Agreements with developing countries. While this topic lies well beyond the scope of this Comment, readers should be aware that the flexibilities concerning governmental powers to grant compulsory licenses of patented pharmaceutical medicines under the legal regime described above could be severely limited, or even largely abrogated, by the one-sided intellectual property provisions of specific FTAs.³⁰ Moreover, threats and political pressure from USTR and other governmental agencies, including some spokesmen for intergovernmental agencies and even for the European Commission, effectively kept most governments — until recently — from actually invoking or using the legal rights they had doggedly managed to obtain at the international level.

There was, in short, a conspicuous absence of compulsory licensing in the pharmaceutical sector even after the decision of the South African authorities, in 2003, to the effect that two foreign firms had violated the domestic competition law by refusing to grant licenses for patents on essential AIDS medicines.³¹ While this decision did result in the issuing of compulsory licenses (within the ambit of TRIPS Agreement article 31(k)), the heated legal battles and controversy surrounding this case, plus renewed pressures from powerful governments, may actually have diminished, rather than strengthened the developing countries' appetites for attracting unwelcome attention by such means. This pressure was intensified by mushrooming FTAs that aimed to circumscribe their rights under TRIPS.

B. The Legal Giant Escapes Its Chains

Beneath the surface, however, health ministries in a number of countries had quietly begun to use the threat of compulsory licenses to rein in the prices of selected

medicines, particularly AIDS drugs.³² Because negotiated deals under threat of compulsory license are often kept secret, the surface calm appeared greater than it really was. Beginning in 2006, this calm was shattered by the sudden appearance of compulsory licenses on pharmaceuticals — or public threats thereof — in both the southern and northern hemispheres. In the period 2006-2007, for example, Thailand's public health authorities issued two compulsory licenses on AIDS drugs and one on clopidogrel bisulfate (Plavix), a major cardiovascular treatment. Thailand did not issue the licenses discreetly, but with considerable fanfare and with a list of other drugs slated for similar treatment in the future.³³ In April 2007, the president of Brazil signed an order for a compulsory license for government use of Merck's patent on the antiretrovi-

which the U.S. intended to stockpile as a defense against anthrax.⁴⁰ Bayer drastically lowered its price in response.

In the European Union, meanwhile, the French government extended an already potent system of *ex-officio* compulsory licensing for public health reasons to cover genetic diagnostic patents in 2004, in response to concerns about excessive prices and restrictive licensing conditions on patented diagnostic tests for breast and ovarian cancer.⁴¹ In 2005, the Belgian government adopted even broader new measures allowing the authorities to grant compulsory licenses in the interest of public health generally, with accelerated procedures in case of a public health crisis.⁴²

These bold provisions in Belgium are even more remarkable because they do not purport to derive their

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ral drug, efavirenz (Sustiva), in a public ceremony that was broadcast around the world.³⁴

All these licenses were issued under the authority of existing TRIPS provisions, i.e., article 31 as it stands,³⁵ without regard to the Waiver. In 2007, Rwanda issued a compulsory license for AIDS drugs that it could not produce locally and applied for assistance from Canada, thus triggering the first set of back-to-back compulsory licenses under the Waiver provisions that had implemented Paragraph 6 of the Doha Ministerial Declaration.³⁶ In 2008, Indonesia threatened originator pharmaceutical companies with compulsory licensing and even expulsion unless they were willing to invest in local production of pharmaceuticals.³⁷

Other compulsory licensing procedures that led to agreements with major pharmaceutical companies had reportedly been initiated in Malaysia (2004), Indonesia (2004), Brazil (2003 and 2007), Zambia (2004), Zimbabwe (2004), and Mozambique (2004).³⁸ Moreover, compulsory licenses were threatened against Roche for the use of oseltamivir (Tamiflu) in Indonesia, India, Vietnam, and South Korea, in the period 2003-2006. As a result, Roche selected partners in those countries to assist in the manufacture of sufficient supplies of Tamiflu to combat Asian influenza.³⁹

Even the United States threatened Bayer with a compulsory license on ciprofloxacin (Cipro) in 2001,

authority from article 31 of TRIPS. Belgian officials claim their actions are justified under articles 8 and 30 of the TRIPS Agreement, which respectively allow "measures necessary to protect public health" and limited exceptions to the patentee's exclusive rights under article 28.⁴³ In effect, the Belgian provision attempts to sidestep the conditions set out in article 31. While neither the French nor the Belgian authorities have so far issued compulsory licenses under these provisions, "[l]awyers and patent attorneys argue...that the presence of these mechanisms brings pressure to bear upon non-cooperative patent holders and serves as a convincing argument to settle and drag them into a licensing agreement."⁴⁴

On still another front, the Italian Competition Law authorities issued compulsory licenses against Merck, on certain antibiotics, for abuse of a dominant position in 2005; against Glaxo, for refusal to license a patented migraine headache drug in 2006; and against Merck again for a refusal to license a treatment for baldness in 2008.⁴⁵ Also in 2008, the European Commission began a sweeping investigation of pharmaceutical company practices⁴⁶ which, if found anticompetitive, could lead to additional compulsory licenses.

In short, the pre-existing period of calm has given rise to a proliferation of compulsory licenses in various parts of the world, which in turn has generated heated controversy in both legal and public health circles. It

is against this background that we must evaluate the contributions to this Symposium.

II. Contemplating the Giant's Footprints in the Sand

This Symposium, guest edited by Professor Kevin Outterson, a leading authority on international public health law, brings together three papers espousing rather different views of the compulsory licensing phenomenon. For the sake of convenience, we may characterize them respectively as providing "A Realistic View," "A Sympathetic Skeptic's View," and a "Hostile Sympathizer's View." I propose to examine them separately, but within the larger context sketched above.

comparable to those of generic producers, who are not charitable institutions and who profitably market off-patent medicines in poor countries. Economist F. M. Scherer made this point clearly when he established that global welfare would be improved if the poorest countries were permitted to free ride on pharmaceutical innovation.⁴⁹

So why do the pharmaceutical companies — with possibly one recent but clamorous exception⁵⁰ — decline to escape the heat by overtly adopting an optimal price discrimination strategy (coupled with binding agreements to limit parallel exports, which otherwise remain perfectly legal under article 6 of the TRIPS Agreement⁵¹)? One authoritative answer, pro-

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A. The Realists' Perspective

Most economists would agree that, in a perfect world, originator pharmaceutical companies would avoid the risk of compulsory licensing by pricing their products so close to the marginal cost of production that poor people around the world could afford to buy them.⁴⁷ Assuming that ways could be found to keep products sold at low prices to poor countries from being re-exported as parallel imports to rich countries, the originator suppliers could, in theory, price-discriminate their products on the basis of per capita GDP. They would thus obtain a large volume of sales at low profit margins in the poorest countries, offset by higher priced sales in middle income countries, and purely monopoly priced revenues in countries that decline to institute price controls, such as Medicare and private insurance markets in the United States.

Price discrimination would, in turn, reduce the deadweight loss — that is, losses that occur when consumers who would buy the products cannot afford to do so — without causing the originator companies to sell below cost. Assuming that the originator company expects to recoup its R&D costs and make the bulk of its profits in rich OECD (Organization for Economic Cooperation and Development) countries,⁴⁸ selling the same products to large numbers of poor people at very low prices (but still above the marginal cost of production) should nonetheless yield profits at least

provided by Patricia Danzon and Adrian Towse, is that the originator companies are wary of so-called "reference pricing" in rich OECD countries that maintain price control regimes for pharmaceuticals.⁵² If the originator company profitably sold its drug in Ruritania for a penny a pill, regulators in Occitania might balk at allowing it to charge fifty or a hundred dollars for the same pill, even if those regulators understood perfectly that the company must recoup the often cited (but still controversial) billion dollar cost of R&D that each new FDA-approved molecule allegedly incurs.⁵³ Hence, Danzon and Towse propose a system of secret rebates that might promote greater price discrimination by limiting the foreign regulators' ability to discover the prices actually charged to distributors in poor countries for use as reference prices in rich countries.⁵⁴ One of Danzon's colleagues recently proposed a similar scheme of pricing opacity and secret discounts for the global vaccine procurement system.⁵⁵

I. THE CONVEX DEMAND CURVE PROBLEM

While this thesis undoubtedly identifies one relevant factor, the contribution to this Symposium by Sean Flynn, Aidan Hollis, and Mike Palmedo⁵⁶ provides a more compelling explanation for originator companies' resistance to price discrimination in poor countries. Indeed, we should be grateful that, by publishing this article, the *Journal* will bring Aidan Hollis'

brilliant economic analysis, long circulating among NGOs, to the attention of a wider audience.

Hollis shows that, in very poor countries characterized by great disparities of income, the rational-acting originator company seeking to maximize profits will logically charge high prices to the affluent sector of the society, because it will earn much greater profits than if it had distributed the same drug to poverty stricken masses at prices they could afford. Calling this the problem of "highly convex demand curves"⁵⁷ for essential goods in countries with large disparities of income, Hollis shows, for example, that the rational-acting firm operating in South Africa would maximize profits "by selling at the price that only the top 10% can afford."⁵⁸ In effect, "the firm will maximize its profits by setting a price unaffordable for at least 90% of ...[the] people."⁵⁹ That finding translates to a deadweight loss of 90 percent, in a pharmaceutical sector where, as James Love famously observed, deadweight loss tends over time to become dead bodies.

Hollis contrasts his figures on South Africa with conditions in Norway, where there is a high degree of income equality and the "convex demand curve" problem largely disappears. He demonstrates that a rational-acting originator company that price discriminated a patented medicine in Norway would accordingly make much greater profits than one who charged a high flat rate for a privileged few.⁶⁰ The former company will considerably reduce deadweight loss as well, in its own self-interest.

Flynn, Hollis, and Palmedo thus answer the question that mystifies so many newcomers to this field: originator companies avoid price discrimination in poor countries because it is considerably more profitable for them to charge monopoly prices to affluent citizens, as their patents enable them to do. The government of a poor country that wants lower prices in order to supply the bulk of the population thus priced out of the market must accordingly force the company to act against its private self-interest in the larger interests of public health. And the most powerful tool for achieving this end remains that of a threat by the state to impose a compulsory license. As the Thai Government explained in a White Paper, for example, the goal behind its recent barrage of compulsory licenses was to move the relevant pharmaceutical companies from a "low volume-high margin" pricing strategy to a "high volume-low margin" alternative approach.⁶¹

A complementary strategy might focus on building price discrimination tools into the developing countries' pharmaceutical distribution systems, with a view to enabling more rational policies. Most commentators neglect this question, but if the U.S. can maintain many levels of pharmaceutical price discrimination,

perhaps developing countries could achieve two or three.⁶² In Mexico, for example, Professor Outtersson suggests that three distinct markets could be segmented: the elite private insurance markets, the Seguridad Social system for those working in the formal economy, and the public health system for the remaining citizens.⁶³

2. USING COMPULSORY LICENSES TO REMEDY THE PROBLEM

Governments adopting the compulsory licensing strategy must exercise caution in choosing the legal instruments best suited to accomplishing their goals, in order to withstand both the political and economic pressures they are certain to elicit and to emerge unscathed from any legal action filed against them at the WTO. Here Flynn, Hollis, and Palmedo cast a yearning glance back to the days before 1992, when Canadian law imposed a "license of right" on all patented pharmaceutical products marketed in that country.⁶⁴ Any would-be generic distributor could apply for such a license and, if granted, could produce and market the patented medicine at competitive prices, in return for a four percent royalty that the Commissioner of Patents typically imposed.⁶⁵

The Canadian license of right, which lasted for more than 50 years, undoubtedly helped to establish that country's robust generic industry, although critics contend that it discouraged the establishment of a research-based pharmaceutical sector at the same time. Both the generic industry and any research-based companies must, of course, operate in the shadow of larger U.S. competitors, and under the regulatory constraints of national and provincial public health programs.

In the early 1990s, the Reagan Administration pressed the Canadian government to abandon its license of right scheme, in exchange for a commitment by U.S. producers to contribute a share of their profits to support medical research in Canada.⁶⁶ The Canadian compulsory licensing approach was then formally prohibited by the intellectual property chapter in the North American Free Trade Agreement (NAFTA), whose provisions, in turn, became a blueprint for article 31 of the TRIPS Agreement.⁶⁷

Under the latter provision, a WTO Member government cannot subject whole classes of pharmaceuticals — such as "essential medicines" — to a pre-established compulsory licensing scheme. It must, instead, adopt a case-by-case approach and shape the compulsory license to meet the purpose for which each license was authorized.⁶⁸ Under ordinary circumstances, the license would issue only after a failed negotiation with the rights holder,⁶⁹ and — at least in principle — could

be terminated “if and when the circumstances which led to it cease to exist and are unlikely to recur.”⁷⁰ Any decision to grant such a license must be subject to judicial review (or comparable review by another higher authority),⁷¹ and “adequate remuneration in the circumstances of each case” must be paid.⁷²

Given these legal obstacles to a pure “open access” scheme, Flynn et al. stress the importance of competition law as a viable alternative in many cases.⁷³ While an action sounding in anticompetitive conduct under article 31(k) will require some judicial or administrative process,⁷⁴ a finding of such conduct exempts the government from any need to negotiate with the patent holder, and even from the obligation to confine a compulsory license predominantly for the supply of the domestic market.⁷⁵ The amount of remuneration may also become negligible in such cases, given the punitive aspects of remedying anticompetitive behavior.⁷⁶

However, our authors make resorting to competition law sound much easier than it has so far proved to be for most developing countries. Competition law, as practiced in developed countries, entails complex economic analysis, high transaction costs, and skilled regulators.⁷⁷ Moreover, the E.U. practice, built around measures to prevent abuse of a dominant position, varies considerably from the much less aggressive stance of the U.S. authorities,⁷⁸ which looks for evidence of actual monopolization or intent to achieve it.⁷⁹ Both regimes depend on a complex showing of market power, although long-standing (but increasingly disfavored) common law precedents sounding in patent law still allow U.S. courts to impose compulsory licenses for “misuse of patents” in the absence of market power.⁸⁰

Besides these technical intricacies, there are high-level policy decisions that must be made about the goals of competition law in general, i.e., efficiency or fairness, or some combination of both,⁸¹ and then about the proper relationship to be struck between that version of competition law and the incentives to innovate that flow from the exclusive rights of intellectual property law.⁸² Increasingly, competition law in developed countries is seen, rightly or wrongly, as providing a supportive and complementary role of promoting welfare — one that is consistent with the goals of intellectual property law, rather than a serious restraint upon it.⁸³ This view makes doctrines that override intellectual property rights, such as the “essential facility” doctrine recommended by Flynn et al.,⁸⁴ much harder to obtain in practice than may appear in theory.⁸⁵

Developing countries have lagged behind in the field of competition law, and some, such as China, are just

beginning to explore its possibilities. These countries would be well advised to track early U.S. cases, emphasizing fairness over efficiency;⁸⁶ and to adopt both the “abuse of a dominant position” theory of E.U. law and a flexible doctrine of “patent misuse” historically rooted in U.S. patent law, which could reach refusals to deal, excessive prices, and undersupply of the market, without a showing of market power.⁸⁷ But such measures must be applied equally to domestic firms as to foreign firms,⁸⁸ without discrimination, and therein lies a serious rub.

While competition law can provide useful tools in appropriate cases, developing countries envisioning a need for compulsory licensing of patented pharmaceuticals should look to other tools not explored by our authors that lie outside competition law. One is the Waiver (and, eventually, Amendment scheme under pending article 31*bis* of the TRIPS Agreement), which enables developing countries without manufacturing capacity to implement compulsory licenses with the aid of countries that do possess such capacity, a topic already mentioned above.⁸⁹ A second tool worth exploring is the Belgian model also identified above, which facilitates compulsory licensing in the interest of public health under articles 8 and 30 of the TRIPS Agreement, rather than article 31 as such. While the legality of this route has yet to be tested by WTO tribunals,⁹⁰ the modalities it offers arguably remain consistent with TRIPS, so long as the preconditions of article 31 are largely observed in practice.

B. A Sympathetic Skeptic

In his contribution,⁹¹ Professor Robert Bird sympathizes with the more than 1.7 billion people who have little or no access to essential medicines.⁹² He recognizes that, by their growing reliance on compulsory licensing, developing countries have begun to lower prices below those the patent owner would otherwise charge, thereby “potentially saving millions of lives and improving the public health of dozens of nations.”⁹³ His skepticism stems from concerns that the social costs of such licenses — what he calls “secondary effects” — may “negate any benefits from increased access.”⁹⁴

Chief among the social costs warranting such concern are:

- A risk of diminished direct investment in countries that resort to compulsory licensing because patent owners will seek out more business-friendly legal environments;
- A risk that those who obtain compulsory licenses will “shadow price” the patentees and thus generate deadweight loss of their own in pursuit of profits;

- A risk that compulsory licensing will reduce the research-driven pharmaceutical sector's incentives to innovate; and
- A risk that the patentees' governments will retaliate with trade sanctions that could "cripple the economy of the licensing nation."⁹⁵

The bulk of Professor Bird's article then proposes a number of strategies for improving consumer access to medicines at lower social costs, without necessarily relying on the generosity of donors.⁹⁶ To this end, he espouses five strategies to alleviate the social costs of compulsory licensing in developing countries, namely:

- More consultation and collaboration with the originator companies, with a view to preserving an investor friendly climate where possible;⁹⁷
- Narrowly tailored licenses that focus on real public health needs and avoid the appearance of impropriety, and that also ensure consumers actually obtain lower prices;⁹⁸
- The need to focus public opinion on the suffering avoided by those who benefit from lower priced pharmaceuticals;⁹⁹
- The need to lower tariff barriers that still impede imports of patented pharmaceuticals into developing countries;¹⁰⁰ and
- The need to address social and cultural barriers that discourage the use of modern medicines in those countries.¹⁰¹

While it is hard to quarrel with Professor Bird's five-pronged strategy, or the empirical evidence on which it rests, a degree of caution remains nonetheless in order.

Consultation and collaboration with originator pharmaceutical companies only become feasible when the latter are willing to negotiate. The patent-holding drug companies lack an incentive to negotiate so long as there are no clear legal sanctions with which to threaten them in case of refusals to deal. Negotiations are likewise less likely if powerful governments, such as the United States, are prepared to retaliate with trade sanctions and other economic pressures (most of which are illegal under international law)¹⁰² when developing countries actually utilize TRIPS flexibilities.

The climate for negotiations does seem more favorable now than it was in the recent past. But this greater willingness to negotiate is partly because the multilateral system has devised a set of legal tools that states can use to lower prices, beyond price controls, which though perfectly legal under TRIPS, are seldom

employed by developing country governments. Professor Bird also recognizes that the new tools make pooled procurement strategies both feasible and desirable (as Fred Abbott and I have been at pains to show),¹⁰³ and I shall return to this theme later on.

One must also be wary of criticizing governments for over-extending the range of their medical concerns, lest one fall into the trap of thinking that people in developing countries do not suffer from the same Type I diseases as those that burden developed countries. The opposite is true, as Professor Outterson points out,¹⁰⁴ because studies show just how heavy the incidence of such diseases, including heart disease, really is in many developing countries. The difference does not lie in the disease burden as such, but in the means available to cope with it.

As Outterson demonstrates, for example, high patent prices charged for Type I diseases in developed countries are ameliorated by "private and social insurance mechanisms, relatively high per capita incomes, and (in some cases) government monopsony procurement;" whereas in low and middle income countries, "[p]atent-based pricing denies access to the majority of direct purchasers."¹⁰⁵ Hence, the Thai government issued a compulsory license on Plavix when the manufacturer allegedly refused to deal, on the grounds that people in Thailand suffer from heart disease just as they do in the United States.¹⁰⁶ By the same token, one may ask why 90 percent of Egyptian males should be denied access to life-improving drugs, such as Viagra, so that exorbitant profits can be extracted from the most affluent 10 percent in that country.¹⁰⁷

Professor Bird rightly argues that efforts to reduce the prices of any medicines in the interest of public health must be accompanied by a scrupulous "clean hands" approach that ensures the drugs will actually be distributed at the lowest profitable prices, with adequate compensation to the patentees. The level of compensation was questionable in the Thais' treatment of Plavix,¹⁰⁸ the compulsory license on Viagra in Egypt was tainted by the appearance of impropriety and self dealing,¹⁰⁹ and complaints about "shadow pricing" in some Latin American countries merit serious attention.¹¹⁰

While all developing countries would benefit from Professor Bird's five-pronged strategy when considering the use of compulsory licenses on patented medicines, his higher level concerns about negative impacts on foreign direct investment, about diminished incentives to invest in innovation, and about the risks of retaliation all require a more nuanced response. Because the article by Kristina Lybecker and Elisabeth Fowler raises these same concerns more vigorously, I

prefer to address them below in connection with comments on that study.

C. Views of the Hostile Sympathizers

In their contribution to this Symposium,¹¹¹ Lybecker and Fowler express sympathy for compulsory licenses that are “invaluable when used to address healthcare emergencies or remove technological supply bottlenecks” in developing countries.¹¹² However, they devote most of their article to denigrating Thailand’s use of compulsory licenses, which they deem ill considered and illegitimate, while faintly praising Canada’s own admittedly contorted efforts to implement the Waiver provisions of the Doha Ministerial Declaration as at least maintaining a higher degree of legitimacy. In short, they are decidedly hostile to much current practice and the legal reasoning that supports it.

At the outset, the basis for comparing Thailand’s and Canada’s use of compulsory licenses is open to question. Thailand acted to obtain lower cost supplies of AIDS and cardiovascular medicines for its domestic markets. Canada used its compulsory license to meet Rwanda’s need for AIDS drugs under the Waiver.¹¹³

In this scenario, Canada is at best a Good Samaritan *manqué*, whose actions have zero impact on the Canadian market for the goods in question. Its authorities remain free to allow Canada’s generic industry to assist Rwanda or not, at some or no profit, as the participants deem fit, without incurring any of the pressures and costs that would derive from a need to address Canada’s own public health problems. At most, one may observe that Canada’s action to assist Rwanda will perhaps adversely affect the patentee’s global market expectations for sales of its AIDS product,¹¹⁴ and that this constitutes a common denominator underlying the two situations. All the same, Thailand’s concerns to meet its own public health needs by such means do not strike me as truly parallel with Canada’s concerns to be a Good Samaritan. One must accordingly remain wary of drawing conclusions from a comparison of these two scenarios, even if they were depicted in a factually accurate manner.

Unfortunately, the authors tend to accept the pharmaceutical industries’ views of both the facts and the law as they pertain to Thailand, without sufficient attention to contrary evidence. For example, more peer-reviewed evidence would be advisable to claim that Thailand’s quality standards were so low that they endangered AIDS patients by exposing them to drug-resistant strains of the disease.¹¹⁵ Without such evidence, one is left to wonder if the drug resistance rates in Thailand were dissimilar from those in, say, Malawi, where FDA-approved drugs are available, or for that matter, in certain more developed countries,

where resistance has been encountered despite the use of drugs meeting the highest quality standards.

The authors also question the sincerity of the Thai government’s stated goal of reducing the costs of drugs supplied under its public health program and thereby to promote universal access to essential medicines. Echoing spokesmen for the industry, this criticism stems from the claim that the government-owned producer turned a “profit” on the products it distributed.¹¹⁶ Yet, as Abbott and Reichman reported, when the authorities issued a government use license for efavirenz, “Merck’s price was approximately double that of the Indian generic price,” although Merck later offered a price about 20 per cent above the Indian generic.¹¹⁷ The Thai government expected to reduce the price of Kaletra to about 20 per cent of Abbott Laboratories’ current price, and it hoped “to reduce its costs for clopidogrel (Plavix) by a factor of 10.”¹¹⁸ These products are all distributed “through publicly funded government organizations” (which aim to provide universal access to HIV-AIDS treatment in that country). Thailand’s soaring expenditures on public health “now constitute approximately 10% of the total government budget.”¹¹⁹ In this context, claims of “profit” appear tendentious without proof that the funds in question did not benefit the public health sector as a whole.

To their credit, Professors Lybecker and Fowler recognize some of the infirmities in Canada’s Access to Medicines Regime (CAMR), which was enacted ostensibly to enable Canadian generic drug manufacturers to assist poor countries obtain medicines they could not manufacture, under authority of the Waiver to (and, eventually Amendment of) article 31 of the TRIPS Agreement. For example, they criticize “the layers of bureaucracy and technicalities” (not required by TRIPS) “that it takes to work through the legislation,”¹²⁰ obstacles that took Apotex about three years to ship a modest supply of AIDS drugs to Rwanda and convinced the firm not to repeat the experience in the future.

Passed over in silence, however, is the fact that the Canadian Act limited would-be local suppliers of foreign needs to 57 drugs or vaccines, mostly concerning AIDS, and most of those already available in generic form. As Outtersen elsewhere explains, “Almost all of the other drugs on the list are off-patent or face legal generic competition in a similar form.”¹²¹ The very narrow list of drugs available under the CAMR thus “operates as a disease-specific limitation on compulsory licensure under Paragraph 6” of the Doha Declaration,¹²² even though that Declaration clearly supports the use of compulsory licensing “without regard to the type of disease.”¹²³ In contrast, the European Union, spurred by vigorous Parliamentary oversight,

adopted a comprehensive implementing Regulation¹²⁴ that appears to successfully incorporate most of the flexibilities available to WTO Members in making use of the Waiver Decision.¹²⁵

Professors Lybecker and Fowler nonetheless praise the Canadian regime for its "legitimacy," while castigating Thailand's approach as a "controversial and possibly abusive Thai regime, both of which operate under the same WTO rules."¹²⁶ In their eyes, "CAMR can be viewed as a success in that safe, effective and less expensive medicines were eventually shipped to Rwanda,"¹²⁷ whereas Thailand's regime (apart from questions of product quality) appropriates patented products, such as Plavix, and is "more difficult to understand as the public health necessity the Thai government has described." Therefore, Thailand's "expansion of the compulsory licensing program weakens the international health community's consensus on the policy and could strip Article 31 of all future legitimacy."¹²⁸ In promoting "industrial policy" rather than access to medicines, they conclude, this regime violates both the letter and spirit of WTO law.¹²⁹

These assertions reflect the influence of industry propagandists, who relentlessly misinterpret the few TRIPS provisions that escaped their control while insisting on strict compliance with all the rest. In reality, there are no disease-specific restrictions under either Article 31 or the Doha Declaration and its implementing measures.¹³⁰ Nor is there any requirement of a "national emergency" to justify recourse to a compulsory license. All that an emergency adds is the power of WTO Members to waive the duty to negotiate with the patentee under article 31(b),¹³¹ which applies under ordinary circumstances. For that matter, article 31(b) also dispenses with the duty to negotiate with patentees in the event that the WTO Member issues a government use license, rather than a public-interest license open to the private sector,¹³² which is exactly the path that Thailand chose to follow.¹³³ Indeed, a government use license is the route normally preferred by the pharmaceutical industry because it can avoid (and did avoid, according to Thai authorities) disrupting private-sector distribution channels not financed by the government.¹³⁴

In short, the Thai approach was a perfectly "legitimate" exercise of the State's powers under the TRIPS Agreement, with a possible caveat for the low royalty paid the patentees (not mentioned by Lybecker and Fowler), which the Thai authorities claim was left open for negotiations that the patentees declined to undertake.¹³⁵ No similar cloak of legitimacy can, however, be extended to the U.S. reprisals against Thailand which — as we shall see in a moment — appear

directly in conflict with both the letter of WTO foundational law and an actual decision against the U.S. by a duly constituted WTO tribunal.¹³⁶

D. The Big Picture Items

Disregarding these legal inaccuracies, Lybecker and Fowler raise a number of policy issues that overlap to some extent with Professor Bird's own evaluation. Here the major concerns that merit a fuller appreciation are the potential loss of foreign direct investment (FDI) that compulsory licensing may engender; a corresponding reduction of incentives to invest in innovation; the need for cooperative rather than confrontational approaches to the public health problems

There is something intriguing about these threats to withhold new pharmaceutical products, or to withdraw from the territory, that merits deeper reflection.

at issue; and the risk of retaliation against developing countries that continue to implement these TRIPS flexibilities. Let me end this Comment by briefly considering these issues one by one.

I. POTENTIAL LOSS OF FDI AND INVESTMENT OPPORTUNITIES

Professors Bird, Lybecker, and Fowler all express concerns that, when faced with the risk of compulsory licensing, pharmaceutical companies may vote with their feet. For example, patent-holding drug companies may cancel or reduce planned investments in the area,¹³⁷ decline to bring new products to the country in question,¹³⁸ or even withdraw from the territory altogether, as was threatened in both South Africa¹³⁹ and Thailand.¹⁴⁰

In approaching this issue, let us first note the evidence showing that there is no clearly defined or established relation between the level of intellectual property protection a developing country provides and FDI. Some countries, such as China, attracted massive amounts of FDI, despite woefully inadequate intellectual property protection, because the market opportunities and other conditions remained irresistible.¹⁴¹ Other poor countries, with little to offer in the way of comparable economic opportunities, attract virtually no FDI despite patent laws that sometimes afford more protection than that of the United States.¹⁴²

This said, there is something intriguing about these threats to withhold new pharmaceutical products, or to withdraw from the territory, that merits deeper reflection. Consider, for example, what might happen if similar threats were carried out against Ruritania, whose government is assumed to possess legal expertise and a measure of political independence for present purposes. First, the Ruritanian health authorities would immediately understand that all new pharmaceutical products not the subject of local patent applications had fallen into the public domain by definition.¹⁴³ The authorities would thus remain free to reverse-engineer the relevant molecular entities in private laboratories or at their universities, as supplemented where necessary by hiring outside technical experts in order to obtain the key active ingredients.¹⁴⁴

Once the molecule was successfully reverse-engineered, the Health Ministry could tender bids to generic producers anywhere in the world — including Brazil, India, and China — to establish plants in Ruritania for production of the drug in question. These producers could arguably supply both the local population and, as exporters of legitimate parallel drugs unfettered by patents, any country in the rest of the world that had adopted a policy of international exhaustion (which remains perfectly consistent with article 6 of the TRIPS Agreement). More importantly, Ruritania could also export these drugs to any other country that, lacking manufacturing capacity of its own, had issued a compulsory license for them under the Waiver machinery of the Doha Declaration.¹⁴⁵

Of course, the market in Ruritania might afford insufficient economies of scale to attract such investment, although that apparently was not the case in Egypt or Thailand, where disgruntled foreign pharmaceutical companies canceled similar investments.¹⁴⁶ In that event, Ruritania, as a WTO Member without manufacturing capacity, could appeal to any other Member having that capacity for assistance under the Waiver to article 31 of the TRIPS Agreement.¹⁴⁷ Such an appeal would be administratively simpler to handle than was the case with Rwanda, because it would require only one compulsory license — in the exporting country — rather than back-to-back compulsory licenses in two countries, as the Waiver would normally entail.

Either way, a determined Ruritania appears likely to obtain the drugs, and possibly the capacity to compete with the originator company in third markets as well, while the originator company would lose its foothold in Ruritania and, perhaps, tarnish its image there and throughout the developing world. All this because the originator company had been unwilling to supply the drug at profit-making prices that a large percentage

of the population could afford instead of at monopoly prices that only the richest elite could afford.¹⁴⁸

At this point, the reader may well begin to ask who is threatening whom? Let us return to this question when we discuss the advantages of a cooperative, rather than a confrontational, approach below.¹⁴⁹

2. REDUCING INCENTIVES TO INNOVATE

Most informed observers agree that investing in pharmaceutical R&D is a very risky business, which is the principle justification offered for strong pharmaceutical patents. So Bird, Lybecker, and Fowler logically worry about lessening those incentives by exposing originator firms to the risk of compulsory licenses (i.e., *ex post* liability rules, in the form of a reasonable royalty) in place of the *ex ante* exclusive rights they had initially planned to exploit.¹⁵⁰

In reality, as Professor Outtersson and others have demonstrated, investment in cures for Type I diseases are geared to developed country markets and not to potential returns from developing countries, at least at the present time. The value of markets for these drugs in most poor countries remains relatively so low — compared to conditions in, say, the U.S. and E.U. — that Outtersson envisions a “buy out” scheme that would enable patent-free distribution in poor countries, side-by-side with monopoly pricing in OECD countries.¹⁵¹ In short, and under present-day conditions, the issuance of compulsory licenses on Type I medications in poor countries would have virtually no impact on incentives to innovate in rich countries.¹⁵²

Over time, however, the emergence of major middle-income markets, such as those in India, China, and Brazil, could increasingly affect incentives to invest in such drugs by expanding the potential for long-term aggregate revenues.¹⁵³ That prospect is another reason why big originator companies will likely invest in local production in those countries anyway, despite policies to ensure broader access to medicines that their governments may pursue. One way forward is to permit the drug companies to retain the elite markets in these poor countries, and to focus access proposals on the public sectors. In Brazil, for example, branded AIDS drugs are sold to the privately insured, despite the fact that any Brazilian may receive them for free at public clinics. The wealthy seldom frequent public clinics, and are willing to pay more for the branded drugs.

Professors Lybecker and Fowler express concerns about R&D pertaining to tropical, neglected, and other diseases prevalent in poor developing countries.¹⁵⁴ There is virtually no investment in cures for such diseases by the major research-driven companies that compulsory licensing could discourage.¹⁵⁵ On the contrary, the hope for treating these diseases

rests on public-private collaborations, funded largely by donors, in which big pharmaceutical companies have laudably participated for humanitarian reasons, with mixed results thus far.¹⁵⁶ This collaborative process may benefit from compulsory licensing machinery when some particular patented component blocks collective action, rather than the other way around.¹⁵⁷

In the future, one may imagine private research-based pharmaceutical industries in certain developing countries turning their attention to tropical, neglected, and poverty-related diseases, in the hopes of financial gain, and they may also seek to adapt cures for Type I and Type II diseases to developing world conditions. In that event, the use of compulsory licenses must be handled with care to ensure that incentives were maintained by means of a suitable correlation between risk and profit. If and when that eventuality should materialize, one might also dare to hope that the very firm that had invested in such projects might be inclined to market the resulting medicines on a "high-volume, low profit margin" basis, for the benefit of both private and public interests, in which case compulsory licensing would become superfluous.¹⁵⁸

3. THE ADVANTAGES OF COLLABORATIVE ACTION

Professors Bird, Lybecker, and Fowler rightly emphasize the need for a more collaborative approach to the issues that surround compulsory licensing, and both articles point to the advantages of a pooled procurement strategy, which Professor Abbott and I have recently explored in depth.¹⁵⁹ Without delving deeply into this topic here, let me stress in passing that the legal machinery adopted under the aegis of the Doha Declaration serves to promote, rather than to hinder, this very sort of collaboration.

If a number of developing countries pooled their procurement needs by coordinating the potential use of compulsory licenses for selected medicines, they could generate economies of scale and scope to entice even the originator pharmaceutical companies to play ball with them, rather than against them. The carrot in such a scenario is the possibility for the originator company to exercise its exclusive rights, including trademarks, over a suitably large area that would make it worth their while to collaborate even at discounted prices. Ideally, incentives can be calibrated to provide still greater rewards to those originator companies willing to invest in local production facilities serving the areas or countries that had coordinated their procurement needs.¹⁶⁰ Local production, in turn, implants know-how into the local community, and it tends to stimulate both capacity for — and commercial interest in — conducting research on diseases of

local importance, with the possible use of indigenous resources.¹⁶¹

By the same token, originator companies unwilling to cooperate in a pooled procurement strategy would run the risk that the potential market for the drugs in question could be handed over to investors from other developing countries. If that occurred, it would provide the coordinating countries with many of the same advantages that would otherwise accrue from cooperation with the originator companies. In other words, pooled procurement strategies under the aegis of the Doha Declaration could produce a win-win situation for all concerned, in which the overall goal was that envisioned by Flynn, Hollis, and Palmedo, namely, to make medicines available at prices most people in developing countries could afford, and not just a privileged few.¹⁶²

4. THE RISK OF RETALIATORY ACTION

Meanwhile, living as we do in a more confrontational climate, one must remain acutely aware of the risks that powerful governments may retaliate against developing countries that press their rights under the Doha Declaration by issuing compulsory licenses on patented medicines. Both Bird and Lybecker emphasize these risks,¹⁶³ with Thailand as a case in point. Not only did USTR place Thailand under the 2007 Special 301 "Priority Watch List Surveillance,"¹⁶⁴ it threatened to terminate Thailand's Generalized System of Preferences (GSP) privileges to export certain products to the U.S. at low or no tariffs, in retaliation for its resort to the compulsory licenses in question.¹⁶⁵

At the outset, it is well to acknowledge that we cannot infuse public officials in developing countries with the courage to defend themselves if they are unwilling to do so. What can, and should be said, is that governments ought not to contemplate issuing compulsory licenses on patented pharmaceuticals unless they are prepared to stand up for their legal rights; and if they do stand up for those rights, then it is the retaliating state — not the victims — who will most likely be found to violate WTO rules.

Article 23 of the WTO Dispute Settlement Understanding (DSU) obliges Members to seek redress for alleged violations of the WTO Agreement, including its TRIPS component, by means of specified multilateral venues and procedures.¹⁶⁶ Under this provision, if the U.S. authorities believe that a developing country government has abusively issued a compulsory license, they may lawfully haul that country before a WTO dispute settlement panel and state their case, with a right of appeal to the WTO Appellate Body. What USTR cannot legally do is to unilaterally impose sanctions for the loss of

expected trade benefits, as it appears to have done in the case of Thailand.¹⁶⁷ In fact, there is already a WTO panel decision criticizing USTR for past use of Section 301 listings for TRIPS-related matters, and that decision expressly warned that sanctions would likely be authorized if such violations continued in the future.¹⁶⁸

From a legal rather than a political-economic perspective, there is accordingly a greater risk that unilateral retaliatory action will be held in violation of WTO law than that governments issuing compulsory licenses in conformity with the Doha Declaration will themselves incur sanctions under WTO rules. Moreover, if powerful states continue to engage in unilateral retaliations of this sort, they run still another set of legal risks that has thus far been underappreciated. Because such action constitutes a violation of the DSU and of the framework Agreement Establishing the WTO,¹⁶⁹ it would entitle the aggrieved party to all the remedies that the Vienna Convention on the Law of Treaties provides for breach of the relevant agreements.¹⁷⁰ A primary remedy thus provided is the age-old right of self-help implicit in the power of an aggrieved party to suspend its obligations under the treaty in question, pending compensation for breach.¹⁷¹

In sum, if Occitania wrongfully retaliates against Ruritania for issuing a compulsory license, then Ruritania may become entitled to suspend its obligations to protect patented pharmaceuticals under the TRIPS Agreement, with respect to Occitania, until the treaty violation was either purged or compensated. In that event, if Occitania sued Ruritania at the WTO for nullification or impairment of benefits under TRIPS,¹⁷² the likely result would be a vindication of Ruritania's counterclaim that Occitania's unilateral retaliation had violated article 23.1 of the DSU and, thereby, justified Ruritania's own self-help defensive action.

There is little reason to suppose that the new administration in Washington will change pre-existing intellectual property policies, given that it continues to draw considerable support from those industries that obtained such policies from the Clinton and Bush administrations. Nevertheless, the new administration has expressed serious concern to promote the rule of law in international relations, unlike its immediate predecessor. If so, there is hope that it will take steps to avoid the dubious legal position and corresponding risk of sanctions to which unilateral retaliatory action necessarily exposes it.

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5. *Id.* (TRIPS), at art. 65-66, 70; World Trade Organization, *Declaration on the TRIPS Agreement and Public Health*, November 20, 2001, WT/MIN(01)/DEC/2, at para. 4, available at <http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm> (last visited April 17, 2009) [hereinafter cited as Declaration on TRIPS]. From this date on, developing countries were required to provide at least 20 years of patent protection to a broad range of products, including pharmaceutical products, and mailboxes with pending patent applications were opened and began being processed. A few least-developed countries (LDCs) remain exempt from protecting patents until 2013 and patents on pharmaceuticals until 2016. See *Extension of the Transition Period Under Article 66.1 for Least-Developed Country Members*, Decision of the Council for TRIPS of 19 November 2005, WTO doc. IP/C/40, November 30, 2005; *Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products*, Decision of the Council for TRIPS of 27 June 2002, WTO doc. IP/C/25, July 1, 2002.
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8. See J. Watal, *Intellectual Property Rights in the WTO and Developing Countries* (Boston: Kluwer Law International, 2002): at 33-44.

9. Compare Paris Convention, *supra* note 1, at art. 5A, with TRIPS, *supra* note 4, art. 31; see Reichman and Hasenzahl, *supra* note 2.
10. See TRIPS, *supra* note 4, at art. 31(b).
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20. See *id.* (Abbott & Reichman), at 937.
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23. See TRIPS, *supra* note 4, at art. 31(h). See generally A. Taubman, "Rethinking TRIPS: 'Adequate Remuneration' for Non-Voluntary Patent Licensing," *Journal of International Economic Law* 11, no. 4 (2008): 927-970.
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27. *Id.*; see Abbott and Reichman *supra* note 19, at 929.
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42. See Debrulle et al., *supra* note 14, at 159 and 163.
43. *Id.*, at 171; but see *infra* note 90.
44. See van Zimmeren and Requena, *supra* note 14, at 137.
45. See Love, *supra* note 38, at 10-11. For details see R. Coco and P. Nebbia, "Compulsory Licensing and Interim Measures in Merck: A Case for Italy or for Antitrust?" *Journal of Intellectual Property Law & Practice* 2, no. 7 (2007): 452-462.
46. S. Castle and J. Kanter, "European Antitrust Regulators Raid Drug Companies," *International Herald Tribune*, January 16, 2008, available at <<http://www.iht.com/articles/2008/01/16/business/drug.php>> (last visited March 7, 2009); DG Compe-

- tion, *Pharmaceutical Sector Inquiry: Preliminary Report*, November 28, 2008, available at <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf> (last visited March 7, 2009).
47. For a view consistent with that of the patent-based drug industry, see P. M. Danzon and A. Towse, "Differential Pricing for Pharmaceuticals; Reconciling Access, R&D and Patents," AEI-Brookings Joint Center for Regulatory Studies, Working Paper No. 03-7, 2003, at 28-29, available at <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=422821> (last visited April 21, 2009). For a synthesis more attuned to the problems of access, see K. Outterson, "Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets," *Yale Journal Health Policy, Law & Ethics* 5, no. 1 (2005): 193-291 [hereinafter cited as *Pharmaceutical Arbitrage*].
 48. K. Outterson and A. Kesselheim, "Market-Based Licenses for HPV Vaccines in Developing Countries," *Health Affairs* 27, no. 1 (2008): 130-139, at 136-137.
 49. F. M. Scherer, "A Note on Global Welfare in Pharmaceutical Patenting," *World Economy* 27, no. 27(2004): 1127-1142, at 1141.
 50. Gilead has announced a policy of price discrimination for major AIDS products that has elicited complaints from other companies. See D. P. Baron, K. Krehbiel, and B. Tayan, *The Gilead Access Program for HIV Drugs*, 2007.
 51. See TRIPS, *supra* note 4, at art. 6; Declaration on TRIPS, *supra* note 5, at par. 5(d).
 52. P. M. Danzon and A. Towse, "Theory and Implementation of Differential Pricing for Pharmaceuticals," in K. E. Maskus and J. H. Reichman, eds., *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime* (Cambridge: Cambridge University Press, 2005): at 425. See also G. Duffield, "Delivering Drugs to the Poor: Will the TRIPS Amendment Help?" *American Journal of Law & Medicine* 34, nos. 2-3 (2008): 107-124, at 114 (citing authorities). The term "reference pricing" is somewhat confusing as it also applies to pricing mechanisms within wealthy countries. An alternative term is "virtual arbitrage." See Outterson, *supra* note 47, at 283.
 53. J. A. DiMasi, R. W. Hansen, and H. G. Grabowski, "The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics* 22, no. 2 (2003): 151-185; see also J. H. Reichman, "Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach," *Marquette Intellectual Property Law Review* 13, no. 1 (2009): 1-68, at 9-11 (citing authorities with different estimates).
 54. See Danzon and Towse, *supra* note 52, at 445.
 55. S. McElligott, "Addressing Supply Side Barriers to Introduction of New Vaccines to the Developing World," *American Journal of Law & Medicine* 35 (forthcoming 2009).
 56. See Flynn et al., *supra* note 15.
 57. *Id.*
 58. *Id.*
 59. *Id.* While relatively few countries may fit the 10-90 matrix of South Africa, the principle could apply equally to other countries where the relevant matrix was 20-80 or 30-70, rather than 10-90.
 60. *Id.*
 61. The Ministry of Public Health & The National Health Security Office Thailand, *Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand*, at 14-15, available at <www.moph.go.th/hot/White Paper CL-EN.pdf> (last visited April 23, 2009); see Abbott and Reichman, *supra* note 19, at 953.
 62. See Outterson, *supra* note 47 at 203-216, 232-235.
 63. Personal communication with Professor Kevin Outterson, March 10, 2009.
 64. See Flynn et al., *supra* note 15.
 65. For details, see J. H. Reichman with C. Hasenzahl, *Non-Voluntary Licensing of Patented Inventions: The Canadian Experience*, UNCTAD/ICTSD Project on IPRs and Sustainable Development, October 2002, at 37-38; see also D. G. McPetridge, Intellectual Property, Technology, Diffusion and Growth in the Canadian Economy, in R. D. Anderson and N. T. Gallini, eds., *Competition Policy and Intellectual Property Rights in the Knowledge Economy* (Calgary: University of Calgary Press, 1998): at 65.
 66. *Id.* (Reichman with Hasenzahl), at 38-44. Industry Canada has, at various times, expressed satisfaction with the results of this arrangement.
 67. *Id.*, at 42-43; see North American Free Trade Agreement, Canada-U.S.-Mexico, at ch. 17, December 17, 1992, 32 *I.L.M.* 605 (1993) [hereinafter NAFTA].
 68. See TRIPS, *supra* note 4, at arts. 31(a), (c).
 69. *Id.*, at art. 31(b). This provision is waived in the case of national emergency, other circumstances of extreme urgency or in cases of governmental use. *Id.*
 70. *Id.*, at art. 31(g). For example, an abusive use of a patent could be purged, allowing a claim to void such a license.
 71. *Id.*, at art. 31(j).
 72. *Id.*, at art. 31(h). The remuneration must take "into account the economic value of the authorization." *Id.* See also J. Love, *Remunerations Guidelines for Non-Voluntary Use of a Patent on Medical Technologies*, WHO/TCM/2005.1, 2005, available at <http://www.who.int/medicines/areas/technical_cooperation/WHOTCM2005.1_OMS.pdf> (last visited April 23, 2009); see also Taubman, *supra* note 23.
 73. See Flynn et al., *supra* note 15.
 74. See TRIPS, *supra* note 4, at art. 31(k).
 75. *Id.*
 76. *Id.*
 77. See, e.g., H. J. Hovenkamp, "The Intellectual Property-Antitrust Interface," University of Iowa College of Law, Legal Studies Research Paper No. 08-46, 2008, at 1979-2007, available at <<http://ssrn.com/abstract=1287628>> (last visited April 23, 2009); E. M. Fox, "Can Antitrust Policy Protect the Global Commons from the Excesses of IPRs?" in K. E. Maskus and J. H. Reichman, eds., *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime* (Cambridge: Cambridge University Press, 2005): at 758,758-769.
 78. See, e.g., E. Arezzo, "Intellectual Property Rights at the Crossroad between Monopolization and Abuse of a Dominant Position: American and European Approaches Compared," *John Marshall Journal of Computer & Information Law* 24, no. 3 (2006): 456-494.
 79. See, e.g., Fox, *supra* note 77, at 759-64; H. Ullrich, "Expansionist Intellectual Property Protection and Reductionist Competition Rules: A TRIPS Perspective," in K. E. Maskus and J. H. Reichman, eds., *International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime* (Cambridge: Cambridge University Press 2005): at 726, 726-757.
 80. See Hovenkamp, *supra* note 77, at 1991; *Illinois Tool Works v. Indep. Ink*, 126 Sup. Ct. 1281 (2006); see also T. F. Cotter, "Misuse," *Houston Law Review* 44, no. 4 (2007): 901-964; M. D. Janis, "Minimal" Standards for Patent-Related Antitrust Law under TRIPS," in K. E. Maskus and J. H. Reichman, eds., *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime* (Cambridge: Cambridge University Press, 2005): 774, 790-792.
 81. See, e.g., Fox, *supra* note 77, at 758; Ullrich, *supra* note 79, at 726.
 82. See, e.g., G. Ghidini, *Intellectual Property and Competition Law: The Innovation Nexus* (Cheltenham: Elgar, 2006): 103-111.
 83. See *supra* note 77; J. Drexel, "The Critical Role of Competition Law in Preserving Public Goods in Conflict with Intellectual Property Rights," in K. E. Maskus and J. H. Reichman, eds., *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime* (Cambridge: Cambridge University Press, 2005): at 709-725.

84. See Flynn et al., *supra* note 15.
85. See, e.g., R. Coco, "Antitrust Liability for Refusal to License Intellectual Property: A Comparative Analysis and the International Setting," *Marquette Law Review* 12, no. 1 (2008): 10-21 (citing authorities).
86. See Fox, *supra* note 77, at 768.
87. See Paris Convention, *supra* note 1, at art. 5A; G. H. C. Bodenhausen, *Guide to the Application of the Paris Convention for the Protection of Industrial Property, as Revised at Stockholm in 1967*, 1968, at 71. However, current precedents governing misuse in the U.S. may no longer support such outcomes. See Hovenkamp, *supra* note 77, at 1091-1095; Reichman with Hasenzahl, *supra* note 2; Cotter, *supra* note 80.
88. See TRIPS, *supra* note 4, at art. 3, 8.2, 40; Paris Convention, *supra* note 1, at art. 2(1).
89. However, for the disappointing story of the first attempt to use the Waiver, see Goodwin, *supra* note 29.
90. For an existing WTO panel decision that casts doubt on efforts to use art. 8 of the TRIPS Agreement to expand the limited exceptions to a patentee's exclusive rights under art. 30 of that Agreement, see Canada-Patent Protection of Pharmaceutical Products, WT/DS114/R, March 17, 2000.
91. R. C. Bird, "Developing Nations and the Compulsory License: Maximizing Access to Essential Medicines while Minimizing Investment Side Effects," *Journal of Law, Medicine & Ethics* 37, no. 2 (2009): 209-222.
92. *Id.*, at 1 (citing World Health Organization, The World Medicines Situation at 61 (2004)).
93. *Id.*
94. *Id.*
95. *Id.*
96. *Id.*
97. *Id.*
98. *Id.*
99. *Id.*
100. *Id.*
101. *Id.*
102. See *infra* text accompanying notes 166-172.
103. See Abbott and Reichman, *supra* note 19, at 973-980; see *infra* text accompanying notes 159-160.
104. See Outterson, (*Access to Medicine and TRIPS*), *supra* note 21, at 289-91.
105. *Id.*, at 296.
106. See Abbott and Reichman, *supra* note 19, at 952, 954-956.
107. See Flynn et al., *supra* note 15; Bird, *supra* note 91.
108. See *infra* note 135 and accompanying text.
109. See Bird, *supra* note 91.
110. *Id.*
111. See Lybecker and Fowler, *supra* note 33.
112. *Id.*
113. See Goodwin, *supra* note 29, at 2.
114. Compare Abbott and Reichman, *supra* note 19, at 957.
115. See Lybecker and Fowler, *supra* note 33.
116. *Id.*
117. See Abbott and Reichman, *supra* note 19, at 953.
118. *Id.*
119. *Id.*, at 952.
120. See Lybecker and Fowler, *supra* note 33.
121. See Outterson (*Access to Medicine and TRIPS*), *supra* note 21, at 282.
122. *Id.*
123. *Id.* (citing Declaration on TRIPS, *supra* note 5, at para. 4, 5[b], 5[c], 5[d]; U.S. Gen. Accounting Office, GAO Report 07-1198, U.S. Trade Policy Guidance on WTO Declaration on Access to Medicines May Need Clarification 15, 19, 23, September 2007); accord Abbott and Reichman, *supra* note 19, at 936-37 (citing Paragraph 6 Decision, *supra* note 22; Amendment of TRIPS, *supra* note 22).
124. Regulation (EC) No. 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.
125. See Abbott and Reichman, *supra* note 19, at 947.
126. See Lybecker and Fowler, *supra* note 33.
127. *Id.*
128. *Id.*
129. *Id.*
130. See *supra* note 123 and accompanying text; see also Outterson, (*Access to Medicine and TRIPS*), *supra* note 21.
131. See TRIPS, *supra* note 4, at art. 31(b).
132. *Id.*
133. See Abbott and Reichman, *supra* note 19, at 952. The extent to which negotiations actually occurred is disputed by both sides.
134. See *id.*, at 953.
135. *Id.*, at 952-953 (noting compensation at 0.5%).
136. See *infra* notes 166-172 and accompanying text.
137. See, e.g., Bird, *supra* note 91 (case of Pfizer with respect to Viagra in Egypt).
138. See, e.g., Lybecker and Fowler, *supra* note 33 (case of Abbott Laboratories in Thailand).
139. See Bird, *supra* note 91.
140. See Lybecker and Fowler, *supra* note 33.
141. See, e.g., P. Yu, "Intellectual Property, Economic Development, and the China Puzzle," in D. Gervais, ed., *Intellectual Property, Trade and Development* (Oxford: Oxford University Press, 2007): 173, 176-183.
142. K. E. Maskus, "The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer," *Duke Journal of Comparative & International Law* 9, no. 1 (1998): 109-161, at 129-130.
143. See TRIPS, *supra* note 4, at arts. 2.1 (incorporating Paris Convention arts. 1-12), 27 (novelty); Paris Convention, *supra* note 1, at arts. 2(1) (national treatment), 4bis(1) (independence of patents).
144. The task of reverse-engineering key active ingredients (APIs) nonetheless remains difficult and costly for most developing countries. See, e.g., F. M. Abbott and G. Dukes, *Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World* (Cheltenham: Elgar, forthcoming 2009): at 123-24.
145. See TRIPS, *supra* note 4, at art. 6; Paragraph 6 Decision, *supra* note 22; Abbott and Reichman, *supra* note 19, at 975-976.
146. See e.g., Lybecker and Fowler, *supra* note 33; Bird, *supra* note 91.
147. See *supra* note 22.
148. Compare Flynn et al., *supra* note 15.
149. See *infra* text accompanying notes 159-162; compare J. H. Reichman, "The TRIPS Agreement Comes of Age: Conflict or Cooperation with the Developing Countries?" *Case Western Reserve Journal of International Law* 32, no. 3 (2000): 441-470.
150. See Lybecker and Fowler, *supra* note 33; Bird, *supra* note 91; A. O. Sykes, "TRIPs, Pharmaceuticals, Developing Countries, and the Doha 'Solution,'" *Chicago Journal of International Law* 3, no. 1 (2002): 47-68. But see Bird, *supra* note 91, noting contrary empirical studies.
151. See, e.g., K. Outterson, "Patent Buy-Outs for Global Disease Innovations for Low- and Middle-Income Countries," *American Journal of Law & Medicine* 32, nos. 2-3 (2006): 159-173, at 161; see also J. O. Lanjouw, *Beyond TRIPS: A New Global Patent Regime*, Brief No. 3, The Center for Global Development, July 2002 (market segmentation); J. Love, *Proposal for Patent Pool for Essential Medicines* (PPEM), Addis Ababa, March 13, 2005.
152. See, e.g., Outterson and Kesselheim, *supra* note 48, at 136-137; Outterson, *supra* note 151.
153. Compare Sykes, *supra* note 150.
154. See Lybecker and Fowler, *supra* note 33.
155. See Outterson and Kesselheim *supra* note 48, at 136-137; Outterson, *supra* note 151, at 159-173.
156. See M. Moran, A.-L. Ropars, J. Guzman, J. Diaz, and C. Garrison, *The New Landscape of Neglected Diseases Drug Development*, 2005, available at <www.thegeorgeinstitute.org/

- shadomx/apps/fms/fmsdownload.cfm?file_uuid=F2B06396-EEA0-851E-3049-C9A030AEDEF&siteName=iih> (last visited April 23, 2009); Drugs for Neglected Diseases Initiative (DNDi), *New, Once-a-Day Fixed-Dose Combination Against Malaria Now Available*, March 1, 2007; DNDi, *MSF and DNDi Call For Scale-Up of R&D For Neglected Diseases*, Press Release, February 23, 2009, available at <http://www.msfaccess.org/media-room/press-releases/press-release-detail/?tx_ttnews%5Btt_news%5D=1535&cHash=86e19504b2> (last visited April 23, 2009); J.-R. Kiechel and B. Pecoul, "Innovative Partnership Brings New ACT Free of Patents," Guest Blog, *PLOS*, February 26, 2007, available at <<http://www.plos.org/cms/node/208>> (last visited April 23, 2009).
157. See, e.g., A. D. So, "Enabling Conditions for the Scientific Commons," paper presented at the Conference on Technology Development in the Life Sciences, Program on Science, Technology and Global Development, The Earth Institute at Columbia University, May 20-21, 2004.
158. See, e.g., Abbott and Reichman, *supra* note 19, at 981-982.
159. *Id.*, at 969-981 ("Making the Amendment System Work").
160. *Id.*, at 973-974.
161. *Id.*, at 977-978. See also J. H. Reichman and T. Lewis, "Using Liability Rules to Stimulate Local Innovation in Developing Countries," in K. E. Maskus and J. H. Reichman, eds., *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime* (Cambridge: Cambridge University Press, 2005): at 337, 337-366.
162. See Flynn et al., *supra* note 15; Abbott and Reichman, *supra* note 19, at 982 ("Changing the Marketing Model").
163. See Bird, *supra* note 91; Lybecker and Fowler, *supra* note 33.
164. See Abbott and Reichman, *supra* note 19, at 954.
165. Food & Drug Letter, *Brazil, Thailand Lose Trading Privileges in Wake of IP Disputes*, August 17, 2007. In 2006, Thailand had \$4.2 billion in GSP qualified exports to the U.S. V. C. Jones, *CRS Report for Congress, Generalized System of Preferences: Background and Renewal Debate*, at Table A2, January 25, 2008, available at <<http://www.nationalaglawcenter.org/assets/crs/RL33663.pdf>> (last visited April 23, 2009).
166. The DSU, *supra* note 6, at art. 23 provides as follows:
 1. When Members seek the redress of a violation of obligations or other nullification or impairment of benefits under the covered agreements or an impediment to the attainment of any objective of the covered agreements, they shall have recourse to, and abide by, the rules and procedures of this Understanding. 2. In such cases, Members shall: (a) not make a determination to the effect that a violation has occurred, that benefits have been nullified or impaired or that the attainment of any objective of the covered agreements has been impeded, except through recourse to dispute settlement in accordance with the rules and procedures of this Understanding, and shall make any such determination consistent with the findings contained in the panel or Appellate Body report adopted by the DSB or an arbitration award rendered under this Understanding; (b) follow the procedures set forth in Article 21 to determine the reasonable period of time for the Member concerned to implement the recommendations and rulings; and (c) follow the procedures set forth in Article 22 to determine the level of suspension of concessions or other obligations and obtain DSB authorization in accordance with those procedures before suspending concessions or other obligations under the covered agreements in response to the failure of the Member concerned to implement the recommendations and rulings within that reasonable period of time.
167. See Abbott and Reichman, *supra* note 19, at 980-81. Freedom from unilateral action is, indeed, a major reason developing countries signed onto the Agreement Establishing the WTO of 1994 in the first place.
168. See Panel Report, United States - Sections 301-310 of the Trade Act of 1974, WT/DS152/R, December 22, 1999; Abbott and Reichman, *supra* note 19, at 980-981. While GSP privileges are not bound by GATT, and therefore remain revocable, one may doubt that this revocation can be used as a unilateral sanction for some alleged violation of TRIPS.
169. See Marrakesh Agreement Establishing the WTO, *supra* note 4, at art. II (2) (DSU is "binding on all Members"); DSU, *supra* note 6, at art. 23 (quoted *supra* note 166).
170. Vienna Convention on the Law of Treaties, UN Doc. A/Conf.39/27, 1155 UNTS 331, 8 *I.L.M.* 679, at art. 60 (1969), available at <http://untreaty.un.org/ilc/texts/instruments/english/conventions/1_1_1969.pdf> (last visited April 23, 2009).
171. *Id.*, at art 60.2.
172. See TRIPS, *supra* note 4, at art. 64.