

# Compulsory Licensing: Models for State Practices in Developing Countries, Access to Medicine and Compliance with the WTO TRIPS Accord

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Third World Network

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is published by  
Third World Network  
131 Jalan Macalister  
10400 Penang, Malaysia

© Third World Network 2004

Printed by Jutaprint  
2 Solok Sungei Pinang 3, Sg. Pinang  
11600 Penang, Malaysia.

ISBN: 983-2729-37-8

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**NOTE:**

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# 1

# INTRODUCTION<sup>1</sup>

This booklet addresses the issue of government authorization to use a patent without the permission of the patent owner. In particular, models for compulsory licensing and government use of patents are examined, as a tool to increase access to medicines in developing countries.<sup>2</sup> The recommendations in this booklet are based on the following facts.

Contrary to much of the debate over the World Trade Organization (WTO) rules for intellectual property, the Trade-Related Aspects of Intellectual Rights (TRIPS) Agreement accord is actually fairly permissive with regard to what is permitted in terms of government decisions to authorize third parties to use patents without the permission of the patent owners.

For example, for public non-commercial use, a country may use or authorize a third party to use a patent without negotiation or without a licence (31.b), the only obligation being the payment of “adequate” compensation (31.h). This approach too can be used for emergencies, including public health emergencies (31.b). When an authorization is to remedy anticompetitive practices, such as high prices from the exercise of monopoly power, the products can even be exported (31.k).

TRIPS also allows countries to make virtually all of its decisions on these issues, including those regarding compensation or appeals, through administrative processes (31.c, 31.i, 31.j, 31.k). Moreover, TRIPS specifically does not require governments to grant injunctive relief to patent holders (44.2) in cases where government authorizations of patent use satisfy the Article 31 framework.

Taken together, these provisions in the existing TRIPS accord permit countries to create very simple and easy to administer systems for permitting production or import of generic products from the competitive sector. However, what TRIPS permits and what countries actually do are two different things, and in the end, it is national law and practice that will be decisive, both in terms of providing access to inventions, including medicines, and in establishing the state practice framework in which TRIPS rules will be interpreted. Also, there remains an important issue with respect to the degree to which countries can tailor their laws to specific concerns regarding access to medicines, due to the Article 27.1 restrictions on discrimination of patent rights by field of technology.

Many governments have good national laws for public use of patents, which is a similar but more direct and less restrictive method of authorizing non-voluntary use of a patent than a compulsory licence. For example, under 28 USC Sec 1498, the US government can use patents or authorize third parties to use patents for virtually any public use, without negotiation.

Patent owners have no rights for injunctive relief, and may only seek compensation, not as a tort, but as an eminent domain taking.<sup>3</sup> This is not unique, however, and the Australian, Irish, Italian, German, New Zealand and UK public use provisions also provide very similar powers, as do several other countries, including the Philippines, Malaysia and Singapore, among others. See below for example of specific national laws on this. TRIPS rules are designed to accommodate these practices.

Compulsory licences have been used extensively in North America, Japan, and Europe for a variety of purposes, including many that have been issued for computers, software, biotechnology and other modern technologies. In 2000 the US issued several compulsory licences for tow truck technologies.

Canada has the most extensive experience with the use of compulsory

licences for pharmaceutical drugs. Until pressured by the US, as a condition to join NAFTA, to abandon a compulsory licensing approach that was nearly automatic, Canada routinely granted compulsory licences on pharmaceuticals, with compensation based upon royalties, typically set at 4percent of the competitor's sales price.

Despite a public health crisis of enormous proportions for HIV/AIDS, apparently no African country has issued a compulsory licence for any medicine. Given the permissive global trade framework for compulsory licensing, one has to wonder why this is so.

Virtually all national patent law systems are modeled after European and US patent legal traditions, often based upon colonial statutes, or the modern day equivalent, laws informed by WIPO technical assistance.

The United States spends \$1 billion annually on its patent and trademark office. Europe and Japan also spend large sums to examine patents. Despite these investments in rich countries, the quality of US patent examinations is poor. According to a study by Lemley and Allison of patents litigated to judgment, 54percent were found to be valid, and 46percent were invalid.<sup>4</sup>

Critics of US patent examinations believe a much larger number of issued patents are not valid under any reasonable tests of utility and invention, and would be busted if the patent owners sought enforcement. Patent examination offices in developing countries, if they exist at all, are understaffed, undertrained and have less access to research materials on prior art.<sup>5</sup>

## Litigation Costs

The costs of litigation are not trivial. In (27 December) 1998, the *New York Times* reported the median cost of US patent litigation was \$1.2 million, per side, and the costs of litigation in complex cases are much higher. In

Polaroid v. Kodak, each side reportedly spent over \$100 million. Consider this quote from a judge in the AZT patent dispute.<sup>6</sup>

"In the twenty-five months transpiring between the filing of the initial complaint in this consolidated patent infringement action on May 14, 1991, and the commencement of the trial on June 28, 1993, approximately five hundred forty-one pleadings have been filed and dozens of hearings on motions and discovery matters have been conducted by the court. The court has entered eighty-eight written orders and numerous bench rulings. Thus, the court is intimately familiar with the facts of this case and the legal contentions of the parties. To state that the case has been hotly contested would be an understatement. The parties have amassed learned, experienced and sizable trial teams who have represented their clients zealously and competently. The administrative complexity [of] conducting a trial of this magnitude has been enormous for the court and the parties. The sixty-year-old courtroom in New Bern, North Carolina, has been converted into a contemporary high tech facility utilizing real time court reporting and six computer-integrated video display monitors. It is highly conceivable that the cost of this trial for the parties exceeds \$100,000 per day, in addition to the time and expense associated with this court and the jury. As the case enters its fourth week of trial, the parties estimate, somewhat conservatively the court suspects, that the trial will last an additional six to eight weeks."

See also this quote by Professor Michael Meurer:<sup>7</sup>

"First of all, frequency of litigation and the cost of litigation for biotech patents is very high. Drug and health patents are litigated more than any other kind of technology. There is one empirical study that showed that six lawsuits are spawned by every 100 corporate biotech patents.[17]<sup>8</sup> There is also research that shows that most of the start-up companies are spending a comparable amount on legal costs to what they are spending on research.[18]<sup>9</sup> So this is a very big concern for start-up companies."

Few if any developing countries have a significant capacity to examine patent applications, or to litigate patent claims. Some developing countries have patent registration systems that do not require patent examination at all. In the US, Japan or European markets, there are substantial financial incentives for generic drug companies to bust bad patents. These incentives do not exist in small national markets. It is predictable that a considerable number of patents in developing countries will be bad patents, because the countries or competitors will not have the capacity or economic incentives to evaluate and litigate overreaching patent claims.

For a variety of reasons, poor countries are extremely reluctant to sue or be sued. Litigation is expensive, and can overwhelm already limited program budgets. In some countries, a cultural reluctance to engage in litigation restrains public officials from pursuing courses of action likely to involve protracted litigation.

Developing countries have not enacted good TRIPS-compliant state practice models for authorizing the use of patents on medicines. Prior to TRIPS, many countries simply excluded pharmaceuticals from the patent system. Under TRIPS, countries must issue patents on medicines. Unless they can invent a model for state practice that will actually work in developing countries, countries will not be able to obtain less expensive medicines from the competitive sector.

# 2

## FEATURES FOR A GOOD STATE PRACTICE MODEL

While I am interested in the development of a state practice model for developing countries, I have also drawn on examples from patent laws in developed countries. People looking at these issues can obtain translations of foreign Intellectual Property Rights (IPR) laws from the World Intellectual Property Organisation (WIPO) in both paper and electronic formats.

A WIPO source which the Consumer Project on Technology (CPT) has excerpted sections of several patent laws, including compulsory licensing, government use and patent exception provisions, can be found on: <http://www.cptech.org/ip/health/cl/examples2.html>.

The recommended features for a good state practice model are as follows:

- (i) The system must not be overly legalistic or expensive to administer, or easily manipulated by litigation. The large pharmaceutical companies are masters of IPR litigation and routinely misuse regulatory and IPR laws, exploit loopholes, and harass competitors, in the courts. Any system which permits the big pharmaceutical companies to do this will not work very well in practice. For this reason, we recommend models that rely upon administrative processes.
- (ii) The government-use provisions should be strong. The rules in TRIPS give governments very broad powers to authorize use of patents for public non-commercial use, and this is one area where there are many good state practice models to consider. No developing country should have statutory public-use provisions that are

weaker than the US, German, Irish, or UK provisions.

- (iii) The system of setting compensation should be relatively predictable and easy to administer. We recommend adoption of royalty guidelines to reduce uncertainty, and to speed up decisions, and an administrative process that places burdens on patent owners to disclose essential economics data if they seek to appeal administrative decisions. It is important to have greater transparency in this area. This process should also be fast, with initial decisions setting initial compensation, and revisions, such as from administrative appeals, providing forward looking adjustments.

When there are complex IP rights for a product, as is sometimes the case for medical technologies, one approach is to permit a decision setting a royalty for all claims to be paid into an escrow fund, and to have the various patent owners settle claims between each other, possibly through arbitration, with the arbitration costs borne by the competing patent owners.

- (iv) Production for export should be permitted. Under TRIPS, the most straightforward way would be to permit exports if an administrative process found that a lack of competition within the therapeutic class of drugs has given the producer market power, creating a barrier to access. This would be consistent with Article 31.k of TRIPS. This can be done by a health agency, or even by administrative action.

A different approach would be to authorize production for export when the legitimate interests of the patent owner are protected in the export market, such as when the export market provides reasonable compensation to the patent owner, as an Article 30 exception to patent rights. A number of NGOs are also urging countries to adopt an Article 30 patent exception for products that are produced for humanitarian purposes.

The Article 31.k and Article 30 approaches are both stronger if accompanied with an administrative finding, such as finding that:

- (a) increasing returns to scale in the production of a product are important
  - (b) the product is used to treat infectious diseases
  - (c) the export of the product will benefit the public health, and/or
  - (d) the export of the product will address humanitarian objectives.
- (v) There should be a provision for authorization of the use of patents to address public health emergencies. Under 31.b, this triggers the same fast track liberal procedures as those that exist for public non-commercial use. Many European governments have a large public sector role in funding health care, but for most developing countries, there is little capacity to provide expensive drugs for HIV/AIDs or other severe illnesses. In these countries, it is possible to expand access to now expensive drugs by permitting the competitive generics sector to enter the commercial market, where there are opportunities for expanded access to medicines, at least among some income groups.

By declaring a public health emergency for HIV/AIDs, tuberculosis, malaria or other illnesses, a government could give general authorization for the competitive sector to supply particular types of drugs, subject to paying a modest royalty to the patent owner, and can eliminate the steps of negotiation normally required for commercial use, saving time and lowering barriers to entry, and probably increasing the number of generic competitors. In our opinion, this should be done right now for all HIV/AIDS related medicines in Africa, Romania, Thailand and other countries where AIDS drugs are protected by patents, and the high price creates access barriers.

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# 3

## ADMINISTRATIVE PROCESSES AND TRIPS

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As indicated earlier, TRIPS permits the use of administrative practices in all Article 31 decisions, including the setting up of compensation and appeals processes. The key thing for each country is to settle basic issues, and determine which agency, official, committee or other body will make the initial decision, and which will receive and act on appeals.

TRIPS requires that the processes be fair, transparent, and accountable, relying, for example, on written records and decisions, with opportunities to provide evidence and be heard, and that there exists an appeals process by an independent body from the one that makes the initial decision.

Several countries give very broad powers to a wide range of government officials to make decisions regarding the initial authorization of use, when the use involves public non-commercial use. In some cases, including the US, the statute gives the power to authorize the use of the patent to any government official, for example by issuing a contract or agreement that contains the authorization to use patents or copyrights, and the agency's administrative procedures may provide additional guidance on how these decisions are made, such as, for example, the procedures spelled out in the US federal acquisition regulations.

The procedures for authorizing third parties to engage in commercial use of a patent tend to be more specific, in terms of who can make such an authorization. In Belgium, the statute provides for a committee that includes persons representing consumer, labor and small business interests. In Switzerland, compulsory licensing decisions are made by the

Federal Council. In many countries, the licences are issued by the registrar of patents or the Ministries of Trade or Industry. In the US, the Secretary of the Department of Health and Human Services makes the determination in cases involving the Bayh-Dole “March-In” rights, while compulsory licensing of patents for nuclear energy or clean air are handled by different bodies. In Spain, the Minister of Industry is required to consult with the Minister of Health on compulsory licensing applications that involve patents that concern public health.

Article 31 of TRIPS requires that the administrative process provide an “independent review by a distinct higher authority.” For example, the Minister of Health could appoint an officer to make decisions, and also an independent body to review decisions, with the power to overrule, modify or remand the initial decisions. The review could be provided by another office, such as the registrar of patents, the Attorney General. The task is to create a system that will carry out the purposes of the compulsory licensing or government-use program, and to have a process that is perceived to be fair and straightforward.

With respect to Article 31, TRIPS is more about having a rules-based system than it is about the specific rule or outcomes, at least as far as the WTO is concerned. That is, in a WTO dispute resolution procedure, many different approaches and outcomes will be acceptable to the WTO, if they follow in good faith the procedural safeguards.

While the purely administrative process is one option, countries could also have a mixed system where the appeals are handled by a federal court. If judicial appeals are permitted, the statute could set out the basis for an appeal, and could be very specific with regard to the standards used to overturn an administrative decision. For example, the statute could make it very difficult to overturn an administrative decision, or it could make it easier for either the patent owner or the person seeking the licence to prevail on an appeal. This is one of many areas where policy makers have discretion and choices to make.

A decision to permit a judicial appeal does not need to include the right of the patent owner to obtain injunctive relief. For example, in the US system for public use, nearly any government employee can authorize use, which is not considered an infringement of the patent, and the patent owner does not get the right to obtain an injunction against either the government or third parties authorized by the government. The patent holder does, however, have a right to compensation, and the decisions regarding compensation, including appeals, are made by federal courts.

# 4

## GOVERNMENT USE OF PATENTS

There is a high variance in national provisions for government or public use of patents. Some are quite permissive, while others are not. Below are some examples of countries with fairly liberal public-use provisions in national patent laws.

The US has very broad rights to use patents for public purposes. As noted earlier, the government can use patents for any government purpose, is not obligated to negotiate for licences, and does not authorize any injunctive relief to the patent owner. The patent owner is granted compensation, as a government taking under eminent domain laws.

Italy gives the government the right to expropriate patents for “Military or public interest” uses.

In Australia, “Exploitation by the Crown” of a patent, including use “by a person authorized in writing by the Commonwealth or a State” is “not an infringement” of a patent.

In Germany, “a patent shall have no effect where the Federal Government orders that the invention be exploited in the interest of public welfare.”

The Malaysian patent law has a special provision for “Rights of Government” which authorizes “the Government of the Federation or of any State, a Ministry or Government department or any person authorized by such Government, Ministry or Government department” to “make use and exercise any invention”, subject to the payment of “reasonable

compensation”. Like many other countries, in Malaysia, government-authorized uses of patents are not considered an infringement.

In Singapore, the patent law has a provision for “Use of Patented Inventions for Services of Government”, which permits “a Government department or a person authorized by a Government department” to “make, use, exercise and vend the patented invention for any purpose which appears to the Government department necessary or expedient” for several stated purposes, including “public non-commercial use”.

The New Zealand patent law has a provision for “Use of patented inventions for services of the Crown” which states, “notwithstanding any other provision of this Act, any Government Department, and any person authorized in writing by a Government Department, may make, use, exercise, and vend any patented invention for the services of the Crown and anything done by virtue of this subsection shall not amount to an infringement of the patent.” Interestingly, the only limitation on the sale of a good to the public under this provision concerns integrated circuits.

In the Philippines, the relevant provision is “Use of Invention by Government” which says, a “Government agency or third person authorized by the Government may exploit the invention even without agreement of the patent owner where: The public interest, in particular, national security, nutrition, health or the development of other sectors, as determined by the appropriate agency of the government, so requires; or A judicial or administrative body has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive. ”

Like other countries, this is a separate section in the national law from the sections on compulsory licensing.

The Irish patent law has provisions for “Use of Inventions for the service

of the State" which authorizes a government Minister "to use the invention for any purpose which appears to such Minister to be necessary or expedient – for the maintenance of supplies and services essential to the life of the community; for securing a sufficiency of supplies and services essential to the well-being of the community; for promoting the productivity of commerce and industry, including agriculture; generally for ensuring that the whole resources of the community are available for use and are used, in a manner best calculated to serve the interests of the community; for assisting the relief of suffering and the restoration and distribution of essential supplies and services in any country or territory other than the State that is in grave distress; or for ensuring the public safety and the preservation of the State."

The Switzerland patent law provides for "Expropriation of the Patent" and states, "If public interest so requires, the Federal Council may wholly or partially expropriate the patent."

The UK law provides for "Use of patented inventions for services of the Crown" and the government's powers are quite broad. It provides that: "Notwithstanding anything in this Act, any government department and any person authorised in writing by a government department may, for the services of the Crown and in accordance with this section, do any of the following acts in the United Kingdom in relation to a patented invention without the consent of the proprietor of the patent, that is to say –

- (a) where the invention is a product, may –
  - (i) make, use, import or keep the product, or sell or offer to sell it where to do so would be incidental or ancillary to making, using, importing or
  - (ii) in any event, sell or offer to sell it for foreign defence purposes or for the production or supply of specified drugs and medicines, or dispose or offer to dispose of it (otherwise than by selling it) for any purpose whatever;

- (b) where the invention is a process, may use it or do in relation to any product obtained directly by means of the process anything mentioned in paragraph (a) above;
- (c) without prejudice to the foregoing, where the invention or any product obtained directly by means of the invention is a specified drug or medicine, may sell or offer to sell the drug or medicine;
- (d) may supply or offer to supply to any person any of the means, relating to an essential element of the invention, for putting the invention into effect;
- (e) may dispose or offer to dispose of anything which was made, used, imported or kept in the exercise of the powers conferred by this section and which is no longer required for the purpose for which it was made, used, imported or kept (as the case may be), and anything done by virtue of this subsection shall not amount to an infringement of the patent concerned.

# 5

## SETTING COMPENSATION

Use of a patent under Article 31 of the TRIPS requires that the patent owner is compensated. The general rule is in 31.h:

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

In many respects, this is the most fundamental obligation in Article 31. It is clear that countries have considerable discretion in setting compensation. Article 1 of the TRIPS says that countries

“shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”

There are of course limits to what would satisfy this requirement, but there is already a rich diversity of national approaches in terms of compensation in compulsory licensing and government use, and the WTO would be hard pressed to justify intrusive reviews of this.

Like most Article 31 issues, the most important issue is to provide a fair process for reaching a reasonable result. There is no question about the power of states to rein in IPRs in order to assure affordability and access, but in the process of doing so, governments are advised to provide an administrative record which explains the basis for policy and specific outcomes. This doesn’t have to be complex or involve endless proceedings. It can be simple and quick.

The easiest way to proceed is to create a set of compensation guidelines, based upon reasonable royalties in most cases, that will provide a framework for decision-making, and also provide some predictability and transparency for the system. These guidelines can be administrative, or even be set out in statute.

In practice, a straightforward royalty guidelines system will facilitate early action. Government officials can simply pick the royalty rate from the guidelines that provides a rough match with the specific facts, and the products can be put on the market without delay. Patent owners or generic producers could appeal initial decisions, but the appeal process should not slow down the introduction of generic competitors.

One issue that should also be addressed concerns cases of complex rights on the same product, a situation that is likely to become more commonplace. One solution is to have the government set a reasonable royalty that would compensate all of the various patent owners, and have the money paid into an escrow account. The patent owners could work out their differences, possibly with arbitration, and split the escrow funds when the international differences are resolved. Again, this would permit rapid introduction of the generic products, without waiting for the distributional issues to be resolved among competition patent owners.

Japan, Germany, the Philippines and other groups have adopted various forms of royalty guidelines, and countries can invent their own models for this as well. PhRMA, the US based big pharmaceutical trade group, presented data to the USTR in February 2000 that 5 percent was the average US royalty rate for pharmaceutical drugs, and Japan has used rates from 2 to 4 percent in the past for some purposes, while for pharmaceuticals Germany has used 2 to 10 percent. In the Canadian case, which according to the WHO is the most extensive use of compulsory licensing for pharmaceutical products, the government typically ordered royalties around 4 percent.

Whatever the rate, it should be manageable, and there is no reason for the WTO to demand the poor countries of the world to pay top dollar on medicines while millions are dying for lack of access to treatment. Indeed, the target royalty payment could be an approximation of the average or median royalty paid on pharmaceutical products, for which there exists reasonable competition among therapeutic substitutes, and some other methodology which does not impose high royalties from blockbuster drugs as a norm for the developing country poor.

In a recent presentation to the Indian domestic competitive industry in a meeting in Mumbai, the following royalty guidelines were recommended for developing countries:

Innovative products — 3 to 5 percent

Production with modest innovation — 2 to 3 percent

Minor patents — 1 percent or less

There could be different numbers, a study to choose the rates, or additional compensation, such as an extra royalty payment of 1 to 2 percent over the guidelines for productions that are particularly useful from a therapeutic point of view, unusually expensive to develop (based upon real evidence of costs), that reach limited audiences, or that have other special considerations. There could also be lowering of payments when R&D was supported by public sector organizations, including tax based subsidies, such as the US orphan drug tax credit program.

In the best of all possible worlds there could be much more analysis, such as the thoughtful pharmino-economic analysis conducted by the Australian government to determine reimbursement for pharmaceutical drugs. However, this is expensive in terms of money and time of training of staff, and not only may be hard to justify in terms of resources, but it may also make the program harder to understand and manage.

One important innovation in this area is to place specific requirements

that parties who seek royalties provide basic data to governments and for the public. For example, no company should be permitted to make entirely un-supported claims regarding the costs of developing products, in order to plead for higher royalty payments.

If a firm wants to argue that it has undertaken large investments and risk, as of course it may have done so, the firm should be required to provide evidence to back up the claim. For example, the firm should disclose the actual costs invested in the development of the product, using a standardized disclosure format, so the data would contribute to deeper public sector and citizen understanding of the actual investments in products and the economics of new drug development. This should be accompanied by data on the actual sales of that product, since its introduction, to provide more information on the returns from the company investments.

No appeal of a royalty rate should be permitted without such disclosures, and indeed, countries could and I hope would require such disclosures before granting any compensation at all. Such disclosures are addressed now in the Trans Atlantic Consumer Dialogue's recent recommendations to the US and the EU on transparency in pharmaceutical economics.<sup>10</sup>

# 6

# DISCRIMINATION BY FIELD OF TECHNOLOGY

A troublesome area of TRIPS concerns Article 27.1, which reads in part:

...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.

The meaning of this text isn't clear, because the phrase, "field of technology" is not a well established legal term. The big pharmaceutical companies cited this Article of TRIPS in their complaint against the South African Medicines Act.<sup>11</sup>

2.4. it is discriminatory in respect of the enjoyment of patent rights in the pharmaceutical field which discrimination is in conflict with the provisions of Article 27 of the Trade Related Aspects of Intellectual Property Rights Agreement [hereinafter referred to as the "TRIPS Agreement"], an international agreement binding the Republic and to which Parliament has given effect by the promulgation of the Intellectual Property Laws Amendment Act, No. 38 of 1997, and consequently such provision is in conflict with Section 44(4) of the Constitution read with Sections 231(2) and 231(3) of the Constitution.

The issue of the Article 27.1 discrimination language was raised in WT/DS114/R, a recent WTO dispute involving Canadian patent exceptions for research and testing on generic drugs used for drug registration (the so-called "bolar" exception) and a Canadian patent exception that per-

mitted stockpiling of production in anticipation of the patent expiration. The EU submission to the WTO stated:<sup>12</sup>

#### Article 27.1 of the TRIPS Agreement

(b) That Canada, by treating patent holders in the field of pharmaceutical inventions by virtue of these provisions less favourably than inventions in all other fields of technology, violated its obligations under Article 27.1 of the TRIPS Agreement requiring patents to be available and patent rights enjoyable without discrimination as to the field of technology.

The WTO considered very technical arguments over whether or not its patent exceptions violated Article 27.1. Canada referred to Article 32(b) of the Vienna Convention on the Law of Treaties, which said the interpretation of treaty terms “should not produce manifestly absurd or unreasonable results.” As summarized by the WTO panel, Canada argued:

The adoption of the meaning of Article 27.1 reflected under (a) above would clearly violate that rule of construction. It would lead to a requirement for “across-the-board” derogations from patent rights, thus compelling exceptions where there was no practical need and reducing patent protection more than was required in all areas save those in which a balancing measure was actually required. Such an incongruous result would not be consistent with the objectives of the TRIPS Agreement Article 27.1 that was consistent with the intent of Article 30, i.e., allowing exceptions that were “limited” because they were not spread across all sectors of technology, and which respected the objective, as reflected in the TRIPS Agreement, of ensuring balance, by avoiding an anti-discrimination rule which would overwhelm other important societal interests if it had to be applied “across the board”, without regard for particular circumstances.

— The European Communities and their member States did not seek to read Article 27.1 in its context and in light of the TRIPS objectives but, instead, asserted that Article 27.1 was absolute in nature, such that “violations” of its provisions could not be justified under Article 30. This approach, in failing to give effect to the applicable rules of interpretation, simply led to the undesirable and absurd results referred to above. It deprived Members of the ability to create appropriate solutions for specific problems on a case-by-case (or product group by product group) basis, and instead obliged them to impose universally applicable measures which could be entirely inappropriate in most contexts. It required “limited exceptions” to be unlimited.

. . . A reference to the drafting history of Article 27.1 was instructive. Its structure and wording reflected two separate negotiating thrusts: (a) a desire to ensure that subject to certain listed exceptions, patents would be available for inventions in all fields of technology<sup>13</sup>; and (b) a desire to eliminate compulsory licence provisions respecting food and drug products in national patent laws.<sup>14</sup>

. . . There was nothing in the drafting history to suggest that the prohibition against discrimination on the basis of field of technology was ever meant to override limited exceptions.

The WTO decision in the case is more than 110,000 words, and explores a number of key issues in interpreting TRIPS. There are extensive discussions on TRIPS Article 7, 8, 27, 28, 30 and 31, plus substantive discussions on the pharmaceutical market. The decision includes language that declares one of the reasons for Article 27.1 was to prevent countries from enacting compulsory licensing laws that dealt specifically with pharmaceuticals. There is also text such as this concerning access to generic drugs:

(b) The Global Need for Access to Essential Medicines

— Although not manufactured in all countries of the world, generic medicines of course had a role to play in promoting public health in all countries. According to the World Health Organization, more than one third of the world's population lacked regular access to essential drugs. Every year, millions of children and adults in developing countries around the world still died from diseases that could be readily treated by drug therapies, and more economically treated with generic drugs.<sup>15</sup>

— Many countries still lacked the facilities and expertise needed to review the safety, efficacy and quality of drugs destined for their national markets, and remained dependent on reliable foreign authorities to set the necessary standards and on foreign generic companies to do the necessary testing to those standards. For example, a 1993 study of 36 African countries conducted by the World Health Organization had found that only three had a "limited drug regulatory capacity". Not one African nation had what the WHO called a "comprehensive drug regulatory capacity".<sup>16</sup>

— A refusal to allow testing of generic medicines for the purposes of foreign regulatory submissions during the term of patent protection, while permitting it for domestic submissions, would needlessly delay the regulatory review process in many countries. As a result, generic drugs would not be readily available, and many treatable diseases would remain untreated, in the period following patent expiry. Moreover, such a refusal would require that tests be repeated in their entirety in foreign countries. The World Health Organization opposed multiple human testing because of its resource implications for developing countries.<sup>17</sup>

- Consequently, if permissible “pre-expiration testing” were to be confined to activities related to domestic regulatory review only, the protection of public health would unquestionably suffer. An important value expressly recognized in Article 8.1 of the TRIPS Agreement would be impaired.

In the end, the March 17, 2000 WTO panel report held that the Canadian “bolar” provisions were not violations of Article 27.1 of TRIPS. This decision seemed to be based largely on the fact that the legislation itself did not specifically limit itself to the pharmaceutical industry, even though it was clear that this was the primary area where the legislation was having an effect.

In sum, the Panel found that the evidence in record before it did not raise a plausible claim of discrimination under Article 27.1 of the TRIPS Agreement. It was not proved that the legal scope of Section 55.2(1) was limited to pharmaceutical products, as would normally be required to raise a claim of de jure discrimination. Likewise, it was not proved that the adverse effects of Section 55.2(1) were limited to the pharmaceutical industry, or that the objective indications of purpose demonstrated a purpose to impose disadvantages on pharmaceutical patents in particular, as is often required to raise a claim of de facto discrimination. Having found that the record did not raise any of these basic elements of a discrimination claim, the Panel was able to find that Section 55.2(1) is not inconsistent with Canada’s obligations under Article 27.1 of the TRIPS Agreement. Because the record did not present issues requiring any more precise interpretation of the term “discrimination” in Article 27.1, none was made.<sup>18</sup>

In general, the issue of permitted discrimination by sectors of the economy seems to be an important albeit unanswered question, even after the WTO’s decision in WT/DS114/R, and poses perhaps the most difficult issue for drafting legislation. All of the contractions and tension so the Canadian bolar case will likely be revisited in the future. For this reason,

reports by UN agencies, including the WHO, UNAIDS, UNCTAD or UNDP would be useful and timely. The issues presented by this decision border on the absurd, as countries will find it extremely difficult to write laws to address in specific and limited ways important social concerns. The United States compulsory licensing laws for clean air and civilian nuclear energy are faced with the same issues.

The current thinking is for countries to adopt laws that provide for compulsory licensing in broad areas like “health” and make the argument that health isn’t a field of technology. But at a certain level it becomes ridiculous to argue that countries cannot fashion laws that have the expressed mission to expand access to medicines.

## Endnotes

<sup>1</sup> Thanks to Robert Weissman for comments on this first draft, to Thirukumaran Balasubramaniam for research on foreign patent laws, and to participants at several seminars, including the November 2000 UNDP meeting for HR2001 consultants, the 28 November, 2000 Geneva UNCTAD Workshop on Trade in Pharmaceuticals and Human Rights, a 6 December, 2000 Bangladesh seminar organized by MSF for the People's Health Assembly, and a 12 December meeting of the India Drug Manufacturers Association in Mumbai, India.

<sup>2</sup> This is only one of many important areas in patent law. For a discussion on this and other issues, with models for state action, see Carlos Correa, *Integrating Public Health Concerns Into Patent Legislation In Developing Countries*, Geneva, October 2000, South Centre.

<sup>3</sup> In several US cases, compensation has been based upon "what the owner has lost, not what the taker has gained." (Leesona, 599 F.2d at 969), rejecting the argument, by patent owners, that they are entitled to lost profits based upon sales at prevailing commercial market rates.

<sup>4</sup> 26 AIPLA Quarterly Journal 185 (1998)

<sup>5</sup> One example of the problems from under-resourced patent examination involved *ddI*, a drug for HIV/AIDS. Bristol-Myers Squibb (BMS) was able to obtain patents for formulation claims in Thailand that were rejected by the US Patent and Trademark Office. BMS used this patent to block generic production of *ddI* pills in Thailand, even though BMS was not the inventor of *ddI*, and did not own a patent on the use of *ddI* for treating HIV/AIDS.

<sup>6</sup> Burroughs Wellcome Co. v. Barr Lab., 828 F. Supp. 1208, 1209 (E.D.N.C. 1993).

<sup>7</sup> <http://www.bu.edu/law/scitech/volume6/Panel2.htm>

<sup>8</sup> Footnote 17 in the text is: [17] See Josh Lerner, *The Importance of Trade Secrecy: Evidence from Civil Litigation*, paper presented to the Conference on the Economics of Intellectual Property Rights, ICARE Institute, University of Venice, Italy (October, 1994).

<sup>9</sup> Footnote 18 reads: [18] See JEAN O. LANJOUW & MARK SCHANKERMAN, STYLIZED FACTS OF PATENT LITIGATION: VALUE, SCOPE AND OWNERSHIP 3 (National Bureau of Economic Research Working Paper No. 6297, 1997) (noting that crowded fields and new fields of technology generate more patent litigation); JEAN O. LANJOUW & JOSH LERNER, THE ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS: A SURVEY OF THE EMPIRICAL LITERATURE 13 (National Bureau of Economic Research Working Paper No. 6292, 1997) (correlating number of times that a patent is cited in future applications to the value of the patent and noting that innovative technology patents are cited with increased frequency).

<sup>10</sup> TACD, Doc Health 6-00.

<sup>11</sup> High Court of South Africa, Case number: 4183/98, the Pharmaceutical Manufacturers' Association of South Africa, *et al.* v. the President of the Republic of South Africa, the Honourable Mr. N.R. Mandela N.O., *et al.*

<sup>12</sup> From the WTO decision:

"The European Communities and their member States argued that, by treating patent holders in the field of pharmaceutical inventions less favourably than inventions in all other fields of technology, Canada infringed its obligations contained in Article 27.1 of the TRIPS Agreement.<sup>12</sup> The following points were advanced in support of this argument:

— The Canadian patent legislation, which under Section 55.2(2) and 55.2(3) together with the Manufacturing and Storage of Patented Medicines Regulations practically speaking provided only for a 19½-year term of patent protection, applied exclusively to product and process patents for inventions in the field of pharmaceutical products. During the legislative process, other fields of technology were not even considered and no draft legislation to extend the scope of these provisions to other or all fields of technology was, according to the information available to the European Communities and their Member States, presently pending in the Canadian legislature. In this context, it was also noteworthy that Section 55.2(2) of the Canadian Patent Act was, taken in isolation, an inoperative provision and created only legal effects through the promulgation of the Manufacturing and Storage of Patented Medicines Regulations. This Regulation was expressly limited to "patented medicines" and could not apply to any other product.

— Thus, the Canadian legislation discriminated against pharmaceutical inventions by treating them less favourably than inventions in all other fields of technology and therefore Canada violated its obligations under Article 27.1 of the TRIPS Agreement

<sup>13</sup> Reference was made to the TRIPS 10+10 meeting, 16 December 1991, Speaking Note for the Chairman (unpublished).

<sup>14</sup> Op. Cit. at p. 8

<sup>15</sup> The Worldwide Role of Generic Pharmaceuticals, Presentation to International Generic Pharmaceuticals Association by Dr. Jonathon D. Quick, Director of Essential Drugs and Other Medicines, World Health Organization, June 1999. The diseases and death rates are: respiratory infections (4 million); diarrhoeal disease (3 million); tuberculosis (2 million); measles (1 million); malaria (1 million); tetanus ( $\frac{1}{2}$  million); heart attack and strokes (5 $\frac{1}{2}$  million); and cancer (3 $\frac{1}{2}$  million).

<sup>16</sup> Status of Drug Regulation and Drug Quality Assurance in WHO African Region and Selected Countries, World Health Organization, March 1999.

<sup>17</sup> Developing International Standards for the Generic Pharmaceutical Industry, Presentation to International Generic Pharmaceuticals Association by Dr. Juhana E. Idanpaan-Heikkila, Special Advisor, Quality Assurance and Safety, World Health Organization, June 1999.

<sup>18</sup> 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 of technology — *de jure* or *de facto* — are necessarily “discriminatory” by virtue of that fact alone, or whether under certain circumstances they may be justified as special measures needed to restore equality of treatment to the area of technology in question. The Panel’s decision regarding Section 55.2(1) did not touch on that issue.

## **Compulsory Licensing: Models for State Practices in Developing Countries, Access to Medicine and Compliance with the WTO TRIPS Accord**

In this booklet, James Love addresses the issue of government authorization under the Trade-Related Aspects of Intellectual Rights (TRIPS) Agreement to use a patent without the permission of the patent owner.

He examines models for compulsory licensing and government use of patents as a tool to increase access to medicines in developing countries, drawing on examples also from patent laws in developed countries.

A good state practice model, he argues, should have the following features:

- (i) The system must not be overly legalistic or expensive to administer, or easily manipulated by litigation.
- (ii) The government-use provisions should be strong.
- (iii) The system of setting compensation should be relatively predictable and easy to administer.

The author also looks at other related areas such as the TRIPS-permitted use of administrative practices in all Article 31 decisions; the high variance in national provisions for government or public use of patents; and the “troublesome area of TRIPS” — the phrase, “field of technology” found in Article 27.1.

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