INTELLECTUAL PROPERTY RIGHTS IN GLOBAL TRADE FRAMEWORK: IP TRENDS IN DEVELOPING COUNTRIES

INTRODUCTORY REMARKS BY ELIZABETH CHIEN-HALE*

Although it is traditionally a distinctive area of law, legal issues relating to intellectual property rights are increasingly being addressed in the context of international trade. For a number of reasons, including avoiding the potentially trade-distorting effects of inadequate protection, narrow protection, or preferential treatment based on the national and technical origin of intellectual property rights, an international standard of minimum protection was established in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) administered by the World Trade Organization (WTO).

In this post–TRIPs era, this panel focuses on the legislative trends in developing countries in Asia, Africa, and the Middle East as these countries strive to comply with their international obligations under the TRIPS Agreement, while maintaining their rights to access technology for public health or economic development reasons.

It was my aim in organizing this panel to bring together speakers from different regions of the world and those who may hold views at opposite ends of the spectrum. We were indeed fortunate to have such a diverse panel: Frederick Abbott of the Florida State University Law Center, Claudia Schulz of the Brazilian law firm of Castro Barros Sobral Gomes, Yansheng Yu of the Chinese law firm of China Patent & Trademark Agent (U.S.A.) Ltd, Linda Lourie of the United States Patent and Trademark Office, and Mark Wu of the Office of the U.S. Trade Representative.

Although the topic is far too complex to be dealt with in one session, I trust that through the discussion we will begin to identify the sources of differences in opinions between developed and developing countries, and sometimes among countries within the same bloc. As with most legal issues, finding the right balance point will be the key to successful international harmonization of intellectual property rights.

REMARKS BY FREDERICK M. ABBOTT**

I will discuss trends and countertrends regarding the implementation and enforcement of intellectual property rights (IPR) in developing countries, with special attention to IPRs that affect public health. Of course, IPRs and their application in developing countries affect a wide range of subject matter; by focusing on a particular area I do not intend to diminish the importance of other areas, but IPRs bear a particularly complex relationship to the development and distribution of medicines, and it is difficult to give this subject adequate attention within a more general discussion of trends.

The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) today is the benchmark for national and regional IPR systems for all countries, developed, developing, and least developed. Even for nonmembers of the WTO, that agreement is the de facto standard, for the benefits of various trade preferences are made to depend on compliance with it.

The negotiation and basic framework of the TRIPS Agreement are by now an old story that I will not recount here. I would note, however, that under the auspices of the UN Conference on Trade and Development (UNCTAD) and the International Centre for Trade and Sustainable

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Development, a new *Resource Book on TRIPS and Development* (for which Professor Carlos Correa and I served as Principal Consultants) is available in draft online,[3] and soon in hard copy. The book goes through the negotiating history and interpretation of the TRIPS Agreement in considerable detail. It was prepared expressly with the perspective of developing countries in mind, and I recommend it to those implementing the agreement in national or regional law.

Beginning in June 2001, the WTO TRIPS Council began an intensive program to consider the relationship between the TRIPS Agreement and public health. This led on November 14, 2001, to the adoption by the Ministerial Conference in Doha, Qatar, of the Declaration on the TRIPS Agreement and Public Health (the Doha Declaration).[4] The Doha Declaration marked the end of a struggle between developing countries seeking to affirm and extend the flexibilities embodied in the TRIPS Agreement to promote and protect public health, and the United States and a small group of like-minded countries (Australia, Canada, Japan, and Switzerland) that wanted to limit the scope of the Declaration so as to avoid encroachment on the perceived interests of pharmaceutical patent holders.

A combination of factors, both internal and external to the negotiating process, led to the adoption of a statement very strongly supporting developing country public health interests. The external factors included the events of September 11, the anthrax scare, and actions to threaten or grant compulsory licenses by the United States and Canada, in addition to an overall sense of global insecurity at the time of the Doha Ministerial. Given that milieu, the United States softened its opposition to promoting access to affordable medicines so that larger national security objectives could be achieved.

It is very important that, as part of the Declaration, a measure was adopted (paragraph 7) that extended until January 1, 2016, the obligation of the least developed members to implement pharmaceutical patent and data protection; more important, it authorized least developed members not to enforce patents and data protection rules until that date.[5] From a technical advisory standpoint, this extension on behalf of least developed members is critical.

The Doha Declaration put over one important item of business. In its Paragraph 6, the ministers directed the TRIPS Council to address the problem of countries with insufficient or no pharmaceutical manufacturing capacity in the pharmaceutical sector, rendering them unable to make effective use of compulsory licensing, and to make a recommendation to the General Council by December 31, 2002. The TRIPS Council further spent close to two years in highly contentious negotiations. In December 2002, the United States blocked a consensus in the TRIPS Council on the grounds that the solution accepted by other members did not sufficiently restrict the scope of diseases that could be addressed under the solution, and also out of concern that too wide a range of countries could make use of the system as importers. However, on August 30, 2003, the United States joined the December 2002 consensus solution when members accepted that the Chairperson of the General Council would read a statement before the solution was adopted that expressed certain shared understandings of the members.[6]

The system established by the Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health is complex. I do not propose to go into the details here. However, briefly, it waives both the requirement set out in Article 31(f) of the

[3] *See* <http://www.iprsonline.org > (Cambridge University Press, forthcoming).

[4] *See* Frederick M. Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO*, 5 J. INT'L ECON. L. 469 (2002).

[5] Paragraph 7 of the Doha Declaration is implemented by decisions of the WTO TRIPS Council and General Council; *see* Decision of the Council for TRIPS of 27 June 2002 (IP/C/25, July 1, 2002) and Decision of the General Council of 8 July 2002 (WT/L/478, July 12, 2002).

[6] I have prepared a detailed analysis of these negotiations under the working title "The Containment of TRIPS to Promote Public Health," which will be published in due course.

TRIPS Agreement that a compulsory license should be predominantly for the supply of the domestic market of the country issuing it and the remuneration requirement of Article 31(h) so as to avoid dual compensation. The Decision on Implementation (Decision) establishes conditions under which compulsory licenses for export may be authorized, some of which relate to the quantities and the destination of products and others of which relate purely to notifications for transparency purposes. Despite U.S. efforts to the contrary, the decision does not restrict the scope of diseases that form the basis of public health needs.

There is a great deal of work presently going on to implement the decision. Norway was the first country to adopt implementing legislation, authorizing the King in Council to adopt regulations giving it effect. The Norwegian government has published proposed regulations with the expectation that they will enter into force this summer. After an appeal from Stephen Lewis, Kofi Annan's Special Envoy for HIV/AIDS in Africa, the government of Canada announced it would take steps to implement the decision. The bill the government initially introduced into the parliament was poorly done. It is being redrafted to take into account numerous criticisms from access-oriented nongovernmental organizations (NGOs), TRIPS experts, generic producers, and others. It is worth noting, though, that the pharmaceutical patent holders are lobbying hard in Canada to prevent the adoption of potentially effective legislation, and may yet prevail.

A provision in India's new Patent Amendments Bill is very similar to the basic Norwegian mandate authorizing the adoption of regulations to give effect to the decision. Other developing countries are now reviewing their legislation. The World Bank Global HIV/AIDS Program and the World Health Organization each are undertaking ambitious efforts to provide technical assistance in this area.

This we might say is the good news: At the WTO, steps have been taken to help developing countries. The solutions are by no means perfect, and NGOs have been critical of the bureaucratic requirements embedded in the Decision, but many of those same NGOs are actively participating in implementation efforts.

Regrettably, there is bad news as well, and in many ways the bad news is more noteworthy than the good news. While multilateral negotiations were going on in Geneva and progressive strides towards promoting access to medicines were being made, the U.S. Trade Representative (USTR) and Pharmaceutical Research and Manufacturers of America (PhRMA) were busy incorporating an alternative and highly restrictive set of rules in new "free trade" agreements that will effectively undermine the flexibilities in the Doha Declaration and the Decision on Implementation, thus preventing access to lower priced generic medicines. The extent of these restrictions is extraordinary, and they will have bad effects on the poor.

The restrictions most recently incorporated in the Central American Free Trade Agreement (CAFTA) the U.S.—Australia Free Trade Agreement (FTA), and we presume also the U.S.—Morocco FTA[7] did not come about overnight. They had their predecessors in Singapore and Chile. However, they certainly had become more virulent by the time of the CAFTA.

Here, in a nutshell, is what these new provisions accomplish, as demonstrated by Article 15.10 of the CAFTA: Measures Related to Certain Regulated Products. The Australia—U.S. FTA goes further, requiring modifications to Australia's Pharmaceutical Benefits Scheme (PBS), which is a more significant economic matter for that country than the provisions agreed upon in the CAFTA. Since today I am concerned with developing countries, I will not pursue this here.

First, CAFTA Article 15.10 prevents the registration of generic medicines for a period of five years after marketing approval of an originator medicine, whether or not that is patented. This five-year marketing exclusivity rule was sought unsuccessfully by the United States in the

[7] The draft text of the U.S.—Morocco Free Trade Agreement was posted by USTR the day after this panel met (USTR Releases Draft Texts of U.S.-Morocco FTA, April 2, 2004, *available at* < http://www.ustr.gov>).

Uruguay Round negotiations. Yet it appears in the CAFTA in a particularly strong form not at all contemplated by Article 39.3 of the TRIPS Agreement. It does not allow registration of generic medicines for public noncommercial use (as in public clinics), with no hint of the TRIPS limitation that data restrictions only concern *unfair* commercial use. Beyond that, the rule applies to any previously unapproved medicine, whereas Article 39.3 of the TRIPS Agreement applies only to new chemical entities. This opens the possibility that marketing exclusivity will be accorded to older formulations that are well known at the time registration is sought in a CAFTA country, significantly increasing the range of medicines that may be given effective monopoly positions.

This is only the beginning. Not only are countries in Central America (Honduras for example) prohibited from allowing an Indian generic producer from registering a medicine if it was previously registered by an American company in Honduras, they are also prohibited from registering the generic if the American company registered the medicine anywhere in the world, say the United States or Switzerland. So now we have extraterritorial control over data submissions where it is not even relevant that the American pharmaceutical company never actually submitted any data in Honduras but only in the United States or Switzerland. The way the provision is written, the period of protection may be as long a ten years, since the U.S. company is given a five year grace period in which to submit an application for approval in Honduras. There is a hidden PhRMA agenda in this restriction that extends to the World Health Organization (WHO) prequalification program in Geneva, which is the most important development in pharmaceutical regulation for the past decade, and which PhRMA is effectively trying to shut down.

From my standpoint, that is still not the most problematic provision. This is reserved for the new provision that a third-party generic producer, relying on "evidence or information concerning the safety and efficacy of a product that was previously approved, such as evidence of prior marketing approval in the Party or in another territory," must be prevented from obtaining marketing approval that would allow that third party to market the product "during the term of that patent, unless by consent or acquiescence of the patent owner" (Article 15:10(3)(a)).

It takes something of a specialist to appreciate the effect of this. The nonspecialist might say, if a patent prevents the marketing of generics before the expiration of the patent term, what is the problem with allowing the patent holder to preventing marketing based on registration? There are two key responses: First, drug regulatory authorities, generally speaking, do not have the capacity to evaluate the validity of patents. This is what the U.S. Food and Drug Administration (FDA) says. The FDA allows companies to list any patent they want in its Orange Book, and those listed patents form the basis for blocking marketing of generics. It is, as our own Federal Trade Commission recently reported, a system rife with abuse by patent holders; it effectively requires generic applicants to engage in multiyear litigation with patent holders before they may market their medicines.[8] If we cannot make that system work well here in the United States, it is fair to assume it will not work terribly well in Honduras.

The second point is this: When a government issues a government use or compulsory license on a medicine, the licensee medicine must still be registered and granted marketing approval before it may be sold. But Article 15.10(3)(a) of the CAFTA says that the product may only be marketed with the patent holder's consent or acquiescence. How can a compulsory license ever become effective if the marketing approval requires the patent holder's consent or acquiescence? This effectively subverts the Doha Declaration and the Decision on Paragraph 6.

We can make sophisticated technical arguments about how one rule must be read consistently with another, and so forth. The CAFTA even contains a provision expressly preserving the

[8] *See* U.S. Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration: An FTC Study, July 2002, *available at* <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

rights and obligations of the parties under the TRIPS Agreement—while undertaking to override them. The U.S.—Australia FTA and the later U.S.—Morocco FTA drop this nonderogation clause. Perhaps we can make some technical arguments, but I ask you: Are the regulatory authorities in Central America going to be fighting those battles with the USTR and PhRMA under the threat of U.S. economic retaliation? .

This involves, no doubt, a question of ideology and perspective. If you are here today as a representative of Pfizer or Merck, and your interest is in making more money for your officers and shareholders, the CAFTA may sound great. If you are here because you might be worried about whether people in developing countries can afford medicine, you may come to a rather different conclusion. It is not in the global public health interest to prevent generic producers from introducing and selling lower-priced medicines in developing country markets when the net effect will only be to strain public health budgets and make medicines unaffordable for the poor.

Agreements like the CAFTA and the U.S.—Australia FTA are entered into by states in their sovereign capacity. The U.S. pharmaceutical industry gains rents from these arrangements in the form of higher prices for medicines. From a mercantile standpoint it is not difficult to explain why a particular segment of U.S. industry pressures its government to negotiate such deals, but what is it that induces the Central American countries and Australia to accept them?

The answer is relatively simple. Neither the Central Americans nor the Australians are major producers of generic pharmaceuticals. There is a limited industry constituency in those countries demanding that their trade authorities resist U.S. demands that would restrict their access to the market. Instead, textile and agriculture interests in Central America and some agricultural and farming interests in Australia will benefit from the agreements. For the owners of the Central American and Australia industries that will benefit from the agreements, the price of paying more for medicines may not be hard to bear. The uninsured and underinsured buyers of medicines in those countries were not at the bargaining table.

As each additional country signs on to an FTA with the United States and gives up rights to introduce generic medicines, it becomes more difficult for the next country to resist. So far, the states that have agreed to U.S. demands may be smaller actors—Singapore, Chile, Central America, Australia—but others know that fences are being build around them. Brazil, for example, is increasingly worried that the United States will be able to isolate it by negotiating these agreements with other countries in Latin America, making it more difficult to resist such terms in a Free Trade Area of the Americas (FTAA).

Which news you consider good and which bad may well depend on your own ideology. My ideology and interest on the question of patents and medicines are that the patent monopoly should not be used to extract rents from people who cannot afford to pay them. In circumstances like those related to HIV/AIDS, the invocation of patents to block access to medicines is ethically repugnant. I do not believe that the pharmaceutical industry will stop developing new medicines because poor people do not pay high prices for them. The U.S. National Institutes of Health have a budget of $28 billion per year. Much of the research on new medicines is conducted in teaching hospitals and universities. The patent-based industry does finance clinical trials, but the selection of targets for clinical trial is very heavily skewed toward research on conditions affecting the affluent.

There are many ways we could fine-tune the American system of research and development that would lessen our dependence on the pharmaceutical majors, but that is a separate subject to which we could devote another conference. The point is that neither the United States nor its pharmaceutical industry is dependent for its well-being on patent rents from developing countries; tightening protection to increase the level of rents will do substantial harm.