The cycle of action and reaction: Latest developments and trends in IP and health

Executive Summary

This paper introduces the dialogue by examining the major trends in intellectual property rights regulation as they affect public health, and particularly the pharmaceutical sector. January 1, 2005, will mark the end of a critical transition period under the TRIPS Agreement, after which all developed and developing countries will be required to provide pharmaceutical product patent protection. While this development has been anticipated, its realization will significantly impact the world pharmaceutical supply market.

Since the inception of the TRIPS Agreement, the Pharma companies have sought to restrict the regulatory options available to governments. In the Doha Declaration on the TRIPS Agreement and Public Health and the Decision on Implementation of Paragraph 6, developing country governments succeeded in defending those options, and even enhancing them. Pharma and USTR have responded by negotiating restrictions in regional and bilateral agreements that significantly exceed TRIPS standards.

Developing countries have not yet formulated an effective response to the FTA trend, and this paper lays out several options. The difficulties in slowing or reversing the FTA trend should not be underestimated as governments perceive themselves to be achieving net gains in the negotiations, even if those net gains include a cost in the pharmaceutical sector.

Several proposals have been made to reform the TRIPS-based system for establishing pharmaceutical regulatory standards. The proposal of Love-Hubbard is described. The Love-Hubbard proposal would address the problem of R & D free-riding while providing private and public options for the development and distribution of medicines. Because the proposal reduces the potential for Pharma worldwide therapeutic monopolies, resistance should be anticipated. Nonetheless, the proposal, which continues to evolve, is a constructive step toward developing an alternative approach to addressing U.S. concerns with free-riding that is not based on reinforcing private sector concentration.

IP and public health involves an ongoing tension between the regulated and the regulator. A pattern of action and reaction is evident. Pharmaceutical access issues in developed and developing countries are increasingly difficult to delink. There is substantial incentive for developing a solution to global medicines regulation that diffuses the tension between private profit-seeking enterprise and the consuming public. This is the major challenge confronting participants in this dialogue.

I. The Worldwide Patent and Pharmaceutical Sector Consolidation

January 1, 2005 will mark the end of the TRIPS Agreement transition period for pharmaceutical product patents with respect to developed and developing countries.[1] This will effectively culminate the effort launched by the OECD patent-based pharmaceutical industry ("Pharma") in the early 1980s to require the grant and enforcement of patents on medicines throughout the developing world.[2] After January 1, 2005, it will be possible for originators of new medicines to obtain patent protection for a minimum term of 20 years post-filing in all major economic markets.

Among developing WTO Member countries almost all major pharmaceutical producing countries have already introduced pharmaceutical product patent protection. Shifts in the supply market based on that may largely have taken place. India is the notable exception. It is expected to introduce pharmaceutical product patent protection on January 1, 2005. The Indian pharmaceutical sector until now has operated largely free of patent impediments in its domestic market. India is a major supplier of generic pharmaceuticals to the developing world.[3] Its introduction of pharmaceutical product patents is likely to have a significant impact on the world supply market, although the precise effect is difficult to predict. It will depend, among other things, on how changes to India's existing patent system are made and implemented. The short, medium and long term impacts may vary.[4]

The global pharmaceutical industry is consolidating.[5] The trend toward consolidation is based on a number of factors. Particularly for originator companies, there are high costs associated with developing new medicines, subjecting them to testing and securing regulatory approvals, building and

[1] Least developed countries are not required to implement or enforce pharmaceutical patent protection or data protection rules until at least January 1, 2016, per Paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health and related implementing acts of WTO bodies.

[2] *See, e.g.,* SUSAN SELL, PRIVATE POWER, PUBLIC LAW, THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS 96-108 (2003)(Cambridge) and contributions on TRIPS in THE POLITICAL ECONOMY OF INTERNATIONAL TRADE: ESSAYS IN HONOR OF ROBERT E. HUDEC 245-348 (D. Kennedy and J. Southwick eds, 2002 (Cambridge).

[3] D.G. Shah, *Post 2005: what future for pharmaceuticals and access to medicines*, paper presented at QUNO meeting, Implementing the paragraph 6 decision and Doha Declaration: solving practical problems to make the system work, Jongny-sur-Vevey, Switzerland, May 21-23, 2004, and; Carsten Fink, *Patent Protection, Transnational Corporations, and Market Structure: A Simulation Study of the Indian Pharmaceutical Industry*, 1 J. OF INDUSTRY, COMP. & TRADE 101-21 (2001).

[4] There are a large number of "mailbox" applications for pharmaceutical products that will be processed when the transition ends. With respect to HIV/AIDS, it appears likely that most if not all first line single-compound antiretroviral treatments were patented prior to January 1, 1995, and are not likely to be patentable under the mailbox system. However, combinations of these compounds (such as Combivir and Triziver) have priority dates after that date, and whether patents are granted as to such combinations depends on the terms of the amendments to India's Patents Act, which is yet to be adopted, and interpretation of the Act by the Controller General of Patents. If patents as to combinations are granted, this may affect ongoing production of similar combinations by Indian generics producers. Newer ARV treatments, including fusion inhibitors, are likely to be patented when the transition period ends and, of course, ARV treatments developed after January 1, 2005 will be patentable.

Outside HIV/AIDS, the short term effect on Indian supply of generic medicines will depend on the priority dates of foreign reference patent applications and on the demand for the particular therapies.

[5] *See, e.g.*, Directorate for Financial, Fiscal and Enterprise Affairs Committee on Competition Law and Policy, Competition and Regulation Issues in the Pharmaceutical Industry, OECD, DAFFE/CLP(2000)29
06-Feb-2001, at 12, 28-29, and; Institute for Health and Socio-Economic Policy, *"Big Pharma:" Mergers, Drug Costs, and Health Caregiver Staffing Ratios*, May 2, 2001, at 9-11. Also see, Arthur D. Little, Report, *Unraveling the Pharmaceutical Industry* (2003).

maintaining manufacturing facilities, distribution, and defending against liability.[6] High costs act as barriers to entry, particularly in the "originator" sector. Patent protection allows originator companies to secure protected-market revenues (i.e., monopoly rents) from new products. These revenues may be used to cover development costs. They may also be used to cover the costs of stronger global sales forces, more extensive advertising and promotion, and political lobbying. These activities reinforce the pattern of consolidation in both the patented and generic sectors of the pharmaceutical market. The end of the TRIPS Agreement transition period is another factor that will strengthen the trend toward consolidation. Originators will be able to exercise greater control over price and availability of medicines.[7]

The problem of high pharmaceutical prices and restricted access is not limited to developing countries. Populations in the OECD are aging, and older populations are increasingly dependent on "prescription" medicines. The cost of medicines is straining government budgets and burdening private health benefits systems. The concern of ICTSD is mainly with the situation in developing countries, but the problem of access to medicines in developed and developing countries is difficult to delink. This is due to a number of factors.

1. Pressure is growing within the United States on the pharmaceutical industry to lower prices, particularly for disadvantaged populations. It is politically difficult for the industry to offer price concessions for populations in developing countries without offering corresponding concessions in the United States and elsewhere in the OECD.

2. As developing country enterprises make successful inroads into developed country markets in fields such as electronics and civilian aircraft, this increases pressure in developed countries to secure revenues from areas of technological advantage such as pharmaceuticals. For example, as China and Brazil generate substantial trade surpluses with OECD countries, arguments in favor of price concessions on pharmaceuticals may become less compelling in a wider political arena.

3. Pressures are increasing within the United States for increased "burden sharing" on pharmaceutical research expenditures among trading partners. While at present this pressure is particularly directed to OECD countries, it creates problems in arguing for reduced expenditures by developing countries.

II. Regulatory Response

A. The Regulatory Toolbox

[6] The withdrawal by Merck of Vioxx from the market, as well as Bayer's experience with Baycol, provides a reminder that making and selling medicines is a high-risk business. Even the biggest pharmaceutical companies face the possibility of catastrophic failure.

[7] All other things being equal, the effect of the new situation will be to raise the price of new medicines, and restrict access to them. It is not possible to quantify with certainty the global impact of the universalization of pharmaceutical product patent protection. The pharmaceutical sector accounts for about $450 billion per year in worldwide sales, about 20% of which derives from developing countries, or $90 billion. Only a portion of sales is made up of patented products (which are likely to generate more profit than non-patented products). The "rent transfer" order of magnitude effect of shifting from a non-patent to patent regime on developing countries will be in the billions of dollars per year. *See* data and references in Frederick Abbott, Study Paper 2a for the British Commission on IPRs.

Governments have the power to regulate industry. There are a number of ways that problems of high pharmaceutical prices and restrictions on availability can be approached. Probably the most commonly-used form of regulatory response is the imposition of price controls.[8] Such controls may be implemented in different ways, including through the oversight of insurance reimbursement schemes.[9] Governments may break patent holder monopolies by issuing licenses to third parties or the government to make or import and sell products without the consent of patent holders (*i.e.*, compulsory or government use licensing").[10] Governments may also authorize "parallel importation" of products, permitting the purchase of the lowest cost supplies available on the world market. Governments may take remedial measures against pharmaceutical enterprises that engage in anticompetitive conduct, including by imposing substantial monetary penalties and by granting licenses to third parties to make patented products.

There are other mechanisms of regulatory control over pharmaceutical monopolies. Governments may limit the types of inventions on which pharmaceutical patents are granted. Thus, for example, they may refuse to grant patents with respect to new uses of known compounds, including second medical indication patents. Governments may accelerate the introduction of generic products by allowing for third party testing and regulatory approval prior to expiration of the patent term, and by refusing to extend the term of patents to offset regulatory approval periods. Governments may allow generic producers to rely on the prior regulatory approval of originator products as the basis for allowing registration of bioequivalent products.

B. WTO Rules

The TRIPS Agreement broadly mandates that patents be made available for all fields of technology (Article 27.1). It does not, however, restrict the authority of governments to regulate prices. It establishes rules regarding the grant of compulsory or government use licenses, but permits them to be granted. It permits governments to authorize parallel importation. The TRIPS Agreement does not specify that new use patents must be granted. It allows patents to be used for regulatory approval purposes, and it does not require the extension of patent terms to offset regulatory approval periods. The TRIPS Agreement provides a limited form of protection for submissions of regulatory data, but this protection does not prevent a generic producer from making use of publicly available information to generate bioequivalence test data. The TRIPS Agreement provides substantial discretion for the application of competition laws.[11]

The Doha Declaration on the TRIPS Agreement and Public Health was adopted by Members of the WTO on November 14, 2001, confirming and reinforcing flexibilities inherent in the TRIPS Agreement. It specifically addresses compulsory licensing and parallel importation, and more generally emphasizes that the TRIPS Agreement should be interpreted in a manner conducive to promoting access to medicines for all. The Decision on Implementation of Paragraph 6 of the Doha Declaration was adopted on August 30, 2003 (the "Medicines Decision"), with the objective of

[8] *See* OECD, *supra* note 5, at 41-54.

[9] *Id*.

[10] *See, E.G.*, Frederick M. Abbott, Study Paper 2a For The British Commission On Intellectual Property Rights, *WTO TRIPS Agreement And Its Implications For Access To Medicines In Developing Countries*, Feb. 14, 2002.

[11] *See* Frederick M. Abbott, *Are the Competition Rules in the WTO TRIPS Agreement Adequate?* 7 J. INT'L ECON. L. 685 (2004).

permitting countries with insufficient or no manufacturing capacity in the pharmaceutical sector to make effective use of compulsory licensing.[12]

Governments have authority under the rules established by the WTO to facilitate lower prices and enhanced access to pharmaceutical products.

III. Restricting the Regulatory Toolbox

Since the inception of the TRIPS Agreement, the Pharma companies have sought to reduce or eliminate the options in government portfolios for lowering prices and enhancing access. The case brought against the government of South Africa was broadly addressed to generic substitution, prices controls (i.e., the single exit price) and patents (parallel importation and ancillary claims).[13] That litigation illustrated the gaps in the TRIPS Agreement from Pharma's standpoint. It did not provide the basis for eliminating regulatory flexibilities. USTR was placed in the difficult position of arguing that "TRIPS-plus" standards entitled the United States to threaten trade sanctions.

Pharma has consistently pressured USTR (and Congress) to pursue its objective of reducing foreign regulatory flexibility.[14] This pressure has manifested itself in resistance to the Doha Declaration and a comprehensive solution under Paragraph 6, and in the negotiation of provisions in bilateral and regional trade agreements that expressly endorse the Pharma agenda. This pressure also is evident in negotiations at the World Intellectual Property Organization (WIPO) on a Substantive Patent Law Treaty (SPLT). Pharma engages in direct and indirect lobbying at the World Health Organization (WHO). Activity at the WHO is largely defensive; that is, to prevent WHO from developing a distinct IPRs agenda for health that might differ from that maintained at the WTO and WIPO.

The terms of the IPRs chapters of FTAs recently concluded by the United States provides a clear manifestation of the Pharma agenda with respect to restricting regulatory flexibility.[15] While the intellectual property chapters of these agreements vary in their specific terms,[16] the common objectives of the United States, achieved to different degree, are to limit potential exclusions from

[12] The Medicines Decision permits countries with insufficient manufacturing as to particular pharmaceutical products to request other countries to make and export the products under compulsory licensing, specifically when the exporting country is not producing predominantly for the supply of its domestic market. There are a number of conditions associated with use of this system. *See* for details the accompanying paper, Frederick M. Abbott, *The WTO Medicines Decision: The Political Economy of World Pharmaceutical Trade and the Protection of Public Health*, draft of Sept. 27, 2004.

[13] *See* Abbott, Study Paper 2a, *supra* note 10.

[14] *See* series of annual reports submitted by PhRMA for use by USTR in preparation of Special 301 Reports.

[15] Concerns with respect to U.S. FTAs were raised by this author in Frederick M. Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Trade Arrangements*, Quaker United Nations Office (QUNO) Occasional Paper 14, Apr. 2004 (available at http://www.quno.org).

[16] The texts of the FTAs are available at http://www.ustr.gov. The World Bank has compiled tables of IPRs-related provisions in the various bilateral agreements, *see* (forthcoming 2004, in author's files). A number of NGOs have also compiled tables showing the TRIPS-plus provisions adopted on an agreement-by-agreement basis. *See, e.g.*, Oxfam Briefing Note, *Undermining access to medicines: Comparison of five US FTAs*, May 2004, available at http:// http://www.oxfamamerica.org/pdfs/fta_comparison.pdf) and CPTech, *Table of selected provisions related to healthcare in the Free Trade Agreement texts that have been made public*, available at http://www.cptech.org/ip/health/trade. *See also* MSF Briefing Note, *Access to Medicines at Risk Across the Globe: What to Watch Out for in Free Trade Agreements with the United States*, May 2004, available at http://www.accessmed-msf.org.

patentability,[17] require the grant of patents for "new uses" of known compounds,[18] require patent term extension under certain conditions,[19] prevent parallel importation,[20] limit the grounds under which compulsory licenses may be granted,[21] and allow for the prosecution of non-violation nullification or impairment claims.[22] Beyond this, the United States is negotiating for periods of marketing exclusivity based on the submission of data in the regulatory approval process that eliminates the flexibilities of the TRIPS Agreement,[23] and that covers patented and non-patented products. These provisions not only provide marketing exclusivity based on data submitted in the country where regulatory approval is being sought, but also based on data submitted in foreign countries, or based on the fact of marketing approval in a foreign country. The U.S. links patents to the marketing approval process, precluding a country from approving a product with effect prior to the expiration of the patent term, without the "consent or acquiescence" of the patent holder.[24] In the case of Australia, the United States has negotiated an entry point into the national pharmaceutical price control system.[25]

[17] Some agreements, for example, preclude the exclusion of plants and animals from patentability, eliminating the flexibility in Article 27.3(b) of the TRIPS Agreement to exclude such subject matter, and to provide only a *sui generis* form of plant variety protection.

[18] The grant of patents for "new uses" is not permitted in many countries. *See, e.g.*, Andean Community, Decision 486, art. 21 ("Products or processes already patented and included in the state of the art within the meaning of Article 16 of this Decision may not be the subject of new patents on the sole ground of having been put to a use different from that originally contemplated by the initial patent.") In a typical case, a pharmaceutical compound known to be effective for treating one form of disease is found to treat another disease, and a person seeks a patent on the "new use" (sometime referred to as a "second medical indication" patent in that context). The TRIPS Agreement is silent regarding whether such patents should be granted, leaving countries with flexibility to decide the question.

[19] The United States provides a limited patent term extension based on the period during which a product undergoes regulatory review. Country practice varies on this matter, and it is not regulated by the TRIPS Agreement. See Panel Report in *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R**,** 17 March 2000, describing U.S. system and deciding that patent term extension based on regulatory review is not required by TRIPS Agreement. The terms of the FTA base the exception on unreasonable delays in granting patents.

[20] The Doha Declaration, at para. 5(d), confirmed the right of each WTO Member to adopt its own policy and rules with respect to parallel imports. Some FTAs preclude parallel importation of patented products, thereby eliminating this flexibility.

[21] Some FTAs limit the grounds for granting compulsory licensing, for example, to national emergencies and circumstances of extreme urgency, or to remedy anticompetitive practices (*see, e.g.*, U.S.-Singapore).

[22] *See, e.g.,* Frederick M. Abbott, *Non-Violation Nullification or Impairment Causes of Action Under the TRIPS Agreement and the Fifth Ministerial Conference: A Warning and Reminder*, QUNO Occasional Paper 11, July 2003.

[23] Article 39.3 of the TRIPS Agreement requires Members to provide protection against use of confidential information with respect to "new chemical entities" submitted during the regulatory review process against "unfair commercial use". The provisions in the FTAs establish strict "marketing exclusivity" periods following approval based on submitted data (initially five years), do away with the limitation to "new chemical entities", and do not allow exception for fair or non-commercial uses, such as use by government authorities in public health systems. Some of the agreements allow the renewal or "evergreening" of marketing exclusivity periods.

[24] *See* discussion below.

[25] See Parliamentary Library Research Department (Australia), Research Note, The PBS and the Australia–US Free Trade Agreement, 2004–05, No. 3, 21 July 2004, and; P. Drahos, T. Faunce, M. Goddard and D. Henry, *The FTA and the PBS: a submission to the Senate Select Committee on the US-Australia Free Trade Agreement*, 2004.

Despite the provisions curtailing access to pharmaceuticals, developing countries have been anxious to conclude FTAs with the United States, and there is no sign that this trend is abating.[26] Negotiators for developing countries understand that they are giving up flexibility in the pharmaceutical sector, and accept that this constitutes a trade concession in favor of the United States.[27] The provisions are accepted because the governments believe that the FTAs are on the whole of benefit to the countries involved, and that compromise in the pharmaceuticals sector is necessary to achieve gains in other areas. There are, of course, wider political dimensions as governments cement friendly relations with the United States.

The problem with an analysis of FTAs using net economic gains or losses as the developing country benchmark is that gains for a developing country's textile or agricultural producers do not directly translate into higher public or private health expenditures.[28] Salaries for part of the workforce may increase and government tax revenues may rise, and this may indirectly help offset pharmaceutical price increases. But, in order for the health sector not to be adversely affected, there must be some form of transfer payment, whether in the form of increased public health expenditures on pharmaceuticals, by providing health insurance benefits, or other affirmative acts. In a world of economic scarcity, the prospect that governments will act to offset increases in medicines prices with increased public health expenditures is uncertain.

NGOs and European governments have expressed concern about the medicines provisions in the new generation of FTAs.[29] Economists at the World Bank are similarly raising concerns about these developments.[30] There is little indication that the U.S. plans to alter its approach, although members of Congress are more recently taking note that restrictive conditions in the FTAs may impede pharmaceutical policies that the United States may want to pursue.[31]

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[26] For a trend analysis with respect to the negotiation and conclusion of FTAs involving the United States, see Report by the WTO Secretariat, Trade Policy Review, United States, WT/TPR/S/126, 17 December 2003, at pg. viii, para. 8, and pgs. 20-27.

[27] The author has had extensive conversations with developing country negotiators of these FTAs. There is no doubt that the subject provisions are adopted at the initiative and demand of the United States, and are viewed as a necessary concession by the developing country negotiators. These negotiators assume that the country will experience higher pharmaceutical payment outflows as a consequence.

[28] This author has proposed a move toward objective assessment of the economic impact. *See* Frederick M. *Abbott, Toward a New Era of Objective Assessment in the Field of TRIPS* and *Variable Geometry for the Preservation of Multilateralism*, presented at World Trade Forum, Berne, June 2004, forthcoming 8 J. INT'L ECON. L. No. 1 (2005).

[29] *See* CPTech, MSF and Oxfam, *supra* note 16; *See* Pascal Lamy, *The TRIPs agreement 10 years on*, International Conference on the 10th Anniversary of the WTO TRIPs Agreement. Brussels, 23 June 2004 (available at http://europa.eu.int/comm/commissioners/lamy/speeches_articles/spla233_en.htm); Sarah Boseley, *France accuses US of Aids blackmail*, THE GUARDIAN (U.K.), July 14, 2004, referring to a statement of President Jacques Chirac of France read at the XV International AIDS Conference in Bangkok, stating, inter alia, "Making certain countries drop these measures in the framework of bilateral trade negotiations would be tantamount to blackmail, since what is the point of starting treatment without any guarantee of having quality and affordable drugs in the long term?". Also, remarks of WTO Amb. Luzius Wasecha, Switzerland, Policy Dialogue on "Intellectual Property Rights Development 10 Years after Marrakech: Where are we? Where are we heading?", UNCTAD/ICTSD, May 17, 2004.

[30] *See* Trade Policy Note and Global Economic Prospects (forthcoming prior to end of 2004).

[31] For example, see resolution introduced in the House of Representative, "Opposing the inclusion in future free trade agreements of provisions that would have the effect of restricting, undermining, or discouraging the enactment or implementation of legislation authorizing the importation of prescription drugs, and for other purposes." House Resolution 758, 108th Cong., 2d Sess., Sept. 8, 2004 (by Brown of Ohio, et al.), House Resolution Opposes Future FTAs Against Drug Importation, World Trade Online, Sept. 14, 2004.

III. Counter-Responses

A. Addressing the FTAs

There are a number of approaches that developing countries may take to forestall relinquishment of their medicines regulatory portfolio in FTA and bilateral negotiations.[32] Action on some of these approaches has already taken place. They include:

1. The formation of counter-coalitions committed to resisting pressures on public health.[33] Such coalitions may be built within existing regional arrangements. Inter-regional coalition building is also important to avoiding a "domino effect" among regions. Developing countries may find that developed countries have common interests in resisting pressures to reduce regulatory flexibilities. NGOs play an important role in recommending policies and establishing media awareness. U.S. industry is not monolithic, and it should not be assumed that Pharma has broad support within U.S. industry as a whole.[34] Developing country negotiators may find that there is space for concession by USTR on pharmaceutical-related issues.

2. The initiation by affected exporting countries such as India and China of complaints at the WTO based on *de facto* violation of the MFN provision of the TRIPS Agreement;

3. Negotiation of a Doha supremacy clause as part of negotiations on an amendment to the TRIPS Agreement to give effect to the August 30, 2003 Decision, and;

4. Use of the "right to protect public health" clause of the Doha Declaration in interpretation and enforcement of WTO law.

B. Further Action at the WTO

1. Transformation of the Decision

Regarding transformation of the Medicines Decision into an amendment from a developing country standpoint, WTO Members are clearly at odds regarding whether the Decision needs "fixing", and the ways this might be done. There seems limited prospect that, in the near term, negotiations on new subject matter would lead to a consensus around a different outcome, absent some fairly substantial change of political perspective within key Members. Given these circumstances, rather

[32] These options are explained in greater detail in Frederick M. Abbott, *The WTO Medicines Decision: The Political Economy of World Pharmaceutical Trade and Protection of Public Health*, manuscript of Sept. 27, 2004.

[33] *E.g.*, at the XV International HIV AIDS Conference six countries (Brazil, China, Nigeria, Russia, Thailand and Ukraine) signed an agreement to increase cooperation in developing and producing generic drugs. India and South Africa are considering joining this group. *See Brazil to Coordinate Six-Country Anti-AIDS Network*, BBC Monitoring International Reports, July 16, 2004, Lexis-Nexis. According to this report, "The purpose is to form a strong alliance to withstand the interests of major laboratories", and it will be supported by the Ford Foundation.

[34] It is not clear that companies such as General Motors have strong motivation to support Pfizer's position on strengthening protection for originator medicines. See, e.g., Danny Hakim, *Carmakers Face Huge Retiree Health Care Costs*, NY TIMES, Sept. 15, 2004, at a1, discussing serious financial problems facing major automobile producers in paying for prescription drugs for employees and retirees.

than tackling the amendment question immediately, Members might focus their attention on implementing and gaining experience with using the Decision. This would provide a better-informed basis for subsequent negotiation of any changes. Members could return to negotiations in several years. Because the waiver provides a secure basis for implementation, there is no strong legal reason to press for a rapid transformation of the Decision to an amendment.

On the other hand, the trend in the negotiation of bilateral and regional trade arrangements raises a concern. The trend in FTA negotiations at the moment is toward eliminating TRIPS flexibilities, and the Decision is at least a modest success in expanding TRIPS flexibilities. In a few years, the situation at the WTO may have changed as a consequence of the proliferation of FTAs such that a substantial number of developing countries will have agreed to cut back on TRIPS flexibilities on a bilateral basis. The developing countries that have not conceded their flexibilities may find that there is not a sufficient critical mass even to transform the existing Decision into an amendment of the TRIPS Agreement. This possibility may argue in favor of tackling the amendment sooner rather than later. Developing countries might take the FTA trend into account when deciding on the best course of action.

In the present political environment, an "aggressive reopening" of the terms of the Decision is unlikely to produce a positive result because the United States remains dissatisfied with its core terms and would use such reopening as a means to pursue narrowing of its scope. A change in administration in Washington may affect U.S. flexibility regarding the terms of the Decision. Negotiations on an amendment will largely take place after the November 2, 2004, election. Any change in U.S. policy can therefore be evaluated prior to further consideration of this matter.

2. Article 27.3(b) Issues

There is substantial interest among developing countries to address the relationship between patents and genetic resources at the WTO, including requiring disclosure of the source and origin of genetic material as a condition of patent protection. The African Group has proposed that genetic materials as such not be subject to patent protection. These issues are also under discussion at WIPO.[35]

The manner in which these issues are resolved may have a long term effect on the pharmaceutical sector by increasing or decreasing the scope of materials and information that are part of the public domain and by encouraging or discouraging research in particular areas. A principal objective of the negotiations is to assure that compensation is paid for the exploitation of the resources of particular geographic areas or peoples.

The preservation of biodiversity is important to the future development of medicines, and the 27.3(b) issues are part of the public health and IPRs agenda.[36] The United States has opposed consideration of biodiversity issues in the TRIPS Council. The United States largely lacks an internal policy on the relationship between genetic resources and IPRs, and this absence of internal policy manifests itself as a general reluctance to address these issues at the multilateral level. There is also resistance among the patent owner community to proposals that may put patents at risk. The European

[35] *See* WIPO Assemblies 2004, Decision on Agenda Item 10: Invitation Addressed to WIPO by the Contracting Parties of the Convention on Biological Diversity.

[36] There is limited data regarding the potential economic and public health consequences of alternative solutions to the Article 27.3(b) issues.

Union and Switzerland have been more sympathetic to the possibility of including disclosure of source and origin as part of the patent application process. However, they are resistant to including patent forfeiture as a potential remedy for disclosure failures.

The adoption at WIPO of a Decision calling for submission of proposals, preparation of a draft text and convening of a meeting in September 2005 appears to reflect an organized effort to reduce the role of the TRIPS Council in addressing this area.

3. Non-Violation Nullification or Impairment

The TRIPS Agreement directs the TRIPS Council to make a recommendation regarding the scope and modalities of non-violation nullification or impairment causes of action. The moratorium on such actions was extended until the Hong Kong Ministerial Conference in the August 1, 2004 framework agreement for the Doha Development Agenda.[37]

Outside dealing with the FTA problem, resolution of the non-violation question may be the most important single item on the WTO agenda from a TRIPS and public health standpoint.[38] There is good prospect for developing countries to cooperate with developed countries, including Canada and the EU, in resisting to inclusion of such causes of action in TRIPS. However, it is not clear that blocking consensus adoption of recommendations will be an adequate solution to the problem because of the text of Article 63.2-3, TRIPS Agreement. Therefore, it may be important to develop an affirmative proposal to recommend that non-violation actions be prohibited.

The United States is seeking recognition of non-violation actions as to IPRs matters in its FTAs. This signals that it is likely resist elimination of such causes of action at the WTO.

IV. Pharmaceutical Regulation

A. Conventional Mechanisms

A patent is essentially a financial instrument that entitles its bearer to achieve greater than competitive market rates of return on investment. The Pharma companies are market-oriented enterprises that seek to maximize shareholder returns on investment. Pharma treats potential intrusion on the security of the patent and related regulatory support as a threat to return on investment. Pharma justifies its rent-seeking as necessary to the funding of research and development for new medicines.

Protection of patents imposes an economic and social cost on populations that provide it. As Fritz Machlup observed:

> "That existing patents are a social cost, not a social benefit, is most readily appreciated when the patented invention is of such extraordinary importance that society would not tolerate even a temporary restriction in its use. The great inventor of the polio vacci Dr. Salk, generously contributed his idea to society without applying for a patent. If he had taken a patent on his process and sold it to a company

[37] General Council Decision of August 1, 2004, para. 1(h), at http://www.wto.org.

[38] *See* QUNO 11, *supra* note 22.

> which exploited it restrictively enough to make high profits, would the American public have stood for it?"[39]

The Pharma companies and those seeking affordable access to medicines are locked into an action-reaction cycle. The Pharma companies demand rules and enforcement that will protect their income streams, justifying a high return on investment as necessary to drug development.[40] The access community demands rules and measures that reduce the social cost of patents; to reduce expenses for governments, businesses and individual consumers,[41] as well as to exercise greater control over the direction of research.[42]

The current approach to medicines regulation is an action-reaction approach. It plays out on the national and multilateral levels, and involves complex strategies of forum shifting and propaganda.

B. Research Treaties

James Love and Tim Hubbard have proposed an alternative to the TRIPS-based R&D incentive system which would permit governments to adopt alternative private and public models of drug development and distribution provided that certain commitments to the funding of R & D are maintained.[43] The R&D funding commitment would be based on a sliding scale to take into account developmental factors. This proposal addresses the concern increasingly expressed in the United States that other countries are "free-riding" on U.S. expenditures on R&D. The proposal attempts to provide a space within which alternative approaches to drug development and distribution can be used

[39] An Economic Review of the Patent System (1958), Report for the Subcommittee on Patents, Trademarks and Copyrights of the U.S. Senate Judiciary Committee, 85th Cong., 2d Session. Reprinted in FREDERICK ABBOTT, THOMAS COTTIER AND FRANCIS GURRY, THE INTERNATIONAL INTELLECTUAL PROPERTY SYSTEM (1999), at 224, 240. Machlup's reference to "existing patents" implicitly presumes the existence of an invention. It does not answer the question "where do inventions come from, and are patents necessary for invention"? Machlup was skeptical that patents are necessary to encourage invention, but was sympathetic to the idea that patents are important to encourage investment in invention, that is, bringing products to market.

[40] The market aggregates research and development capital and private enterprise is largely responsible for delivering products to end-users.

[41] Governments police the market and are expected to correct market failures. Governments may use the means available in the regulatory toolbox discussed earlier. This includes use of price controls, generic substitution, enforcement of competition law, grant of compulsory licenses and authorization of parallel importation (and re-importation).

[42] For example, it is recognized that disease conditions prevalent among the poor are underserved by market-based incentive systems, and there are a number of projects that seek to overcome this market failure through subsidization of research on "neglected diseases". Some of this research is conducted through public-private partnerships. The inventions of public-private partnerships may be subject to patenting.

To correct market failures regarding the direction of research, governments may rely on subsidization or other alternatives to patenting. There is substantial debate about who should determine the direction of research and how the product of research should be distributed to the public. However, no one involved in the access to medicines debate questions the need for new pharmaceutical inventions. Nor is there anyone arguing for a reduction in the amount of investment in pharmaceutical invention. It has long been accepted that invention may be encouraged through a variety of mechanisms, of which patents are only one. Subsidization is the main alternative approach, and the awarding of prizes is also an option. Alternatives to the patent reward system of encouraging innovation are discussed in WILLLIAM D. NORDHAUS, INVENTION, GROWTH AND WELFARE (1969).

[43] *See* Tim Hubbard, James Love, *A New Trade Framework for Global Healthcare R & D, PLoS Biology*, Feb. 2004, and; James Love and Tim Hubbard, *Make Drugs Affordable: Replace TRIPS-plus by R&D-plus*, BRIDGES, June 2004, at 3.

without threat of legal sanction. It recognizes that different approaches to pharmaceutical development and distribution may be appropriate in different settings.

The Love-Hubbard approach represents a challenge to the Pharma-centric model of drug development because it effectively reduces the prospects for globalized monopoly positions. It shares that characteristic with the proposal of Jean Lanjouw under which patent applicants would elect between rights in the industrialized or developing countries.[44] The Love-Hubbard proposal adds a commitment to R&D that addresses the free-rider problem.[45]

The Love-Hubbard proposal reflects an effort to break the action-reaction cycle by reducing private economic incentives to challenge differential regulation of the pharmaceutical sector. It emphasizes the potential benefits of regulatory heterogeneity. It challenges what Pharma perceives as its best economic interest, and this has resulted in industry counter-lobbying. Nonetheless, the proposal, which continues to evolve, is a constructive step toward developing an alternative approach to addressing U.S. concerns with free-riding that is not based on reinforcing private sector concentration.

John Barton has also proposed a research treaty model designed to reduce national preferences for research and to facilitate the free exchange of information.[46] This proposal is principally directed to increasing the amount of information available for use by researchers in developing countries, which information might ultimately yield new inventions.

C. The Regulated and the Regulator

The global pharmaceuticals trade involves an ongoing tension between the regulated industry and the regulators. The regulated industry seeks space for achieving high rates of return on investment. The regulator seeks to assure that the public interest is protected.

Pharma conceded freedom of action in the Doha Declaration and Paragraph 6 negotiations, but is gaining pricing power in the FTAs. Pharma is under increasing political pressure in the United States and Europe to reduce prices. The U.S. federal government is facing a virtual rebellion by state governments that are ignoring orders against importing price-controlled drugs from Canada. As the costs of providing pharmaceuticals to aging populations in the OECD continue to increase, reaction by governments is inevitable.

Despite Pharma's strong influence on OECD trade negotiators, it is becoming increasingly unpopular among the public.[47] Overt support for an unpopular industry is a political liability. Efforts to protect developing country public health interests in trade negotiations may benefit from finding ways to link those interests to those of the consuming public in the OECD.

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[44] Jean Lanjouw *A Patent Policy Proposal for Global Diseases*, NBER Working Paper …. (April 2001).

[45] In a more immediate sense, Love-Hubbard suggest that individual governments might be able to forego TRIPS-plus obligations in FTAs based on commitment to a level of research funding. For example, in its FTA negotiations with the United States, Thailand could offer to maintain a higher level of R&D in exchange for a less restrictive IPRs chapter. *See* Bridges, supra note 43.

[46] John Barton, *Preserving the Global Scientific and Technological Commons*, in Policy Dialogue on a Proposal for an International Science and Technology Treaty, ICTSD-UNCTAD, Apr. 11, 2003.

[47] *See On the Defensive*, MedAdNews, available at http://www.pharmalive.com, downloaded Oct. 1, 2004.

D. Breaking the Cycle

The continuous action-reaction cycle in the regulation of world pharmaceutical trade diverts intellectual capital and reduces focus on the ultimate objective of the system which is to provide treatment to individuals. There is substantial incentive for developing a solution to global medicines regulation that diffuses the tension between private profit-seeking enterprise and the consuming public. This is the major challenge confronting participants in this dialogue.