STATEMENT TO THE

SENATE FINANCE COMMITTEE

HEARING ON

INTERNATIONAL ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS AND AMERICAN COMPETITIVENESS

JULY 15, 2008

JOHN H. BARTON

(jbarton@stanford.edu)

GEORGE E. OSBORNE PROFESSOR OF LAW, EMERITUS

STANFORD LAW SCHOOL

STANFORD, CA 94305

I have been asked to testify on the concerns that developing nations have presented in response to the global extension of intellectual property (IP) through trade negotiations.

I am the George E. Osborne Professor of Law, Emeritus at Stanford, where I've taught and written on both technology law and international trade issues over the years, with a special focus on developing nation concerns. I was chair of the 2001-2002 U.K. Commission on Intellectual Property Rights. Our report, *Integrating Intellectual Property Rights and Development Policy*, reflected many discussions with developed and developing nation officials and scholars, pharmaceutical firms, and patient advocacy groups. I have also consulted for many years with the international agricultural development community, and have recently written on IP and transfer of climate change technologies.

My presentation has four components. I will first consider the role of Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) TRIPS and IP trade policy generally as it affects developing nations. I will then explore, in turn, pharmaceutical, agricultural, and climate change issues.

TRIPS and IP trade policy. It is not often realized how significant it was to introduce IP policy into world trade negotiations. This introduction has been sought by the U.S. government since the 1980s, both through negotiating TRIPS in the Uruguay Round and through bilateral diplomacy. Traditional trade negotiations were about ways to reduce trade barriers. Because free trade almost always economically benefits both the new importers and the new exporters, the negotiators could be confident that they were facilitating the achievement of mutual benefit. Admittedly, they were working within a politic context that focused on specific new exports and specific import concerns of specific industries, but ultimately they were benefiting all.

This is not necessarily the case for IP diplomacy. To take the pharmaceutical patent example, strengthening IP in a nation that imports pharmaceuticals from the United States normally implies that the citizens of that nation pay more for pharmaceuticals. This is hardly a benefit, and it is disingenuous to describe weak IP as a trade barrier – when a trade barrier is removed, the domestic price generally falls rather than rises. The counter argument is, of course, that the participation of those citizens in the global market at a patent-based price creates an incentive for research. In that sense, they may ultimately benefit. But, on their own, they might have chosen a different balance between short-term current costs and long-term research benefits. International IP policy is thus not about free trade. Rather, it is about global allocation of the cost of research. It is certainly reasonable that other wealthy nations should not be entitled to

free ride on the benefits of U.S. research, but it is also reasonable that the poor should not have to pay as large a share of those research costs as the wealthy.[1]

Indeed, for small poor nations, the benefits of a patent system are minor if not negative: there are few or no local scientists and engineers who can benefit from the possibility of obtaining a patent, the local market is too small to provide any serious return on investment, and the building of a local patent bureaucracy is an absurd waste of resources. Not surprisingly, the majority of the patent holders in such nations are foreign firms. The World Intellectual Property Organization, for example, estimates that Peru granted 383 patents to non-residents and 5 to residents in 2005.[2] (It is hard to find reliable data for smaller or poorer nations.) The TRIPS agreement makes no provision for exclusions for small poor nations. It serves neither these nations' nor the U.S.'s interests to pressure these nations to build a patent system.

Pharmaceutical issues. The political nub of dispute over the U.S. patent policy has, of course, been pharmaceutical access. One of the key diplomatic goals of TRIPS was to change the policies of nations such as India, which had denied product patent protection to pharmaceuticals, and thus produced copied generic versions of the developed world's patented pharmaceuticals. The drug access issue came to wide political visibility in 1998 with the filing of a suit by a number of pharmaceutical firms to try to keep South Africa from importing certain generic antiretroviral drugs that would infringe patents in that nation. That litigation was settled in 2001 – but was a major public relations disaster for the industry. It exemplified a multi-year debate over the terms of access to antiretrovirals to deal with the AIDS epidemic sweeping Sub-Sahara Africa. AIDS activists argued that patents were keeping these nations from obtaining access to such drugs, because they were priced too high. The industry argued in response that the lack of medical infrastructure was the problem, and that many of the relevant drugs were not patented.

As a formal legal matter, the dispute was settled by the Doha Declaration on the TRIPS agreement and public health, an agreement reached at the World Trade Organization Ministerial meeting of 2001. This Declaration stated that public health concerns were to be taken into account in interpreting TRIPS and affirmed the use of a number of TRIPS "flexibilities," including compulsory licenses. Detailed arrangements were negotiated over the next several years to allow the international sale of generics to nations that could not create their own industries. The Doha Declaration result was very understandable considering that the total pharmaceutical market in the poorest nations was at most on the order of 2 % of the global market. Any injury to the economic interests of the industry or to research incentives for the future was minor compared with the benefit to the world (and to U.S. interests) of making the drugs more readily available.

---

[1] See, J. Barton, "The Economics of TRIPS: International Trade in Information-Intensive Products," 33 *George Washington Int'l Law. Rev.* 473 (2001).

[2] World Intellectual Property Organization, *WIPO Patent Report*, 2007.

Nevertheless, there is now contention arising from the fact that the USTR has sought to strengthen developing world IP protection – and narrow some of those flexibilities – primarily through a series of bilateral trade agreements, such as those with Chile and Jordan. Typically, the relevant provisions deal with compulsory licensing (a mechanism of overriding a patent, that often leads instead to negotiated reduction in the royalty), patent term extensions, and data protection (limitation on the circumstances under generic drugs can be granted marketing approval on the basis of information in another firm's regulatory submission). In its 2008 Priority Watch List, for example, the United States specifically criticized Argentina, Chile, India, Pakistan, and Venezuela on this last issue. Many developing nation officials and medical activists criticize these efforts, and view the United States as violating the Doha declaration by seeking to take away the flexibilities of TRIPS.

The critics have a point and the bilateral agreements have actually impacted public health. Oxfam, for example, has studied the impact of the U.S.-Jordan Free Trade Agreement of 2001, and concluded that since it was negotiated, medicine prices have increased by 20 %, the consumer costs of data exclusivity were between $ 6.3 m and $ 22.04 m, and certain diabetes and heart disease products were 2 to 6 times more expensive than in Egypt, which still benefits from TRIPS flexibilities.[3] The World Bank has studied the Thai HIV program and concluded that failure to use compulsory licenses could more than double the cost per life saved of its national program to distribute antiretrovirals.[4]

Developing nations and their advocates make a further criticism that is important to recognize, even though it is not directly a trade matter: this is that the patent system does not encourage research on those diseases specific to the developing world. There is little plausible profit and therefore basically no economic incentive to do research. This point was just made by the World Health Organization, which is fearful of the impact of stronger IP on public health. It has created a Commission on Intellectual Property Rights, Innovation, and Public Health, and recently formulated a research strategy for such diseases.[5] The issue is being dealt with in many ways: through publicly sponsored and foundation sponsored research, and most recent through "public-private partnerships" in which both foundations and the pharmaceutical industry play a major role. But we do not yet have, for example, a malaria vaccine.

For HIV/AIDS in the low-income countries and particularly Sub-Sahara Africa, I think that the patent aspects of drug access are currently pretty much resolved. (I say "currently" because there may be new questions as second-line antiretrovirals become essential[6]). According to World Health Organization data, prices for antiretrovirals have

---

[3] Oxfam International, *All costs, no benefits: How TRIPS-plus intellectual property rules in the US-Jordan FTA affect access to medicines,* (21 March 2007).

[4] Ana Revenga et al, *The Economics of Effective AIDS Treatment; Evaluating Policy Options for Thailand,* The World Bank, 2006.

[5] World Health Assembly, Global strategy and plan of action on public health, innovation and intellectual property, WHA61.21, 24 May 2008.

[6] See C. Chien, HIV/AIDS Drugs for Sub-Sahara Africa: How Do Brand and Generic Supply Compare? PloS ONE 2(3): e278 (March 14, 2007).

roughly halved between 2004 and 2007.[7] The Campaign for Access to Essential Medicines claims even more dramatic declines – from $10,000 to $100 per patient per year between 2000 and now.[8] In 2004-2006, generics supplied about 63 % of the drugs for Sub-Sahara Africa at prices about a third of those charged by brand-name firms.[9] In many respects, however, the real change here is less IP law than the rise of global donors who are funding the procurement of drugs. These include the Global Fund for Aids, TB, and Malaria (GFATM) and the U.S. President's Emergency Program for AIDS Relief Fund (PEPFAR). These entities have buying policies under which they will buy lower cost generics, rather than brand-name drugs under certain circumstances. The GFATM supports purchase of generics when they are legal in the particular country; PEPFAR takes into account whether the generic has been approved by the U.S. Food and Drug Administration. With these sources, supplied in part by generic manufacturers, together with the research-based industry's concessional supplies and with products produced under compulsory licenses in nations such as Brazil, the number of people receiving antiretrovirals in the low and middle income countries has risen from about 0.3 million at the end of 2002 to about 3 million at the end of 2007. This is still reaching only 31 % of those who need the drugs;[10] it nevertheless reflects an important achievement.

The area of current political tension is in the middle income nations. These nations are the growth pharmaceutical markets of the future, so that patent protection is of great importance to the future of the pharmaceutical industry's business model. At the same time, these nations still have many poor people and thus view themselves as reasonably benefiting from the Doha Declaration. South Asia, for example, has more very poor people than Sub-Sahara Africa.[11] Moreover, several, including Brazil and Thailand, have undertaken public programs to supply antiretrovirals to their HIV-affected populations, an expensive task whose overall cost depends heavily on the price of the drugs.

I believe that we must attempt new approaches in dealing with these nations. It is in our national interest to facilitate their growth in health. That may call for low, i.e., generic prices for at least some drugs for some people. This might be an exception for a limited time. In another approach, GSK is developing mechanisms for differential pricing within poorer countries based on charging a generic price to certain public or non-profit distribution channels while charging a higher research-reimbursing price to others.[12] Might the approach be extended? But there will need to be reforms beyond prices. For example, in a number of nations, including China, much medical care is effectively financed through pharmaceutical sales by doctors and hospitals – a process that certainly creates terrible incentives toward price markup to patients and toward

---

[7] Data on HIV drug coverage from World Health Organization, *Towards Universal Access; Scaling up priority HIV/AIDS interventions in the health sector; Progress Report 2008.*

[8] www.accessmed-msf.org/main/access-patents/introduction -to-access-and-patents/patents-and-access.

[9] C. Chien, supra.

[10] *Towards Universal Access,* supra.

[11] S. Chan & M. Ravallion, *How have the world's poorest fared since the early 1980s?*, (World Bank, Fall 2004).

[12] *GSK Corporate Responsibility Report 2007.*

overprescription.[13] In India, the poor are not effectively served by the medical system. And some of these nations are pharmaceutical exporters at the same time that they have many needy citizens. Compromise seems reasonable; it will necessarily be more complex than a pure IP arrangement.

In approaching such a compromise, it is worth noting that price controls are likely to be the key topic for future international negotiations with developed nations in the pharmaceutical area. The importance of such controls is exemplified by the current European disputes over Roche's anticancer drug, Avastin,[14] as well as by the inclusion of price-related provisions in the 2004 U.S.-Australia Free Trade Agreement and the great attention paid to the issue in the 2008 USTR Special 301 Report. Moreover, at some point, price controls will almost certainly be an issue in our own country – health care reform may increase the role of the government in purchasing pharmaceuticals, and it is hard to envision continued significant government purchasing of pharmaceuticals without pressure toward price controls. Unless the price controls are applied thoughtfully, the result will be to decrease incentives for research. Such harm may already have occurred in the U.S. childhood vaccine industry.[15] In approaching health care reform and international trade both, we will need to define effective decision-making standards and procedures to maintain optimal incentives for research in medical technology.

These various trends suggest to me that it is important to moderate our IP focus and to recognize that IP is only part of a broader package of pharmaceutical trade goals. All nations want greater access to health care; all want to contain the cost of that health care; all want more advanced technologies. These are goals that have to be balanced; and the details of the balance may reasonably be different for nations at different income levels. Might we define a global vision that could be the basis of a new sectoral trade agreement governing a number of pharmaceutical issues?

Agricultural technology. Disputes over agricultural technology arose significantly earlier, in response to the developed world's efforts in the 1980s to encourage all nations to adopt plant variety or plant breeders' rights protection. These laws are a weaker form of IP designed to protect the products of traditional breeding. Their strengthening led to arguments that it was unfair to let developed nations protect bred varieties, while the genetic resources held in developing nations were freely available to the developed world breeder. These concerns contributed to the creation of the United Nations Convention on Biodiversity, a convention that has significantly slowed and complicated the scientific exchange of genetic materials.[16] The developing nation's political mood in this area has been worsened by the grant of U.S. patents (probably improperly issued) over developing nation plants such as the 1997 patent on Basmati rice – grants the critics call "biopiracy."

---

[13] Q. Sun et al, Pharmaceutical Policy In China, *Health Affairs*, 27: 1042-1050 (July/August 2008).
[14] See, e.g., A. Jack, "Roche decision denies cancer drug to Britons," *Financial Times*, June 26, 2008, p. 3.
[15] Institute of Medicine, *Financing Vaccines in the 21st Century: Assuring Access and Availability* (2004).
[16] Sabrina Safrin, Hyperownership in a Time of Biotechnological Promise; The International Conflict to Control the Building Blocks of Life, 98 American J. of Int'l Law 641 (2004).

For the newer agricultural biotechnology, the most important issues arise under the regular patent law system. Developing nation patent laws are typically much less comprehensive and clear as to coverage than are U.S. and European laws; China's law, for example, is criticized in the 2008 Priority Watch List. On the whole, however, the concerns are not so much those of trade policy as those of the patent system itself, which, in the United States, reaches deeply enough into basic agricultural science to seriously complicate research. The majority of the breeding focused specifically on developing nations is carried out in the public and foundation sector including U.S. universities and the entities of the Consultative Group on International Agricultural Research (the CGIAR). The U.S. universities are bound by U.S. patent law and even some of the public institutions outside the United States often regard themselves as effectively bound by U.S. and European patents. Currently the public sector is coping through elaborate efforts to encourage the grant of private patent rights to developing nation use. For example, the African Agricultural Technology Foundation has been created by foundations and national foreign agencies to hold a portfolio of agricultural IP, and to supply that technology to Africa. Universities are organizing programs of humanitarian licenses to attempt to ensure that the technologies they develop are available to developing nations.[17]

Today's food crisis makes it imperative that these entities be able to continue to do research. Hence, I would strongly urge that developing nations be encouraged to design their patent systems to avoid patents on very basic scientific insights and to maintain broad and robust research exceptions, so that patents not be exercisable in a way that discourages others from the conduct of research. (There are parallel issues in the context of development of new drugs for diseases endemic to developing nations.)

The private sector is becoming extremely important in developing world agriculture. Thus, Monsanto has developed agricultural technologies used broadly in Argentina and Brazil, and India is one of the largest growers of genetically modified cotton. There, therefore, seems to be no reason for the USTR to refrain from encouraging protection of agricultural biotechnology in the more scientifically advanced and larger developing nations, but it is best to encourage it through arrangements that favor exclusivity in the marketing of specific products but allow great freedom of research.

The agricultural sector is like the medical sector in that the IP issues are only part of a much larger context, in this case, the regulation of genetically-modified organisms. Regulatory issues have been much more serious barriers to trade and research here than have IP issues. There is significant international dispute on the point, but, at least in my judgment, this technology can wisely make an enormous contribution to solving our food crisis. The USTR's efforts to encourage Europe to accept genetically-modified agricultural products are likely to benefit the entire world -- many developing nations have been hesitant to accept such products and technologies either because of the European example or because they hope to export to Europe.

[17] Amanda L. Brewster, Audrey R. Chapman and Stephen A. Hansen, Facilitating Humanitarian Access to Pharmaceutical and Agricultural Innovation, *Innovation Strategy Today* (2005).

Climate change technologies. It is certain that there will be international technology transfer provisions as part of any follow on to the Kyoto Agreement on climate change. Understandably, therefore, there are already calls for a climate change analogue to the Doha Declaration. For example, last November, the European Parliament called for launching a study of possible amendments to TRIPS to allow "for the compulsory licensing of environmentally necessary technologies."[18]

Based on my recent studies, this is probably not needed. This is not because there are not patents – there are many and there will be more – but because the effective royalties on patents in the climate change sector are likely to be small. This is because the competitive and industrial structures in the climate change sectors are radically different from those in the pharmaceutical sector. In the pharmaceutical sector, an individual product is often in a monopoly position, because it is the best available way of treating a particular disease. And the research costs are much greater than product production costs. Therefore, the markup on production cost can be substantial and can allow for broad differences in pricing in wealthy and poor markets. In contrast, in the climate change sectors, each technology is generally in competition with a number of others, and there are relatively competitive markets for the production of electricity and fuel as well as for such products as automobiles and housing materials. Hence, there can be only a small markup on the manufacturing cost. Research and development form a smaller portion of the overall product cost, and there is little room for differential pricing. Compare Merck, the U.S. pharmaceutical firm, and Vestas, the Danish wind turbine firm. Based on the most recent 10-Ks and annual reports, the 2007 cost of product for Merck is 25.4 % of the sales price; for Vestas it is 83.0 %, leaving a much smaller margin for research or for price reductions. It should also be recognized that for technologies like carbon capture and sequestration (CCS), the key markets are likely to be in nations like China and India; IP protection there is therefore crucial.

Before concluding, I should note that climate change may present many non-IP issues for trade negotiations. Unless we move to a large carbon tax, which seems politically unlikely, it is impossible to envision serious reductions in greenhouse gas emissions in any nation without a variety of subsidies and regulations. Will these arrangements be consistent with World Trade Organization rules?

Summary. In summary, I believe that it is the world interest and in our national interest to transfer technologies to the developing world in areas like medicine, agriculture, and clean energy. This reflects a humanitarian concern; it builds markets; and it contributes to building a world that is safe for all of us to live in on a long term basis. In all three of these sectors, the industries and markets are global, the cost of research is shared by public and private institutions, the expenditure and investment patterns are shaped by a variety of regulatory and pricing regimes, and the developing world's access to innovation is beneficial to us. Each of the areas is best approached in a sector-specific manner that recognizes the role of IP without overweighting that role, and that seeks to structure the entire world research incentive system in a way that balances the need for innovation with the need for access to that innovation.

[18] European Parliament resolution of 29 November 2007 on trade and climate change (2007/2003(INI)).