Bilateral and Multilateral FTA Negotiations: Opportunities for Improved IP Protection and Market Access

Summary

One of the key U.S. successes in the Uruguay Round trade negotiations was the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights), which incorporated and made binding many existing treaties under the jurisdiction of the World Intellectual Property Organization (WIPO). These new rules are critical to many cutting-edge, high-export U.S. industries including music, film/video, computers, software and others that can thrive only if protected for a limited time against free-riding on their innovation and creativity.

The obligations contained in the TRIPS Agreement, however, do not rise to the level of protection available in the U.S. to creators of any nation, and so the Congress and the Executive Branch have considered TRIPS to represent the floor, and not the ceiling for the protection of intellectual property needed to support U.S. commercial interests abroad.[1] The Pharmaceutical Research and Manufacturers of America (PhRMA) represents America's research-based pharmaceutical and biotechnology companies. Our companies are leaders in developing innovative medicines that cure disease and enable patients to lead longer, healthier lives. This year, PhRMA companies have invested over $26 billion in research and development of new medicines, leading the way in the search for cures.

Because innovative biomedical research is a prolonged, expensive and risky process, American pharmaceutical research companies seek a global commercial and regulatory climate that recognizes and supports innovation. Key elements include: adherence to global scientific standards supporting innovative biomedical research and development, strong protection of intellectual property (particularly patents, trademarks and proprietary data); transparent, timely, and science-based regulatory systems; a level playing field for American firms, refraining from trade-distorting or discriminatory price controls, consistent with GATT Article III:9; and market-based pricing policies that reflect the value of pharmaceutical innovation in advancing patient welfare.

PhRMA views the recently concluded U.S./Jordan Free Trade Agreement (FTA) as a useful example of how the FTA process, can further important U.S. commercial interests abroad. PhRMA believes that the ongoing Singapore and Chile FTA negotiations, as well as the multi-lateral Free Trade Area of the Americas

[1] See, e.g. the 1995 USTR FACT SHEET "SPECIAL 301" ON INTELLECTUAL PROPERTY RIGHTS, released April 29, 1995, noting that: "'Special 301'" was amended in the Uruguay Round Agreements Act to clarify that a country can be found to deny adequate and effective intellectual property protection even if it is in compliance with its obligations under the TRIPs Agreement."

negotiations, should be used to gain enhanced protection for intellectual property and improved market access conditions. There is no reason to go forward with negotiations that would not provide substantial benefits over those trade obligations already embodied in the WTO TRIPS Agreement. We view the significant achievements contained in the U.S./Jordan FTA as a starting point for future negotiations.

Review of the Benefits of the U.S./Jordan FTA

Over the last eighteen months the Hashemite Kingdom of Jordan has concluded comprehensive economic and regulatory reforms in preparation for WTO Accession, and in December, 1999 became the 136th WTO member. Through the WTO accession process, Jordan amended all of its intellectual property and related legislation, including bringing its patent and Unfair Competition and Trade Secrets Law to meet international standards. In addition, Jordan provided for linkage between regulatory and IP authorities to ensure that the full weight of the Jordanian Government stands behind its intellectual property commitments. On October 24, 2000, the U.S. and Jordan signed the U.S./Jordan Free Trade Agreement (FTA), only the fourth in U.S. history.

In addition to Jordan's WTO-related obligations, benefits of the FTA include:

- Improved data protection - - 5 years for New Chemical Entities or New Chemical Entities (NCEs) and 3 years for non-NCEs and period of non-reliance even if the originator's registration approval was based "on evidence of approval in another country;"

- Elimination of the biotech exclusion for patentable subject matter;

- Limitations on permitted "Bolar" pre-expiry activities, permitting only those activities needed to gain marketing approval--however, export of product will be permitted to other countries with "Bolar" provisions for marketing approval purposes. In addition, the patent owner is to be notified of identity of third party making use of the existing patent during the term of the patent;

- Patent term extension to make up for time lost do to regulatory delay in the original country of application as well as in Jordan; and,

- Limitation of the use of compulsory licenses to three circumstances (anti-trust; national emergency/public non-commercial use and Paris Article 5(4) circumstances.

PhRMA strongly supports Congressional approval for the U.S./Jordan FTA, which brings substantial benefits to the research-based pharmaceutical industry. In recognition of Jordan's favorable investment climate, PhRMA members recently

met in Amman to explore the potential benefits of business ventures with their Jordanian counterparts. PhRMA is also inviting Jordanian pharmaceutical companies to visit the United States on a reverse trade/investment mission later this spring.

Additional Benefits Available through Ongoing FTA Negotiations

PhRMA believes that the ongoing negotiations with Singapore, Chile, and Latin American trade partners engaged in the FTAA talks should go further than the U.S./Jordan FTA. For example, there were topics that were not included in the U.S./Jordan FTA either because they were not relevant (e.g., linkage, which Jordan had agreed to provide in the context of its WTO accession), or for reasons of timing. These issues, described below, should be included in future agreements.

In addition, as was the case in the FTA negotiations with both Jordan and Mexico before it, it is essential that U.S. trading partners, including Chile and other Latin American states, resolve any and all outstanding issues related to fulfillment of existing WTO TRIPS obligations prior to the conclusion of an FTA. For example, Chile should enact fully TRIPS-compliant industrial property legislation and demonstrate full compliance with its TRIPS undertakings and commitments prior to the completion of any new bilateral agreement. Also, the U.S. Government should foreclose the possibility that compliance with previous obligations may be construed as a "new" commitment through the FTA process.[2]

Intellectual Property Rights

Adequate and effective protection of intellectual property, especially related to inventions, trademarks, and proprietary data, remains the foundation for continued U.S. leadership in the research-based pharmaceutical industry. Absent strong intellectual property protection, the U.S. research-based pharmaceutical industry cannot justify the massive ongoing investments into research and development needed to generate new medicines. Indeed, without protection on a global basis, it is difficult to justify continued investments in advanced research and development. The consequences are not simply commercial - instead, ineffective global intellectual property standards diminish the prospects for development of new cures for life-threatening and disabling diseases and the lives, hopes, and welfare of millions of patients.

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[2] For example, a number of Latin American trade partners bar so-called “Second Use Patents,” disallowing legitimate patent applications that meet all requirements of patentability under the TRIPS Agreement and the Paris Convention. The U.S. should insist, as a condition of concluding any FTA, that trading partners first eliminate any legal bar that currently unfairly discriminate within sectors or areas of technology, creating illegal barriers to obtaining patent protection for eligible chemical entities.

PhRMA believes it is critically important for any partner in a free trade agreement with the United States to provide intellectual property protection standards that are equivalent to those available in the United States. Failure to do so prejudices U.S. intellectual property-dependent industries, such as the research-based pharmaceutical industry, by allowing foreign competitors to enjoy the benefits of free trade without granting reciprocal market access that allows U.S. industries to compete fairly in their markets. IP-related provisions for future FTA negotiations should, in addition to the provisions included in the U.S./Jordan FTA, include:

- **Full Protection of Test Data**. For effective protection of commercially valuable and confidential data, it is essential that U.S. trading partners explicitly prohibit not only the disclosure of the data, but the direct and indirect reliance on the data, within the definition of unfair commercial use. In addition, while the data must be protected from the time it is lodged with regulatory authorities, the period of non-reliance (5 years minimum) should commence from the date that marketing approval is granted.

- **National Exhaustion of Patent Rights**. Patents are national instruments, but the exclusive rights provided under the WTO TRIPS Agreement and the WIPO Paris Convention may be undermined by local statutes that consider patents to be "exhausted" by acts performed outside their sovereign territory. The absence of a standard of national exhaustion also undermines PhRMA member efforts to improve access to essential medicines, including HIV therapies, to vulnerable or underserved populations.

- **Legitimate Government Use Provisions**. The USG should use ongoing negotiations to limit the scope of government use authority to exclude the possibility of government use for the purpose of export, or for sale to the general public. In short, government use authority should be limited to those acts required to carry out a legitimate governmental function.

- **Linkage Between Industrial Property Offices, Regulatory Authorities and Enforcement Agencies**. The enforcement of patent rights is difficult in most countries. Measures that are taken by a Government of a country that facilitate infringement run counter to the objectives of granting adequate and effective protection for intellectual property rights. For this reason, we urge the United States to include provisions that will oblige the relevant government Singaporean authorities to ensure that their administrative activities do not facilitate the infringement of patent rights. In particular, we urge the United States to include measures that will prohibit the granting of marketing approval by a health regulatory authority that will take effect during the term of the patent

to a party other than the patent owner. This type of provision is included in the United States system and greatly facilitates the effective enforcement of patent rights by removing the possibility that a new infringer of those rights will be able to enter the market during the term of the patent.

- **Enhanced Trademark Protection**. There is a growing trend in toward measures that directly or indirectly impede the ability of a trademark owner from using those rights as designed. Measures include labeling requirements that foreclose use of the trademark in comparison to the generic name of a pharmaceutical product that is necessary to ensure the strength of the mark. We encourage the United States to include measures in any FTA that prevent adoption of measures that directly or indirectly weaken trademark rights, including for example measures that require the use of a larger generic name than the trademark or which remove rights for use of a trademark instead of a generic name for a pharmaceutical product.

Price Controls

America's research-based pharmaceutical companies share a fundamental goal of saving lives and bringing new hope to patients. In the 20th century, advances in pharmaceutical science, beginning with the invention of antibiotics, brought huge gains in life expectancy and quality of life. As we begin a new millennium, the world is on the verge of equally revolutionary breakthroughs in biotechnology, medicine, and scientific understanding of the human genome.

While PhRMA also understands the natural desire of governments to supply the best drugs to their citizens at a reasonable cost, the process of pharmaceutical discovery is very expensive, and the cost is growing every year. The most recent (1998) estimate is that around $300-500 million is required to bring a drug to market, but this figure is undoubtedly higher now. It will continue to grow rapidly as the world moves into the biotechnology century, because of the massive investments required to fund basic research into the human genome. Such research offers great potential, but will continue only if commercial products can ultimately be developed and marketed. This research is fraught with uncertainty, because it will be 10 to 15 years before significant commercial products can be brought to market. Hence, this high risk, expensive research will only be pursued if there are reasonable prospects for return on investment capital.

Many U.S. trade partners impose punitive price controls that seriously restrict access to innovative U.S. medicines. These price controls are often *de facto* discriminatory. In the absence of a viable local industry, governments impose a disproportionate share of cost containment burdens on innovative U.S. and

European research pharmaceutical firms. Such price controls threaten U.S. global leadership in biomedical innovation.

Accordingly, we look forward to working with USTR to secure FTA commitments that support continued biomedical innovation. We urge that the following provisions be incorporated into future FTAs:

- **Recognition of Innovation**. At the 1998 G-8 Economic Summit, President Clinton and then-Japanese Prime Minister Hashimoto announced a path-breaking U.S.-Japan Enhanced De-Regulation Initiative Agreement regarding recognition of pharmaceutical innovation ("Birmingham Agreement"). It was agreed that Japan's reforms of its pricing and reimbursement system would recognize the value of innovation of pharmaceuticals in the formulation of health care policies and health care measures, so as not to impede the introduction of innovative products, which bring more effective and more cost-effective treatments to patients.

- **Pricing and Reimbursement Principles**. As set forth in H.R. 1942, which was introduced by Representatives Crane, Dreier, and Johnson on May 26, 1999 and sets forth U.S. negotiating objectives for future FTAs, we urge that all future FTAs address non-market based government interventions which restrict patient access to innovative U.S. medicines, such abusive price controls, reference pricing, monopsonistic purchasing practices, state-trading monopolies, unreasonable restrictions on listings in government-established formularies, government toleration of illegal discounts, financial incentives, or practices, that disadvantage innovative U.S. medicines and/or represent a WTO-illegal subsidy to local manufacturers, and other non-market-based practices or measures which have the effect of distorting trade.

- **Transparency**. The U.S.-Japan Enhanced De-Regulation Initiative recognizes the fundamental importance of transparency in the formulation and consideration of health care policy and expanding access by Japanese patients to innovative U.S. medicines. Transparency gives U.S. stakeholders an opportunity to comment during the formulation of government health care policies and regulations that affect trade and access to new medicines. PhRMA urges that the FTA incorporate provisions from the Birmingham Agreement designed to strengthen transparency, ensure meaningful consultation, and advance the rule of law.

Drug Regulatory Processes

New and innovative drugs deliver tremendous benefits to patients. With recent breakthroughs in biotechnology and research into the human genome, the accelerating pace of pharmaceutical innovation has the potential to dramatically reduce disease morbidity and mortality, bringing new hope to patients around the world. Moreover, pharmaceutical innovation lowers overall health care costs by reducing the need for expensive hospitalizations, surgeries, and long term rehabilitation and care. As a result, promoting advanced biomedical research and expanding access to new medicines should be at the top of the global health care agenda.

Non-scientific regulatory processes represent a serious barrier to innovative U.S. medicines and a threat to patients suffering from life-threatening diseases. Specifically, some U.S. trade partners use non-scientific regulatory barriers to delay the introduction of foreign medicines, protect local producers, or as an indirect form of cost containment. Accordingly, any future FTA should include commitments to timely and transparent, science-based regulatory review and approval procedures; and prohibitions on unfair practices used elsewhere in Asia to delay introduction of new medicines, *e.g.* duplicative or scientifically unjustified (local) clinical trials for product submission and registration; undue certificate of free sale requirements that delay either submission or product approval, local testing requirements for small molecule drugs, vaccines, and biologics; and undue regulatory delays. Such barriers distort trade, but more importantly put the lives and welfare of patients at risk by limiting access to advanced medical treatments.

Specifically, we urge USTR to recognize the role of global scientific standards and timely and transparent regulatory procedures by incorporating the following provisions in any future Free Trade Agreements:

- **Drug Regulatory Procedures**. Regulatory procedures for the approval of new medicines should be timely, transparent, and non-discriminatory, and based on generally-accepted international scientific standards.

- **Science-Based Drug Regulatory Requirements**. Regulatory requirements should be consistent with global scientific standards, such as the International Conference on Harmonization (ICH), and decisions regarding product approvals should be based only on the assessment of quality, safety, and efficacy.

- **Transparency of Drug Approval Regulations**. Laws and regulations regarding drug approvals should be transparent and should be formulated through procedures that provide (1) for notice and comment by interested U.S. stakeholders, (2) timely and effective opportunity for U.S. stakeholders to submit comments, positions, and views for due consideration by the relevant authorities; and (3) timely

> and effective opportunity for U.S. stakeholders to consult with the relevant authorities and study groups regarding the formulation of health care regulations and laws.

Such commitments are fully consistent with U.S. and Singaporean regulatory practice and thus can be readily incorporated in the FTA.

Abusive State-Trading Practices

Because New Zealand does not have a domestic pharmaceutical industry, it has adopted punitive state-trading practices designed to shift the principal burden of health care cost containment to foreign producers, *i.e.* U.S. and European research-based pharmaceutical companies. To this end, the New Zealand Government has granted exclusive control over pharmaceutical purchases and reimbursement to a state-trading entity (STE) -- "PHARMAC." Employing its monopsonistic pricing power, Pharmac has implemented a sole-source, single tendering system that denies U.S. and European firms "adequate opportunity" to compete in the New Zealand marketplace on the basis of "commercial considerations" and severely restricts access to many of the world's leading medicines in violation of GATT Article XVII and with adverse outcomes for many New Zealand patients.

Accordingly, specifically with regard to the proposed Singapore FTA, and in light of the Singapore/New Zealand FTA completed in November, 2000, FTA, PhRMA seeks assurances that USTR will bar adoption of a New Zealand-style pharmaceutical procurement model, which would nullify benefits of expanded U.S. access to Singapore's pharmaceutical market, and call into serious question PhRMA's support for the proposed FTA. In this regard, we urge USTR to closely review H.R. 1942, which was introduced by Representatives Crane, Dreier, and Johnson on May 26, 1999, and, while endorsing Asia-Pacific FTAs, provides that any such arrangement should address barriers, such as "government measures such as price controls, reference pricing, and unreasonable restrictions on listings for government-established formularies which deny full market access for United States products."