

For Better International Protection

BY GERALD J. MOSSINGHOFF*



Intellectual property protection is a world problem, some progress being made

The strengthening of intellectual property protection is a goal that over the past decade has been one of the highest-priority items on the political agenda of the Pharmaceutical Manufacturers Association. PMA represents America's research-based pharmaceutical companies — companies that spend more than 20% of their sales revenues on research and development. This year our companies will spend \$6.2 billion in research and development, more than the combined expenditures of all federal agencies engaged in biomedical research and development.

Today, total research and development for a single marketable pharmaceutical product costs more than \$200 million, and it takes more than a decade to bring these products to market. On the other side, someone with an elementary knowledge of chemistry and biology can copy most of these inventions for a tiny fraction of the originator's heavy costs.

This is why — without patents — there would be no research-based pharmaceutical industry. In turn, we would not see the great advances being made in medicine today that save lives, reduce the costs formerly associated with surgery and prolonged hospitalizations, and improve the quality of our lives.

Pharmaceutical inventions are widely not yet protected worldwide. In a 1988 report by the International Trade Committee, it was estimated that just 10 U.S. pharmaceutical companies surveyed lost nearly \$2 billion in patents and trademark prices. Where does patent piracy have its greatest impact? Theoretically, in the countries of Latin America

and Asia where the location of most commercially significant patenting activities exists — countries such as Argentina, Brazil, Chile, Mexico, India, Thailand, and Eastern Europe. In these countries local laws and policies actually encourage the copying of pharmaceutical inventions.

In most developed countries, patent laws are adequate and are effectively enforced, but even among these countries there are troubling exceptions. In a few developed countries laws may not cover patents for products — they only cover processes — as in the case of Spain and Portugal. Or extremely loose compulsory licensing practices damage the right of pharmaceutical patent holders to exercise their legitimate market rights, as in Canada and New Zealand.

ALTERNATE APPROACHES TO STRENGTHENING INTELLECTUAL PROPERTY PROTECTION

This brings me to the main topic of my address: the question of the remedies that must be applied to strengthen overseas intellectual property legislation and regulations. Which is the best approach? There are three alternatives:

First, we can pursue multilateral approaches — utilizing the forums of the General Agreement on Tariffs and Trade (GATT) and the World Intellectual Property Organization (WIPO), both in Geneva. In this approach, many countries try to reach a consensus on what are appropriate standards of protection and methods of enforcement. I must say here that constructive activity in the GATT has, at least in recent years, been of greater significance than that in the WIPO.

Second, we can pursue bilateral mechanisms — using the process of

negotiations with individual countries in the framework of Section 301, Special 301 and trade-trade agreement (TTA) negotiations.

Third, we can rely on unilateral action — acting to deny access to the vast and open U.S. market to those countries that fail to provide adequate and effective intellectual property protection. These actions are taken pursuant to the trade laws of the United States, using such means as the 301-five tariff preferences of the Generalized System of Preferences (GSP) or the Section 301 (i.e. fair trade) retaliation authority.

• All Approaches •

Can any one of these approaches be used to the exclusion of the others? There are the "multilateralists" who say that the GATT negotiations on "Trade-Related Intellectual Property" (TRIP) issues will obviate the need for any future bilateral or unilateral actions. There are the "bilateralists" who discount any utility of GATT or WIPO negotiations as constituting a route for general or vague approach to lead to any concrete results. Finally, there are the "unilateralists" who hold that only by aggressive trade retaliation, using Section 301 and GSP retaliation authority given to the President, can concrete progress be achieved. The latter argues that any negotiation, either bilateral or multilateral, is a waste of effort, since countries that violate patent piracy will only change their policies as a result of tough action in the form of trade restrictions.

*President, Pharmaceutical Manufacturers Association, keynote paper presented at IFA 83/84 in Canada Annual Meeting, New Orleans, Louisiana, October 1989.

by the United States.

PMA's answers to the question of which approach is best is to consider that they all have their tolls, and no one approach is best for all circumstances. We have achieved significant progress using the bilateral negotiating approach of the U.S. Government, backed by the threat of unilateral action, if required. Yet, PMA fully supports the efforts of the Office of U.S. Trade Representatives and the Commerce Department's Patent and Trademark Office to negotiate strong and enforceable patent standards as part of the Uruguay Round of GATT negotiations. We have done so from the very beginning of these negotiations. In 1986, I will return to this, but first I will review the bilateral and unilateral actions that preceded and have surrounded the current GATT negotiations.

BILATERAL AND UNILATERAL INITIATIVES

In 1984, trade legislation was passed that authorized the President to take into account the adequacy of intellectual property protection in considering the extent to which new tariff preferences under the U.S. GSP program should be granted to developing countries. In addition, in 1985 the Reagan Administration, for the first time under Section 301 of the 1974 Trade Act, decided to initiate Section 301 cases on its own initiative, rather than having to wait until a private party requested such action. Finally, in 1988, trade legislation was enacted that established a "Special 301" procedure of each year — identifying countries that fail to have adequate and effective intellectual property protection. The 1988 act includes a specific mandate for the President to take action in such countries. These initiatives by the President and Congress over the past six years have led to significant progress on the bilateral front of negotiating improved patent protection. Let me review the results of some key country actions.

Korea

In 1985, the Reagan Administration initiated a Section 301 case on

behalf of U.S. intellectual property holders including the U.S. pharmaceutical industry. In 1986, there was a settlement under which Korea enacted product patent protection for pharmaceuticals, improved enforcement procedures and, for the first time, provided retroactive market exclusivity rights for pharmaceutical products patented abroad prior to Korea's own enactment of improved protection. The Korean case was a major step forward and set an important example of what could be accomplished using trade instruments to achieve traditional property objectives.

Thailand

In 1987, PMA filed a complaint under the GSP provisions of the 1984 act with respect to Thailand, citing lack of adequate patent protection. In 1989, Thailand lost about \$100 million in duty-free benefits under GSP for its failure to enact such protection. Thailand was cited in 1989 and 1990 under the Special 301 section of 1988 Trade Act. Thailand, still facing international threats to its exports, is now considering reaching adequate patent protection. It is looking to the results of the GATT negotiations for possible guidance.

Mexico

In 1987, Mexico lost approximately \$200 million in GSP benefits for its refusal to pass product patent protection for pharmaceuticals. Finally, Mexico is on the verge of passing greatly strengthened patent protection for pharmaceuticals. We still expect a law to be enacted this year and implemented in 1991. Mexico too had been cited in 1989 under the Special 301 provision, but its actions this year led to its being dropped from the list in 1990.

Brazil

PMA filed a Section 301 petition in 1987 on the grounds that Brazil provides no patent protection for pharmaceutical products. USITB ruled in favor of PMA's petition and imposed economic sanctions against Brazil's exports when that country refused to enact adequate protection after extended bilateral negotiations. However, in response

to Brazil's June 1990 announcement to propose legislation to protect pharmaceutical product and process patents, PMA agreed with Ambassador Carla Hills' recommendation that we withdraw our Section 301 petition. The Brazilian Government is currently drafting the patent law which is expected to be submitted to its Congress next year.

Argentina

PMA filed a 301 petition citing Argentina's lack of adequate patent protection in 1988. Citing progress and Argentine commitments resulting from consultations on its petition between the U.S. and Argentine Governments, PMA again agreed with Ambassador Hills' recommendation and withdrew its Section 301 on September 25. We expect that Argentina will be in a position to implement strengthened patent protection for pharmaceuticals by 1992.

Chile

PMA filed a 301 petition with respect to Chile in 1988. Later that year, PMA agreed with a recommendation by former USITB Clayton Youner that it request favorably in a request from the Chilean Government to withdraw the Section 301 petition. As a result, Chile promised to enact a pharmaceutical patent law by no later than the end of 1989. To date, the Government of Chile has attempted to enact two patent laws — neither of which are acceptable to PMA. No bilateral consultations are still underway.

Eastern Europe

In addition to the use of Section 301 and GSP leverage, there have been bilateral negotiations with East European countries over the subject of intellectual property, particularly patent protection. To date, the U.S. Trade Representative has completed negotiations, leading toward implementation of stronger patent protection, with the Soviet Union, Czechoslovakia and Poland. The new East European laws are to become effective in 1992. Not all aspects of the negotiations with the USSR are completed, particularly those relating to compulsory licensing and pipeline provisions of the

new Soviet patent law; but substantial progress has been made. Further negotiations are underway with other countries of the former Eastern Bloc, and we hope that agreements will be reached with Hungary, Romania and Bulgaria in the near future.

FMA's assessment of the bilateral and multilateral actions in that these approaches have generally both a success. Of course, not all countries have been brought around to exact good patent laws covering pharmaceuticals. China, India and Thailand remain important holdouts. Further, Spain and Portugal will not implement their new patent laws until 1992, as part of their earlier accession agreements for European Community membership. Finally, Canada and New Zealand have either limited-term provisions or compulsory licensing rules — or both — that are discriminatory and incompatible with respect to patents for our products.

THE ROLE OF MULTILATERALISM

While the United States has been making progress in recent years utilizing bilateral and unilateral tools, other countries have been trying to get the United States to use its bilateral and unilateral pressure and to utilize GATT more consistently. These pressures on the United States to use the bilateral and unilateral approaches less in favor of GATT have come from several sources:

First, some developed countries fear that the United States will obtain specific benefits from bilateral negotiations that will not extend to them. This happened in the Korea Section 301 case, where paper-licensing was made available only for U.S.-origin patents.

Second, developing countries, such as Brazil, which have suffered, or might in the future suffer, trade sanctions by the United States, favor multilateral negotiations, where their leverage is perceived to be greater (some would say disproportionately so). In 1985, Brazil filed a GATT complaint against U.S. trade sanctions imposed for not providing pharmaceutical patent protection. Brazil, however,

withdrew its GATT complaint when the sanctions were dropped last summer in exchange for Brazil's patent commitments. Other developing countries would prefer to deal with the United States in GATT, when they can organize together to face the United States rather than face separate bilateral pressures with market access possibly being denied.

Finally, all of our trading partners have complained about the use of Section 301, which provides expedited relief against imported products that infringe U.S. patents. The European Community recently filed and won a GATT case against the United States. But the President has stated that he will not take action until the GATT negotiations are over and the results of the GATT intellectual property negotiations are known.

I should emphasize that there is also a clear U.S. interest in using a multilateral approach. What is missing today is an effective legitimate set of worldwide standards and enforcement mechanisms to protect patents. By putting an improved system into place, we will legitimate internationally the objectives which the United States has had to fight for bilaterally or unilaterally.

MULTILATERAL NEGOTIATIONS IN THE GATT LEGISLATION BEHIND

This leads me to discuss the importance of the GATT negotiations. Here is an opportunity for the procurement world trade organization, with nearly 100 member countries, to address the serious gaps in the protection of intellectual property worldwide. The Trade-Related Intellectual Property (TRIP) negotiations could go well beyond the Paris Convention, and for the first time provide substantive standards of patent protection to supplement the WTO national treatment standard.

FMA companies have taken a strong positive interest in the GATT negotiations. The Phoebe Corporation's Chief Executive Officer, Edmund Phoebe, Jr. in 1985 spearheaded a task force of a Presidentially appointed Advisory Committee for Trade Negotiations (ACTN) to help

develop the Administration's objectives and strategy for the GATT TRIP negotiations. FMA's former Vice-President for International Affairs, Dr. Harvey Bate, who served for 12 years at USIB and worked on the intellectual property issue at the GATT Ministerial meeting in Uruguay, continues to advise the Administration on this issue. Our FMA Board has met twice over the last year with Ambassador Carlo Hills to encourage her in her efforts to strengthen intellectual property protection through the GATT. I should mention here that Ambassador Hills, Commerce Secretary Robert Mankamer and the staffs of the Office of the Trade Representative and the Patent and Trademark Office are doing a Herculean job, under all but impossible deadlines, in pursuing a strategy to strengthen the competitive position of industries, such as ours, that are dependent on strong intellectual property protection abroad.

Internationally, FMA has worked hard with research-based pharmaceutical industry associations overseas, through the International Federation of Pharmaceutical Manufacturers Associations in Geneva, to help develop support internationally for a strong TRIP agreement. We also commissioned a study by the National Economic Research Associates (NERA) of the benefits to developing countries of improved patent protection. We organized a meeting between high-technology associations and USIB staff to focus on the post-GATT Round legislation that will be necessary in order to implement the GATT's results. Finally, we have worked with broad industry groups, such as the Emergency Committee for American Trade or "ECAT" and the so-called INTA Coalition, to help maintain the President's voice of trade quota legislation that would have destroyed the Uruguay Round. In as you can see, America's research-based pharmaceutical industry has placed great emphasis on a successful GATT negotiation and is working hard to bring that about.

What are we looking for in these negotiations? Basically, five things:

1. Protection of pharmaceutical patent patents as well as process

patents, with a minimum 20-year term.

1. The establishment of reasonable working requirements, including the allowance of importation to meet such requirements.

2. Restrictions on government compulsory licensing activities, including the requirement that such licensing be nonexclusive and non-discriminatory toward one patentable subject matter.

3. A short maximum period for countries to adopt adequate patent laws.

4. "Pipeline" protection that would cover products patented in other countries prior to the enactment of a better patent law, when such products are not yet on the market in the country enacting the new law.

In our view, all of these are reasonable demands of the GATT process. The "pipeline" provision is particularly important because it typically takes more than 10 years after a pharmaceutical product is patented before it reaches the marketplace. Thus, coverage of products patented only after laws are enacted means a further 10-year delay before any tangible benefits are realized.

PROSPECTS FOR MULTI-LATERALISM, BILATERALISM AND UNILATERALISM

There is only a little more than a month left before a concluding session of the GATT negotiation is to take place in Brussels, Belgium. What are the prospects? And, what is to be done about the bilateral and unilateral approaches that have been quite effective, as I discussed?

Much respect to the prospects for the Uruguay Round results on intellectual property, optimistically, we predict that important progress will be made. Negotiations between the major countries have tended to result in a consensus on the need to protect pharmaceutical products and to achieve a 20-year term as a minimum period of protection. On compulsory licensing, there is a consensus that such licenses should be restricted and nonexclusive. Already, therefore, the negotiation will have helped to strengthen the

standard of protection given to patents generally, and for pharmaceutical products in particular. Other aspects of the negotiations — for example, the conditions that permit compulsory licensing as well as the transition issue — are key outstanding issues.

An important qualification to this optimism must be made, however. The progress made on intellectual property in GATT still depends upon whether the overall GATT Round itself will succeed. That, in turn, depends on other major issues, such as the state of negotiations on agriculture and textiles. These two will be difficult right up to the Brussels meeting, but last week a front page *Financial Times* article was headed, "World Trade Talks Near Collapse Over Farm Subsidies Row." In these across-the-board trade negotiations, please do not underestimate the political cost of failure, not only in this country but in all trading nations.

One of the most important issues yet to be resolved, besides all of the details of the compulsory licensing and pipeline provisions, is the question of which countries will sign up to the TRIP treaty. This is a central question. And this has important implications for the question of the future of bilateral and unilateral measures. There are at least two possibilities:

First, it is possible that all of the GATT negotiating countries will sign a strong intellectual property agreement. This would be the best we could hope for, but it will be a difficult goal to achieve. Would India and Thailand sign a strong TRIP agreement, given their historic opposition to providing 20-year patent protection even for pharmaceutical and chemical products? Would they agree to tight limits on compulsory licensing and on pipeline protection? Again, it seems unlikely they would sign a TRIP agreement, unless it were seriously diluted. And a watered-down agreement is one we and other industries would oppose as representing a bad precedent for the countries to follow in the future.

However, even if such a desirable outcome — a strong TRIP agreement — were achieved and signed

by all, there would still be an important role for bilateral and unilateral initiatives. U.S.-initiated action would still be required via a few countries, such as China and others, that are not GATT members. And bilateral pressure could be necessary for the purpose of seeing that those GATT members who do sign an agreement enforce their obligations against domestic piracy activities.

On the other hand, the scope for bilateral and unilateral action could be even greater if a number of countries in the GATT negotiations do not sign up to a good TRIP agreement. And this is a strong possibility. For those who do not accept obligations under the GATT TRIP agreement, bilateral and unilateral action will be the only means to enforce the lack of adequate intellectual property protection.

CONCLUSION

Thus, while the GATT negotiations might achieve substantial progress in the area of strengthening intellectual property protection, we can expect that bilateral and unilateral measures will continue to play a significant role in the future. It may not be as significant a role as played in the recent past. However, we expect that there will continue to be bilateral contracts in the form of follow-up bilateral enforcement consultations in connection with the GATT negotiations and a growing number of free-trade negotiations that go beyond the GATT agreement — for example, President Bush's program of "Enterprise for the Americas," which could lead to free-trade agreements with Latin American countries.

At the end of the day, the United States will have to preserve the right — and be prepared to use whatever leverage it possesses to do so — to defend its legitimate economic interests. Thus, it is impossible that we can expect the GATT or any other broadly based initiatives, in the current stage of underdeveloped international cooperation, to have complete responsibility for an international intellectual property regime in the foreseeable future.

The threat of a U.S. resolution for

inadequate protection of intellectual property has been a successful test in achieving objectives that are in the interests for both the U.S. and free and fair international trade. For the reasons I have outlined, the threat of U.S. retaliation is not likely to dissipate even if goals we would

like to achieve in the GATT negotiations are fully realized. As long as the United States is the largest market in the world, as long as it is open to those countries that rely heavily on exports for their economic growth, and as long as we provide first-class intellectual

property protection to citizens of all nations in a free market, we have important leverage to achieve fair treatment for intellectual property worldwide using the complementary and mutually reinforcing tools of multilateralism, bilateralism and unilateralism!