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applied, the injury determination should be based upon the same imports to which an eventual measure would be applied.

In sum, these two cases show the kinds of problems arising from the lack of clarity in some provisions of RTA's that are not consistently established vis-à-vis the corresponding rules, disciplines, or obligations existing at the multilateral level (WTO).

X. THE PHARMACEUTICAL INDUSTRY'S INTERSECTION WITH BUSINESS AND GOVERNMENT

Shannon S. S. Herzfeld[*]

Introduction by Stephen Powell

Shannon Herzfeld is one of the leading trade economists in Washington. She now serves as Senior Vice President for International Affairs for the Pharmaceutical Research and Manufacturers of America.

SHANNON HERZFELD

The Americas are very important to the U.S., and to our companies, especially the pharmaceutical companies of America. These companies are the makers of pills, of capsules, of injectables — those liquids that unfortunately come into you sometimes through intravenous needles. But we are really not in the pill business at all; we are really in the idea business.

To give you some context about our industry (which is important because really the trade rules are about people like us), for every 15,000 compounds or molecules looked at in one of our labs, three become medicines approved for human use, and one turns a profit. This process takes twelve to fifteen years.

Let me restate these odds in a different way. Imagine if, as you embarked on your career, you were handed a hundred textbooks. Each textbook had 150 pages in it, and you were told that you could become a lawyer if you passed the bar exam. Imagine that the bar exam consisted of one question, and the subject of that question was located on three pages buried in those 100 textbooks. Imagine that the answer consisted of one line on one single page. Now I ask you, how many of you would have chosen to roll the dice, and chosen to become lawyers with such harsh odds? And how many of you would have said, no, thanks, I will stay at my

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family business, or stay at the beach, or do something else? Well, in our business it takes 15,000 compounds examined to make three medicines approved for human use, and to make one which makes a profit.

It also takes roughly $500 million, and as I said, a dozen years of work, to produce a single medicine. That is why we say we are in a very high-risk industry. It is a very high-risk proposition. So next time you read about some blockbuster drug making millions of dollars, I just want you to know we are not all living on easy street, and sometimes it is a bit more complex.

I got involved in the pharmaceutical industry because I am interested in those points of intersection between business and government, and frankly, I do not know of a single industry where this happens more.

At the birth of our first ideas, governments are right there in the delivery room, because, in order to identify our idea, we have to file a patent and go down to the Patent Office. Welcome to the world of intellectual property.

We need to ensure that our medicines are both safe and effective. This involves clinical trials, first on the computer, then using animals, then involving healthy people, and then involving people with disease. Governments regulate every step of this process, to insure the citizenry is safe. And that is an essential element, I would add, of sovereignty. The results of these trials, which are quite costly to create, also deserve intellectual property protection. Then we have a medicine, found to be safe and effective, and now we need government approval again. This is because governments around the world have to give us permission to sell, and in many countries, governments not only give us that permission but they dictate our price. And finally, governments determine how we can sell our product, who we can sell it to, what we can say about our product, and who we can say it to.

I challenge you again to find any industry where there is more government intervention. These rules are there, by-and-large, for good public purposes. But rules can be fair, or rules can be trade barriers in disguise. We need rules which are fair, transparent, and do not hamper our ability to sell safe and effective medicines merely because a local industry has failed to stay modern. That is why we, the pharmaceutical industry, have always been firm supporters of the GATT, and continue to be supporters of the WTO.

At this point, I would like to echo the observations of Governor MacKay, about the importance of recent attention, coming out of the private sector as well as governments, to the issue of corruption and bribery. In all of the points of intersection which I just outlined between governments and our industry, there are opportunities for "interruption," shall I say, from those who would like bribes or have other corrupt interests

in mind. This is wrong. And what the pharmaceutical industry has been trying to build, is global acceptance, or at a minimum a global statement, in the name of civil society, that public health ought to be a bribery-and-corruption-free zone. And to the extent that you in academia can help us put forth that principle, I would welcome that.

Beyond that, we believe that trade is good, and that trade under a rules-based system, is our goal. We believe that having trade rules, acknowledged widely, is not only a stable path, but the only stable path towards sustainable economic development.

I stand here and I say "trade is good" and I smile because in my 21-year career, that has always been a given. But I, like some of my colleagues here, were in Seattle, where there were those who felt that perhaps that statement needed to be re-assessed.

For those of you who once took Economics 101, I ask you to remember the very simple logic of David Ricardo nearly 200 years ago, who went on to say to the people of Portugal and to the people of England, "if you just swap your wine for your cloth, both of you end up better." There is a net gain. Countries — their citizens, consumers, and workers-all prosper when free trade is allowed. All suffer when free trade is hindered. The GATT, and now its successor organization, was created with this in mind, and we all know David Ricardo was onto something, because in the 50 years since this system was established, the world has witnessed the most dramatic rise in living standards in history. World output per person has risen 2% per year over the past half-century. That is double the rate of increase in the prior 100 years before the two world wars.

A quarter of global output now crosses borders, and this share is even higher for the developing world, where almost 40% of GDP is traded. That number for many of the countries of Latin America is even higher.

Trade is good for you; trade is good for me; trade is particularly good for Latin America. The booming U.S. economy, enjoying its seventh year of uninterrupted growth, has been an important element, allowing other countries in this region, to enjoy sustained exports and enhanced output. Our own North America merchandise import volume rose by 10.5% alone. This is a good thing. This translates into jobs and economic development in the exporting and the importing countries. I acknowledge, though, that opening one's market, trading by the rules — particularly the WTO rules — is not always easy. It has been painful for some industries and some developing countries, including some in Latin America, as they have amended their own internal structures to conform to the WTO. That is why these rules have implementation phase-in periods. These structural adjustments are needed for people to come into compliance, and they must be made. There is really no viable alternative. Isolationism does not work;

protectionism does not work. Trade works, and sustainable trade needs mutually recognized rules.

As I noted early on, my industry, the pharmaceutical industry, is an idea industry, so in that regard, we are very dependent upon the protections provided for intellectual property in the WTO-TRIPS agreement. So let me take a minute to just explain how we perceive this very important agreement. We believe that TRIPS establishes transparent rules that give a minimum level of protection for ideas through the patent system. It really is not all that hard. A patent is really just a deal between an idea-maker and a sovereign, where the government says, "I'll give you a period of market exclusivity, if you make your knowledge public, and you put it to work." That is all a patent is. Patents, though, are critical to our research and development, because all modern pharmaceuticals are really ideas.

The TRIPS agreement establishes a twenty-year period of patent protection for all products, without discrimination across fields of technology. That, too, is important because it means that patents appropriately apply to medicines.

In addition, TRIPS contains protections for the very sensitive data that I talked about earlier — the clinical trials data — that we must submit to the regulatory authorities for the purposes of obtaining marketing approval. This protection, known as data exclusivity, is an independent protection. It is independent of patents, and in many industrialized countries, we are provided a five to ten-year window, where only the originator of the data can rely upon that data. To us, this is quite valuable because it prevents a copier company from taking unfair advantage of the clinical trials data which we have developed at great expense.

Overall, though, these are the key protections that allow the R&D in our industry to keep flowing. And this year PhRMA-member companies will invest $26 billion in R&D.

The TRIPS agreement's protection for patents provides the important safeguards we need for our high-risk, high-stakes pharmaceutical sector. These investments ensure that there will be new cures tomorrow. And without intellectual property protection, it simply would not happen. Investment — the $26 billion that I just noted — would flow elsewhere. We are all quite aware, as Secretary of State Harris described, about the magic and the wonder of the "dotcoms" — the IT industry — where money is being attracted.

That is a big competitor to our industry for investment money. Don't misunderstand, I am a big fan of the dotcoms, but let me just say, all the dotcoms in the world will not be of much use to me, or to you, or to your loved ones, should you become sick.

We need to keep R&D in the pharmaceutical pipeline. We need that to continue for our collective good health, and those of the ones we love. We all enjoy wonderful medicines today, but we all expect that there is going to be more tomorrow. But this is not a certainty, especially since ideas — our ideas — are relatively easy to steal. And sadly, some governments, including some prominent ones in Latin America, have chosen the piracy path, hoping that it will be a shortcut to economic development and public health. It is neither. The unauthorized copying of a pharmaceutical product is the theft of our ideas. It provides no long-term benefit to foster growth of a dynamic sector, and it does not promote technology transfer. Oftentimes, the copies that are made are not even very good copies, so the short-term benefit is illusory as well.

Because of this, we must all be very cautious when asked to pursue false compromises, like exempting large parts of the world from the rules of intellectual property.

Let me state that again. Intellectual property rights are merely the vehicles which allow an inventor to assert ownership over his or her own idea. We can never let this discussion be falsely reduced to one of an issue of North versus South, or rich versus poor. Nobody — nobody — has a monopoly on good ideas, and to imply that this might be the case gives legitimacy to a dangerous and false idea that elevates expediency over sustainable development. It is the wrong development path.

The Nobel prize winner for chemistry this past year was won by an Egyptian-born scientist, Ahmed Zewail. He developed his idea in America, because he was unable to fully develop and protect his idea in his home country. While this was good luck for America, this was not a good economic development path for Egypt, and now they know that. One of the recipients of this year's PhRMA's Discoverer's Award, Dr. Jiben Chikrabadi, was born in India, but he had to come overseas to develop his break-through medicine, which now gives productive life to people who suffer from schizophrenia. He had to come here, because the U.S. and the EU had intellectual property laws, and India did not.

I admit that sometimes this discussion gets complicated, because it is true that capital markets are imperfect, and it is true that the apparatus, as many of you know, for recording, and enforcing, and adjudicating intellectual property claims, may be weak or ineffective. It is true that investors all over the world need mentoring on how to develop an idea into a product, and how to get that product to market.

But these are basic economic development issues, not shortfalls in the intellectual property laws. Receiving mentoring and basic economic development is where work needs to be done — not weakening intellectual property laws or the other rules of the WTO.

Novel ideas spring forth in Bogota, and in Managua just as much as they can in Paris and in L.A. Strong intellectual property laws and non-discriminatory access to markets are sound trade policy, sound economic policy, and sound public health policy. And on this, from our perspective, there is very little room to compromise.

XI. SUB-REGIONAL ECONOMIC INTEGRATION PROGRAMS IN LATIN AMERICA

Thomas Andrew O'Keefe[*]

It is important to keep in mind, in addition to MERCOSUR, that there are other sub-regional economic integration programs in Latin America that have produced some very significant results.

Two of them are, of course, the Andean Community, which consists of five countries: Bolivia, Peru, Ecuador, Colombia, Venezuela. The second is the Central American Integration System, which also consists of five countries, although there is a sixth one there that is always waiting in the wings. Those are Costa Rica, Nicaragua, El Salvador, Guatemala, and Honduras, and that sixth one, of course, is Panama.

The Andean Community today is a very imperfect customs union. It is imperfect for many of the same reasons why the MERCOSUR is also a very imperfect union. There is a common external tariff or CET. It is basically a four tiered system that consists of four different percentage rates, although there is a fifth one that is usually added, 0%, for certain capital goods that are not produced in the Andean sub-region.

But the reason why the Andean Community is an imperfect custom union is that the CET does not cover all products across the board. There are exceptions. In addition, while the CET is fully adhered to by Venezuela and Colombia, Ecuador has a number of exceptions. Peru right now is completely excluded, and Bolivia has its own import duty system as well.

The Andean Community is also an imperfect customs union for a second reason. The idea with a customs union is that when you pay the CET upon entering the territory of the union — one of the states in the union — it becomes nationalized and can then be circulated among the other member states without having to pay the CET again. Like the MERCOSUR, the Andean Community, unfortunately, has not been able to resolve the issue of the distribution among member states of the money that is collected by

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