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**Discussion Following the Remarks of
Minister Michel Côté
and Dr. Harvey Bale**

QUESTION, Professor King: I want to ask Minister Côté a question about the updating of the copyright and patent laws in Canada. It seems to me that you are updating these in light of new technology, such as computer programs, semiconductor chips, and biotechnology. However, I am sure there will be other future developments. Do you visualize anything further than the changes you have mentioned to take care of these other technological changes? How do you parallel patent and trademark laws with the changing context of technology? You can update it as of now, but what of the future? Should there be some collaboration between the United States and Canada on that issue?

ANSWER, Minister Côté: To begin with, we made important changes when we came into power in September of 1984. We amended, for instance, the old Foreign Investment Review Act that now is being called Investment Canada. Along with that, we had to make some other important steps which relate to intellectual property and are very important to Canada. We have already amended our Combines legislation, for instance, to enhance competition.

Last December we introduced a new competition act, but we also want to deal with the intellectual property. In this area we have announced our intention to do something with the amendments of the Patent Act and, especially, regulations related to the pharmaceutical industry. We know how it is important to our trade partners to receive the signal that Canada is prepared to change and to bring major change. One of the major items that we have in mind is to make sure that we protect the intellectual property which, for instance, in the pharmaceutical sector, we are not doing with the present compulsory license law that has been in force since 1969.

There is important change to bring. On the copyright side, we have received a lot of recommendations from our country. We not only want to bring the laws up-to-date, but we also want a flexibility in the laws allowing for quick readjustments to new technologies and new innovations, both in the country and in the world.

Once again, it is important for us to have our trade partners receive a very unique signal that Canada is ready to make the necessary steps to welcome free enterprise and to create investment, as well. This will allow for better commercial activity, both for Canada and our partners.

QUESTION, Professor King: I have one question for Harvey Bale.

In terms of the actual details of the trade agreement, which you are not obviously going to discuss in detail, do you want to list any specifics that might be included in a trade agreement with Canada in this area of intellectual property?

ANSWER, Dr. Bale: Forecasting is a very difficult business. The issue, as Minister Côté has mentioned, has been raised at the heads of state level and the issues that have already been mentioned would certainly be matters that need to be addressed soon.

Now, to the extent that the two countries believe that intellectual property protection is intrinsically worthwhile to adopt for their own reasons, for trade reasons, or for competitive reasons, this should be done independent of a formal negotiation. My expectation is that before we arrive at a trade agreement of a comprehensive nature, which I hope we do, we will have addressed many, if not most, of the matters in the intellectual property field on both sides. Presently, there are continuing consultations between the patent and trademark experts. These are issues between our two countries that can be dealt with fairly quickly since we do, to a considerable extent, share common goals. Some of these issues involve considerable lost copyright and patent holdings where damages are involved. In these cases, there is a related point that is at stake: the U.S. belief that such practices come under the category of an unfair trade practice where concessions should not be exchanged to see their removal. Instead, the U.S. believes that we should urge, as in the cases of Korea and Brazil, informal section 301 proceedings, where bilateral discussions between our two countries would resolve these problems.

QUESTION, Professor King: In connection with some of the countries that you are mentioning, to pursue multilaterally may be a problem because they are not members of GATT. Does that pose a problem?

ANSWER, Dr. Bale: Many of the countries that are problem countries, such as Singapore, Korea, Malaysia, Indonesia, Egypt, Brazil, Mexico and others, are oftentimes members of GATT in this area, but not members of a major intellectual property institution, such as the Paris Convention, the Berne Convention or the UCC. I think that there is a problem of membership, but I don't believe it is a significant problem. There is a problem, however, in getting developing countries to adhere to stronger international intellectual property protection rules. That is a problem which exists now in the discussions under the Paris Convention, the Berne Convention, and other conventions. Of course, the United States is not a member of the Berne Convention, which is another problem, I'm sure, that should receive some discussion today. The Administration has made a decision to pursue that adherence.

I would also like to point out a policy statement that may be of interest. It was issued on April 7th and addressed this question of multilateral rules. Also addressed were objective standards that need improvement and a legislative package that was issued on that same date.

QUESTION, Professor King: Minister Côté, addressing the subject of pharmaceuticals, I have spoken with some of the pharmaceutical companies in connection with the planning of this conference and they expressed a concern about the 4% royalty and the compulsory licensing provision. These companies feel that a 4% royalty for pharmaceuticals does not pay for the research. Would you please comment on what the Canadian government says?

ANSWER, Minister Côté: As I previously said, the compulsory license has been working since 1969 from the preceding government. The objective when they put that system in place was to lower drug prices in Canada because at that time Canada was the third country to pay the highest drug prices. But by doing that, Canada was becoming probably the only industrialized country to control drug prices by addressing the intellectual property.

In 1981 and 1982, the former government believed that it was time to re-examine the situation and they created, in April of 1984, a commission to review the whole compulsory license system and make recommendations. Dr. Eastman chaired this commission and he presented some recommendations in May of 1985. His recommendation, for the most part, was to give protection, or a period of exclusivity, to the pharmaceutical industry for four years and increase the royalties from 4 to 14%. We have examined these recommendations, but we believe that Mr. Eastman is not going far enough.

The Mulroney government believes that the pharmaceutical industry needs to receive better protection in order to create the investment and jobs and initiatives that we need in this country. Therefore, the changes that we are working to bring will extend that period of exclusivity.

We, as well, want to make sure that the benefit to Canada will come in terms of investment and the creation of jobs and we are dealing with the industry in order for that to happen. However, we have to face a very important political issue. As you know, each province in Canada has a Medicare plan and is paying for the drugs that the senior citizens and welfare recipients are using. So the provinces know that if we have to extend that period of exclusivity, increasing, to a certain extent, the drug prices, these increases will be transferred to the provinces. Therefore, we have to face some political reaction.

On top of that, you also have the insurance companies that if they have to pay or reimburse higher drug prices to their clients. It is that kind of political environment that we have in Canada, but, I think that we are just about ready to make our move. I would say that it's imminent and will be in this area.

Furthermore, we want to make sure that the investment will come in to Canada and we are ready to give the needed protection. Therefore,

we will put in place the mechanism allowing us to monitor or watch the evolution of these drug prices.

QUESTION, Mr. Wolfe: I have a question for Mr. Bale. I have read the April 7th statement. I think you stated the notion of using trade statutes for intellectual property goals more clearly than we understood it.

To take a specific example, you are working with § 337. I wonder if trade policy in the case of § 337 is well suited to what you are trying to do. Although I steal my ideas here a bit from the trade bar in Washington, I wonder if what you are trying to do goes in the direction of using trade policy, not simply to enforce the right, but to establish a right. Is the ITC well suited to doing that? Does that take trade policy in directions to which it is not well suited? Does it take us even farther away, stating Canadian bias here, from national treatment with § 337?

ANSWER, Dr. Bale: I have testified on it before a couple of judiciary committees in the Senate and the House. The question of using a trade statute to protect intellectual property has been there for some time. From the proposals that have been made, the question is whether or not improvements can be made to the trade statute in order to improve the protection of intellectual property; or stated another way, are certain aspects of current laws inadequate or not up-to-date to protect intellectual property in the United States? We believe that's the case and, in some cases, our proposals would extend the use of § 337 to foreign nationals. Some questions have been voiced on that issue. In particular, one of the commissioners of the ITC, the current chairperson, questioned the use of extending the protection of U.S. trade statutes to foreign nationals. However, where the United States registers a patent and grants it protection, we think it appropriate to provide protection of U.S. laws through an extended use of § 337. I would argue in that sense that we are moving toward national treatment, but we would also like to reduce the uncertainties and the costs and broaden the coverage of intellectual property protection by changing a number of laws, including this one.

This is not the only statute where change is being considered. We would also like to extend our protection to process-patent holders under existing patent laws, which is presently unavailable, through a proposal that we have in the process-patent field. It has to be looked at in terms of a package.

QUESTION, Mr. O'Flaherty: I have a question for Minister Côté, which relates also to § 41, but the other aspect of § 41 which you haven't commented on. Section 41 also provides that food products are not patentable in Canada, and to the extent that patent protection can be obtained, they are subject to compulsory license. That was a part of the statute that was taken over from the British and, subsequently, the British rescinded their law. The Canadians, however, kept theirs. It has not been a part of the statute that has been used too often— maybe three or four times in its existence. It could, however, have very serious conse-

quences to people that might be caught up under the Food Product Compulsory Licensing Act. I know that about a year ago you received a number of submissions suggesting that that part of the statute be rescinded. Could you comment on what you are planning to do about that?

ANSWER, Minister Côté: We are just re-examining the whole situation in that context. We have some plans in mind. As I said before, the whole revision of the patent act will happen.

We are dealing now with the pharmaceutical area because it is a more sensitive issue and, I might add, it has become a matter of intense discussion between the United States and Canada. But, I have no doubt that on your point we are also looking to bring up some amendments and some changes.

QUESTION, Mr. Plaia: I have a question for Dr. Bale concerning the amendments to § 337. Is it your latest proposal to eliminate only the injury aspects of the statute and retain the industry requirement?

ANSWER, Dr. Bale: No.

QUESTION, Mr. Plaia: If that is so, do you support eliminating the injury alone, without eliminating the industry?

ANSWER, Dr. Bale: The Administration's proposal is to eliminate the injury based upon certain principles noted in some GATT cases, the desire to broaden the coverage of protection, and the desire to eliminate several aspects of the § 337 criteria with respect to copyright, patent, and trademark protection. It's not a more general change to § 337 but with regard to these types of infringement cases, our proposal would eliminate the injury test. It would also eliminate the industry test.

QUESTION, Mr. Plaia: If legislation were passed through the House of Representatives which eliminated injury, but not industry, would the Administration still support that proposal?

ANSWER, Dr. Bale: We would have to look at that. At present we have no position on that.

QUESTION, Mr. Knopf: Dr. Bale, I wonder if you have anything to say about the timing and status of the long-awaited announcement on Gray Marketing parallel importing?

ANSWER, Dr. Bale: The ITC recommended to the Administration, when the so-called "Duracell Battery" case came up for review, that Gray Market imports of these batteries be excluded. The Administration stood on long-term policy grounds to restrict those imports.

There is a review under way in the Administration, again, however, of the Gray Market issue. One could argue that it is, perhaps, "too little, too late," because one of the primary motivations of Gray Market imports was the over-valued dollar. Now, perhaps, our dollar is over-valued with respect to the Canadian dollar.

In a general sense, the incidence of Gray Market imports, I think,

has diminished. At least we haven't heard about them in Washington as much as we had over the last several years.

Nevertheless, the long-term issue of Gray Market imports continues to be there. Moreover, by saying that that's a problem, I'm giving you my perspective, which is one that is not shared by some in the Administration.

The principle on which the basic policy has been founded is that Gray Market imports are a pro-competitive force. Nonetheless, certain options are being considered, which, at this point, are a little bit too early to discuss. However, I do not see a radical departure from our Gray Market policy in the pending developments of court proceedings presently underway.

The questions that are being discussed are a means of, perhaps, better identifying Gray Market products from a consumer point of view. Therefore, because there is this consumer interest, as well as the pro-competitive interest, it is my view that we need to better balance those interests.

COMMENT, Mr. Jackson: Mr. Bale said that the consumer interest in the United States regarding free trade was not an effective force, while consumer interest in Canada is a very important aspect of the § 41 pharmaceutical drug price question. At the same time, I think top management interests are very important too.

I have worked for a couple of national corporations. I have seen one which has a deliberate policy of encouraging independent decision-making and research in countries other than the United States, and another one where all decisions were made at the head office in the United States. Patenting was all integrated in the head office and research in other countries was either limited, discouraged or treated with a sort of, "we are not really very interested unless this is useful in the United States" attitude.

Now, when we are talking about changes in industrial and intellectual property laws, we should think about the trade off between consumer interests and local interest, in countries where affiliates operate, as well as the centralized management policies and interests in the United States and other highly industrialized countries where the patents originate.

COMMENT, Minister Côté: That is exactly the debate that we have in Canada because, as Mr. Jackson has said, we have to keep in mind the consumers' interest. For instance, Eastman's Commission has examined thirty-two drugs that were sold in Canada. They compared the prices between the pharmaceutical industry prices and the generic prices and the prices that were paid in the United States. You could end up with a savings of \$211 million.

That's only on thirty-two drugs. That shows you that if we bring a change in Canada in order to protect intellectual property, consumers will have to pay higher prices somewhere. If they don't they won't get

the savings that they should have gotten. Those are the concerns that we as politicians have.

That's good to have a philosophy to protect the intellectual property and make sure that we create investment and that we create an environment to bring in research and development. For instance, in Canada, there are over \$2 billion worth of drugs sold in the country.

It only represents, probably, 3 to 5% of all of the drugs sold in the world. That shows you how little it is. On the other end, if we want to bring changes, we can do it, but we want to make sure that research will be spent in this country. In Canada right now the pharmaceutical industry is only spending a little over 4%, in terms of sales volume, for research.

They are spending 4% on research, and yet it's not fundamental research. Most of it is clinical research. We want to make sure that when we bring changes, we will have that kind of commitment from the industry.

We believe in it. We believe it is important to protect intellectual property, but on the other end, it is important to protect the consumers' interest. We have to keep the consumer in mind.

QUESTION, Mr. Duvall: I have an intellectual property protection question for Dr. Bale and perhaps Minister Côté would care to comment well.

It is my understanding that the Reagan Administration is supporting a regional patent office for the western hemisphere comparable to the European Patent Office. It is my understanding that this ties into the patent cooperation convention which a few Latin American countries are, at least, members of. In view of your statement about the nonparticipation of many countries in these patent conventions, I was wondering if you could give us the status of that initiative and what you see as the outlook for it. I assume Canada is also involved in it.

ANSWER, Minister Côté: I just want to say, if it is true, we would like to have it in Canada. There have been only very informal discussions of this idea. It has a certain political sensitivity involving questions of "what" and "where," "how" and "how fast," and "what is involved in it?" This also appears in our April 7th statement in more general terms than it has appeared in certain public documents before. We referred to the desirability of multilateral or regional participation, without necessarily specifying the regions. It is a concept that is worth exploring, but it has to be done in a way that will likely yield some real benefits and not raise concerns on anybody's part.

QUESTION, Mr. Wright: I've been trying to restrain myself from getting up because I think what I'm about to say isn't going to be too popular among some of the people here. As an industrial property litigation lawyer, I sincerely hope the government does restore the full patent protection to pharmaceuticals. We haven't had much interesting phar-

maceutical litigation for quite a few years. I'm getting quite excited about the prospects.

On the other hand, representing the consumer, or the public interest, I have never been able to understand why we have to jump out of the frying pan and into the fire, so to speak. I don't see why we necessarily have to go from something that most of the pharmaceutical companies think it is too low of a royalty, to a sudden restoration of patent protection.

If the act was applied as it was supposed to be applied, and a reasonable royalty was awarded, how can anybody complain? It seems to me that the thrust ought to be directed to whether the government thinks a reasonable royalty is not being awarded.

I can see the Minister's position. He's trying to balance the interest of the pharmaceutical companies, on the one hand, and the consumer interest on the other. Surely that's exactly what § 41 was designed to do. Why can't you do that in the way that you determine the compensation to the pharmaceutical companies for their industrial property rights, rather than saying the only things that we can do is restore the patent rights?

ANSWER, Minister Côté: I think that I have explained the problem. We are politicians. We have to make sure that we want to be here five years from now. We have to make the good decision and sound decision.

We think that in order to provide intellectual property protection we must amend the Patent Act—especially § 41. Primarily we feel this is needed so that the industry can create investment and jobs. But on the other end, as politicians, we want to protect consumer interests as well. If we increase, for instance, royalties, certainly they will transfer it to their costs and the savings won't be there. We want to make sure that whatever happens, we are coming with a fair balance. We think that we have and we are close to having a very good package that will make sure that this will happen.

We are not afraid of tough decisions. We are ready to make them, but we want to make sure that our objectives will be met in the best interests of the industry, for Canada and for Canadian consumers.