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Chair

Mr. David Sweet

Standing Committee on Industry, Science and Technology

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● (1105)

[*English*]

The Chair (Mr. David Sweet (Ancaster—Dundas—Flamborough—Westdale, CPC)): Bonjour and welcome to the 40th meeting of the Standing Committee on Industry, Science and Technology.

We have before us a number of witnesses, as well as witnesses by teleconference. I'll introduce them.

From the Canadian Generic Pharmaceutical Association, we have Jim Keon, the president, and Benjamin Gray, vice-president, and legal and general counsel of Mylan Pharmaceuticals ULC.

From the Ontario Bioscience Innovation Organization, we have Gail Garland, who is the president and chief executive officer.

We also have with us George Dixon, the vice-president of research at the University of Waterloo, who is appearing as an individual.

By video conference, we have Norman Siebrasse, who is appearing as an individual. He is a professor in thefaculty of law at the University of New Brunswick.

We will begin with Jim Keon.

Please contain your opening remarks to six minutes as we have five witnesses.

I would also ask members to remember, once we get into the questioning, that we do have somebody by video conference. I know it's easy to focus on the witnesses at the end of the table and leave out the person who is joining us by video conference. I'm certain that Mr. Siebrasse would not enjoy that.

Mr. Keon, please give us your opening remarks.

Mr. Jim Keon (President, Canadian Generic Pharmaceutical Association): Thank you very much, Mr. Chair and honourable members of the committee, for providing Canada's generic pharmaceutical industry with the opportunity to contribute to your study of our domestic intellectual property regime.

As you mentioned, I am joined today by Ben Gray. Ben is vice-president and general counsel at Mylan Pharmaceuticals in Canada.

I have a couple of words to say about our generic pharmaceutical industry in Canada. We consider it Canada's life sciences success story.

We directly employ more than 12,000 Canadians in highly skilled research, development, and manufacturing positions, and we export our value-added products to more than 115 countries. Our industry, the generic industry, is a net exporter of value-added products and positively contributes to Canada's balance of trade in pharmaceuticals.

Canadian generic pharmaceutical manufacturers operate the largest life sciences companies in Ontario, Quebec, and Manitoba. Canada's single largest research and development spender in the life sciences sector is generic drug maker Apotex, which is Canada's largest pharmaceutical company and also the owner of Canada's largest biopharmaceutical company.

[*Translation*]

Today, we are talking about intellectual property. In our opinion, there is no link between increased intellectual property and pharmaceutical research and development. Any purported links between increased intellectual property and increased pharmaceutical research and development investments are dubious at best.

Patents have national treatment. Countries must grant the same protection regardless of where the research is done. Decisions about where to site research are not linked to intellectual property. Most investments by brand-name drug companies are today directed to corporate headquarters and to developing countries that are not renowned for their intellectual property protection, such as the BRIC —Brazil, Russia, India and China.

Given these investment realities, the question then becomes what is the appropriate level of IP protection to support therapeutic innovations conducted in other countries?

[*English*]

Canada has a small market size, representing just 2.5% of the global market for pharmaceuticals. Nevertheless, Canada has a very strong intellectual property regime for pharmaceuticals. In its totality, pharmaceutical intellectual property in Canada is stronger than that in any other industrial sector in Canada. In many ways it is stronger than pharmaceutical intellectual property in the United States and Europe.

For example, in Canada brand-name pharmaceutical companies benefit from a unique automatic injunction against generic entry up to 24 months long. Most often there are two rounds of patent infringement litigation on the same set of patents, which creates business uncertainty. In contrast, the U.S. patent linkage system, on which Canada's was based, does not allow for multiple rounds of litigation and provides much better business certainty.

In Canada, unlike in the U.S., we have no statutory incentive for generic pharmaceuticals to challenge patents. Our regulatory data protection lasts several years longer than the international average. In Canada, pharmaceutical patentees have the ability to obtain patents on multiple aspects of a drug, without any mechanism for generic companies to oppose such patents, except through litigation.

In fact, importantly, our Canadian system relies on generic patent challenges to operate effectively. This is not often discussed, but it is a key component of pharmaceutical patent policy in every developed country that requires a robust mechanism to ensure that only genuine inventions are afforded monopoly protection.

In Canada we have no mechanism for opposing the grant of a patent. Patents are reviewed and issued based on the representation of patent applicants, without any counterweight.

For pharmaceuticals, these unopposed patents can get listed on Health Canada's patent register and then automatically block approval of generic drugs for up to two years. Some of these patents are genuinely innovative and deserving of protection, but many are not.

This is where the generic industry comes in. The only disciplining agent on the effect of weak pharmaceutical patents in Canada is the generic industry. Generic companies challenge weak patents in the pharmaceutical sector in Canadian courts in order to launch their products in Canada. If we're successful, we open up the market to generic competition and generate substantial savings for Canadians.

However, reforms are needed in our system. Over the past several years stakeholders in the public and private sectors, including judges of the Federal Court, have increasingly expressed concern about the proliferation of complex pharmaceutical patent litigation in Canada. There have been more than 100 pharmaceutical intellectual property cases initiated in each of the past seven years. The current system is an inefficient use of our limited court resources and places the generic companies at a potentially grave financial risk upon launching a product in Canada.

I'll say just a few words about the complexity.

We have a system of patent linkage that links Health Canada's approval to the patent system. That's an extraordinarily powerful enforcement mechanism for a patentee. In Canada it blocks the health and safety approval of a new generic medicine by way of an automatic injunction without any upfront burden of proof. It is interesting to note that such a patent linkage system is actually illegal in the European Union under their competition laws.

Canada has a litigation system for pharmaceutical patents that also has no meaningful deterrents to discourage weak and frivolous patent litigation by brand-name pharmaceutical companies. This system has been described by the Supreme Court of Canada as draconian in terms of its treatment of generic manufacturers. Common law principles for damage injunctions are not available currently in Canada.

The complexity and unfairness of this environment has increased since regulatory amendments were made in October 2006. While positive changes were made at that time to reduce patent evergreening, a new legal tactic has emerged whereby generic manufacturers are routinely sued a second time for patent infringement. This means most generic medicines are launched at risk. This duplicative litigation system makes Canada an international outlier, with no other country providing both pre- and post-market litigation. The system is inefficient, increases business uncertainty, and has a chilling effect on the entry of new generics.

We have submitted proposals to Industry Canada—

● (1110)

The Chair: I'm going to have to cut you off there. We're way over time, and I have to go to the next witness. Hopefully, you can get some more of your material in during the question period.

Mr. Jim Keon: All right. Thank you.

The Chair: Madam Garland, please, for six minutes.

Ms. Gail Garland (President and Chief Executive Officer, Ontario Bioscience Innovation Organization): Good morning. I am Gail Garland, CEO of the Ontario Bioscience Innovation Organization, a private sector, membership-based organization engaged in advocacy to enable development and commercialization in Ontario of life science technology through investment, strategic alliances, stakeholder engagement, thought leadership, and industry promotion.

As I prepared for today's session, I consulted with OBIO's membership—companies engaged in developing therapeutics, devices, and diagnostic technologies. Today I will use their lens in my comments about changes that can be made to Canada's patent regime that will help commercialize life sciences technology out of Canadian biotech companies and academia, and make Canada a better place to commercialize.

The first recommended change is on the subject of scope of patentable subject matter. In Canada, the recent proposed amendments to CIPO's examination guidelines have raised a number of concerns as to how the Canadian Intellectual Property Office, CIPO, will decide whether a claimed invention is considered patentable subject matter. This is particularly troubling for certain claims to diagnostic methods and medical uses, which under the new guidelines would not be considered patentable.

The view of legal experts working with biotechnology SMEs in Canada is that restricting what is considered an invention and therefore patentable subject matter is not an effective way of either increasing the quality of issued patents or encouraging innovation. There are approximately 40 diagnostic SMEs in Ontario advancing personalized medicine technology whose ability to patent their technologies could potentially be impacted by these amendments.

A second recommendation is to allow Canadian applicants to file a terminal disclaimer. In Canada, an applicant must claim all of the embodiments for a single invention in a single application. In the U. S., companies can file a terminal disclaimer as a way to overcome the objection to double patenting. For Canadian biotech start-ups, there are often compelling business reasons why a company may want to get a first patent issued quickly and then also have additional patents directed to other embodiments or aspects of the invention. This is possible in the United States but not in Canada, where the prohibition against double patenting requires that an applicant claim all of the embodiments for a single invention in a single application. This can delay the issuance of patents in Canada that would otherwise be valuable to companies, as they drag out prosecution to ensure they get claims to all the possible embodiments in a single patent. Bilateral agreements, such as the patent prosecution highway, are helpful for SMEs because they accelerate patent prosecution at no extra cost. Further moves towards a globally harmonized patent system will help Ontario bioscience companies compete in the global business environment.

Going against the spirit of global participation, there have been some judgments recently that could potentially damage Canada as a jurisdiction in which to file because of the amount of data required in an application to support the utility of a claim and measured as the “promise of the patent”. In some cases, it was determined that human chronic data that wouldn't normally be available until a product had been on the market needed to be included in a patent application at the time of filing.

The number of these cases is still small, but the impact is felt when companies decide not to file in Canada because they are worried they may not have enough data, or investors simply ignore commercializing in Canada. One way this issue can be addressed is by harmonizing with the U.S., where they use post-filing data to support a claim.

Here are some easy wins for patent reform. As it stands now, the Canadian IP system is unforgiving despite best intentions by applicants. Deadlines can be missed due to events such as correspondence lost in the mail and mistakes in fee payments. Since there is very little discretion to remedy these situations, an SME could lose its patent. If online patent information and file histories were accessible, someone could go online and see if something is missing or if there is a deadline approaching.

By comparison, both the U.S. Patent Office and the European Patent Office have online systems that allow the public to access file histories. Along the same lines, even though the current system allows companies to pay reduced fees by filing as an SME, the reality is that very few do because of the risk that at some point they could be challenged on their SME status and they could lose their patent.

Redrafting these rules so that they are more forgiving would allow SMEs to sleep better at night.

● (1115)

An issue that affects Ontario SMEs hoping to partner their technology is the lack of patent term extension in Canada. SMEs in the U.S. and the EU can have their patent term extended for up to five years to compensate for time lost in regulatory delays. Investors and MNEs valuing an Ontario SME's intellectual property adjust negatively for the lost commercial opportunity resulting from fewer years of market exclusivity. Less market exclusivity in Canada, already a small market for a multinational, may also negatively impact its willingness to market innovative technologies here.

For SMEs to realize their full economic potential, Canada must match global standards for intellectual property protection. To this end, we recommend the adoption of CETA, the comprehensive economic and trade agreement with the European Union. CETA is a unique opportunity for Canada to become the only country in the world with favoured trade status with both the U.S. and the EU. This is a competitive advantage that we need and should embrace.

In conclusion, Canadian patent reform should include global harmonization that is cost effective and speeds up granting of high-quality patents. Bioscience companies looking to make their way in the world need a competitive intellectual property regime that is predictable, stable, flexible, and consistent with trading partners.

The Chair: Thank you very much, Madam Garland.

We'll now go to Mr. Dixon, for six minutes, please.

Mr. George Dixon (Vice-President, Research, University of Waterloo, As an Individual): Thank you, Mr. Chair.

At the hearings of this committee on May 17, the committee received input from Mr. Scott Inwood who is the director of commercialization at the University of Waterloo. He outlined the IP policies at the University of Waterloo. He also discussed the commercialization climate in Waterloo region. I am not going to repeat that activity or those types of observations, because Mr. Inwood summarized those quite well.

What I would like to do is make three observations, and feel free to ask me to expand on them. I'll be quite willing to expand on them in the question period, if it's appropriate. After 20-odd years of working as the dean of science at the University of Waterloo and the vice-president of research, and being active in the commercialization area, these are observations of where I see Canada could improve its performance and optimize the return on investment in research in the intellectual property that has developed from that work.

The first observation has to do with ensuring that work suitable for protection and commercialization is actually disclosed within the university system. You might think that this is not obvious, but within the university you have to effectively support the development of a culture that allows people to recognize what something is when it is worth disclosing and protecting. They need to have the ability in their background to identify whom they go to in order to do that.

Despite extensive educational activity and networking within the university, this is something that has to be worked on continuously in order to get, in particular, an undergraduate student to come forward with an idea that they want to disclose and protect.

While we tend to capture a very significant portion of this at Waterloo, it is by continuous activity in terms of identifying and networking with these people. One area that concerns me, although I won't say it keeps me awake at night because nothing keeps me awake at night, is individuals that have a really good idea, particularly at the undergraduate level, but they're not aware of how to go about disclosing it. We spend a lot of time actually working at that type of activity.

Another observation would be regarding very early stage investment. Significant resources in budget 2012 were put in place for what I'd call late angel and venture capital funding. In my opinion, to some degree the greatest need is in the early pre-commercialization investment. This is the de-risking component, the proof of principle component associated with any intellectual property at the very early stages of its commercialization. I often call it archangel investment. It's the investment before the angel investor is willing to come forward.

Some funds are available. The scientists and engineers in business initiative through FedDev is a very good example. NSERC has an ideas to innovation program, I to I. A number of programs are run at the provincial level. All of these programs have relatively complicated application procedures. The timeline for decision-making is in the range of six to twelve months.

I fully recognize that these folks have to do their due diligence, but if graduate or undergraduate students are looking to found a company, you need to have a timely decision in order to keep the individuals with that IP together to form the company. These are often very sharp people that have a lot of competitive job offers and if they're not making a living, waiting six to twelve months for a decision is not something that is really appropriate.

I think the only way you can get around this is what I'll call local funding, some combination of philanthropic money. There are some venture capitalists who are willing to invest in this type of activity, but this needs to be developed and controlled at the local level so that decisions are made very rapidly.

At Waterloo, we have a fund of about $2 million, based on philanthropic money. We allocate $25,000 a shot for young undergraduate and graduate students who want to move down this trail. We can turn that around in about three weeks. But the demand far outstrips the supply, when I look outside the university at the broader region in Waterloo.

Another point to mention is risk tolerance in the private sector around new products and innovation.

● (1120)

I'm not talking about risk tolerance with respect to investment. I'm talking about receptors for new technology and products either as a first customer, or as a licensee of IPs, that is, first customer start-up or licensee of IPs.

Compared to my experience in Europe and the United States, Canadian business tends to be very risk averse and often doesn't want to be the first to try the new product or innovation. I don't know how we solve that problem.

I would hate to tell you how many companies I have seen where their first sales are offshore and sales in Canada follow once they've demonstrated the approach. One of the approaches here is that government is a very significant purchasing agent within Canada. That may be an opportunity. There may be incentives to try new technology coming through tax incentives, or whatever.

Those are three observations. I don't pretend to have a solution. I would say these are observations from the trenches.

The Chair: Thank you very much, Mr. Dixon.

Now on to Mr. Siebrasse, for six minutes please.

Prof. Norman Siebrasse (Professor, Faculty of Law, University of New Brunswick, As an Individual): Can you hear me all right?

The Chair: You're just fine, thanks.

Prof. Norman Siebrasse: Thank you for inviting me to appear today. The first point I'd like to address in my remarks is the subject of business method patents and patentable subject matter more broadly.

Business method patents have been controversial since the 1998 U.S. decision opened the door, or floodgates as some would call it, to patent a new business method. Many academics have argued that such patents are bad for innovation in business, and for that reason the courts should hold that business methods are not patentable.

I'd like to make two points in this respect. First, this is a matter for the legislature and not the courts, and certainly not the patent office, to decide whether business methods should be patentable. The entire area of patentable subject matter needs clarification to ensure that innovation will be promoted in crucial areas such as personalized medicine. Second, the implications of this decision go far beyond business methods, to important emerging areas such as personalized medicine.

The patentability of business methods has recently been at issue in Canadian litigation over Amazon.com's application for a patent for one-click shopping. The application was refused by the patent office, which said business methods are not patentable in Canada. Amazon.com appealed to the Federal Court, which said business methods are patentable. The patent office appealed to the Court of Appeal, which said, "It depends."

I won't try to explain what it depends on, not because this is a technical area of law, but because I don't understand what they said. My view is that their decision is incoherent and internally inconsistent.

The Court of Appeal sent the application back to the patent office, which granted the patent. The patent office does not make the law; it merely applies the law set out in the legislation and case law. The result of all this is that even though the Amazon.com patent was litigated to the Court of Appeal and then granted, we still don't know if it's valid.

In an article I've written on the subject, I've argued that the best view of current law in Canada is that business methods are patentable. That is, I believe that if someone litigated this to the Supreme Court, the court would hold the patent to be valid, but I might be wrong. The bottom line is a tremendous uncertainty.

I also want to emphasize that there's a difference between whether business methods are patentable under current Canadian law and whether they should be patentable. While I believe that business methods are patentable under current law, I do not necessarily believe that this is a good thing. Whether these patents are good for business innovation is an empirical question, and it's a very difficult question. There's tremendous uncertainty in the empirical evidence.

What we do know is that patents are very important to the innovation process in pharmaceutical and chemical industries. We also know that the importance of patents varies tremendously between industries. For all industries, besides pharmaceuticals and chemicals, the evidence as to the importance of patents is quite ambiguous. The best generalization seems to be that patents are important in so-called discrete product industries, in which a single innovation provides most of the value of a single product. In complex product industries, in which a large number of innovations contribute a small amount to the value of a particular product, patents tend to be less important.

Business methods appear to have the hallmarks of a complex product industry, suggesting that they are relatively less important in that area. But to say “less important” doesn't mean unimportant. The best I can do here is to quote Professor Bronwyn Hall, one of the leading empirical researchers in this field, who said, "The only conclusion that is certain is that allowing business method patents will cause an increase in the patenting of business methods."

Because of the way in which the issue has been handled by the Court of Appeal, the issue has implications that go far beyond business method patents. In a draft practice notice responding to the Amazon.com decision, the patent office indicated that it believes inventions related to personalized medicine are unpatentable. To my mind, this is an extremely troubling position, as personalized medicine bears many of the hallmarks of a discrete product industry in which patents are important to innovation. Certainly the patentability of personalized medicine is not something that should be decided by the patent office.

In summary, there is tremendous uncertainty as to both law and policy. Whether business method patents are good for innovation depends on complex questions that the courts are not equipped to handle. This entire area needs clarification to ensure that innovation will be promoted in crucial areas, from business method patents to personalized medicine.

I'll now turn briefly to two other topics. One is pharmaceutical patents. As I mentioned, there is a consensus that patents are very important to innovation in the pharmaceutical industry as a whole. In broad terms the system works well, but because the patent system is so important, the details vary greatly.

● (1125)

We've heard already some discussion of some high profile issues, such as patent-term extension, data protection, terminal disclaimers, and the drug approval linkage aspect.

I'd point out that detailed points of law are also important. Some points of doctrine recently developed by the courts have had the effect of making Canadian law less friendly to pharmaceutical patents than the law in the U.S. and Europe, at least on these particular points. This isn't to say that our system as a whole is necessarily unfriendly, but at least on these points, they could have important implications for specific patents.

I'm not sure whether this needs to be addressed by the legislature, as the courts may work it out, but it's certainly something for this committee to keep in mind.

Finally, I'd like to say a brief word about patent trolls. To my knowledge, patent trolls have not yet been active in Canada. Further, the courts have some tools to deal with patent terms, at least in the short to medium term. Arguably, there is not presently a pressing need for government action to deal with this problem. However, I think it's important that the government not take any steps that would make the problem worse.

● (1130)

The Chair: Thank you very much, Mr. Siebrasse.

That's the conclusion of the testimony. I remind committee members that we're going to be finishing with our witnesses 15 minutes earlier in order to deal with business, so members should factor that into the rounds of questions.

We'll move on to the first round of questioning.

Mr. Braid, for seven minutes.

Mr. Peter Braid (Kitchener—Waterloo, CPC): Thank you to all of our witnesses for being here this morning. We have received a range of excellent testimony and presentation.

Welcome, Dr. Dixon from the University of Waterloo. I'm pleased to hear that nothing keeps you up at night and that you're well rested, as always.

I have one question for you. In Waterloo region, as you know, we're constantly hearing from the tech industry about the importance of two things: access to talent and access to capital. You touched on the second one in terms of that being a continuing policy issue in Canada.

Do you have any thoughts or suggestions on how Canada, not necessarily government, could incent more venture capital or archangel capital, as you have described it?

Mr. George Dixon: Let's put it this way. I probably shouldn't have brought the issue up if I was expected to find the solution.

I identified it as being very early-stage investment. The only real sources I have seen that are available in a timely fashion are usually some type of philanthropic funding that has been matched by very early-stage venture capital that is available in the market.

One of the programs currently in place with respect to this is the I to I, idea to innovation program, which I already mentioned. This is probably the oldest and best POP, proof of principle, funding area.

I'm not too sure I would be looking at direct investment by government in this area. I would expect that the funding from government would be reserved for encouraging the later stage activity. I don't mean direct investment, but some type of enhanced tax incentive for people to invest in this type of activity would probably be the way to go.

To be perfectly frank, this is risky business. In truth, probably only 25% or 30% of the funding in this area actually will see fruition. When you do a proof of concept or you develop a particular prototype, a lot of the time that's where it ends because it didn't work out appropriately. Making people aware of that fact, particularly in the private sector, and having any incentive for them to invest in this would be appropriate.

Mr. Peter Braid: Great.

You also spoke about within the university setting the importance of ensuring that undergrad students, if they have a new innovation or invention, know when to disclose and protect it. I presume that's an issue across the post-secondary environment, not just at the University of Waterloo.

Are there any best practices, either at the University of Waterloo or at other institutions in Canada, that help raise that awareness level among undergrad students?

Mr. George Dixon: We do this in a lot of ways. I won't go through the whole routine, but there is one which I found to be most effective for all of our co-op students. We do 17,000 co-op placements a year.

There is a specific set of courses that are taken around how to function in the workplace. They're given to students before they go out on their first co-op work term. One of those is a module on IT. We have had the greatest success in terms of activating the undergraduate population by that one module that is taken by co-op students. I think, frankly, that's a best practice.

The other one is something which the Australians ran into. It has to do with the degree to which the commercialization function has roots within the university. The Australians took all of their commercialization activity and dumped it outside the university to a third party, but they moved it so far outside the university that nobody had enough trust to walk over to them and disclose. One of the main activities I see for a commercialization office within a university is that continuous legwork—networking, meeting people, seminars with graduate students, seminars with faculty members, one-on-one contact. It keeps the communication open so when someone actually has something they want to disclose, they'll bring it to you.

It doesn't matter whether it's commercialized through the university, or the individual takes it outside and does it totally independently, which they can do at Waterloo, as long as it gets done.

● (1135)

Mr. Peter Braid: Thank you. I'll move down the table to Mr. Keon.

Mr. Keon, does the generic pharmaceutical industry have its own IP, and can it be better protected?

Mr. Jim Keon: Yes, many of our companies have patents on manufacturing methods, for instance. One of the attributes of the generic pharmaceutical industry is that they are very efficient at manufacturing and distributing large numbers of products. Our large companies could be making 300, 400, or 500 different products. They're very efficient as to how to do that. They will often protect business methods, business processes, manufacturing methods by patents. That is something we have and we use it.

It typically would not prevent a competitor from manufacturing the same product. It's simply a competitive advantage in how the product is brought to market, and lowering the costs of that.

Mr. Peter Braid: Okay, thank you.

Ms. Garland, my impression was that your underlying message was that Canada needs stronger patent protection and more efficient processes. Is that what I heard?

Ms. Gail Garland: Yes.

Mr. Peter Braid: You made some comparisons with the U.S. Could you highlight aspects of the U.S. system that work particularly well, which we should consider adopting here in Canada? Could you elaborate on those that you touched on?

The Chair: Very briefly, please.

Ms. Gail Garland: I'll restrict my comments to one area, and that's the area of terminal disclaimer. The reason I mentioned that this morning is this recommendation has the potential of making Canada a go-to nation for patent filings. Any opportunity to give us a competitive advantage in this area is one we should be considering.

The Chair: Thank you, Madam Garland. I'm sorry but time is always our enemy here. Members have heard me say that over and over again. I always would like to have the option of having people finish, but I can't always do that.

[*Translation*]

Ms. LeBlanc, you have seven minutes.

Ms. Hélène LeBlanc (LaSalle—Émard, NDP): Thank you very much.

I want to thank the witnesses appearing before us today.

I am the member for the riding of LaSalle—Émard, which is located in southwestern Montreal. As you know, Montreal was a hub for pharmaceutical research labs. Unfortunately, over the past several months, we have seen many research centres close. Many researchers and families have lost high-quality jobs. Obviously, these job losses trouble me a great deal, and I am told that Canada is no longer an attractive destination for pharmaceutical research and development investments. Is this true and, if so, why?

Would you like me to repeat that?

Mr. Jim Keon: Could I ask you to repeat the last part, please?

[*English*]

Ms. Hélène LeBlanc: I'll briefly say that my riding is in a place where they did a lot of laboratory R and D. The research centre has closed, there has been the loss of jobs.

[*Translation*]

Apparently Canada is no longer an attractive destination for pharmaceutical research and development investments. Is that true and, if so, why?

● (1140)

Mr. Jim Keon: With regard to the generic pharmaceutical industry, Quebec is an attractive market. We have major plants in Montreal, specifically Pharmascience, which is the largest pharmaceutical manufacturer in Quebec. Our industry continues to invest in that province.

The problem you referred to applies more to brand-name pharmaceutical companies who have seen patents on a number of their products expire. At present, it is extremely difficult to encourage the sector by giving patent extensions, particularly because not enough products are in the pipeline.

I believe that the solution is to establish a fair intellectual property system. We will make some suggestions to improve the situation. A fair system for brand-name companies and manufacturers of generic products would be the best option and would help to increase investments.

Ms. Hélène LeBlanc: Thank you, Mr. Keon.

Mr. Dixon, I would like to have your opinion on that issue, as an outside observer of sorts.

Is Canada a suitable place for research and development activities, particularly in terms of pharmaceuticals?

[*English*]

Mr. George Dixon: My apologies, but I'll respond in English, if that's appropriate.

Ms. Hélène LeBlanc: That's quite all right.

Mr. George Dixon: I'm not all that well versed in the pharmaceutical industry. Most of the experience that I have is with IT and medical devices. Frankly, if you have an environment where you have ready capital, you can probably do the commercialization of this type of activity anywhere.

There was talk about the pipeline and what's in the pipeline. It's where the disclosures come from and how many there are.

[*Translation*]

Ms. Hélène LeBlanc: Thank you, Mr. Dixon.

Ms. Garland, I would ask you the same question.

[*English*]

Ms. Gail Garland: Our view in the human health technology and bioscience industry is that the role of intellectual property is to protect inventions and encourage inventors so that we can commercialize technology here and allow companies to stay here and grow here. Then we as Canadians can reap the economic benefit.

[*Translation*]

Ms. Hélène LeBlanc: Thank you, Ms. Garland.

What is your opinion, Mr. Siebrasse?

[*English*]

What is your point of view on that?

Prof. Norman Siebrasse: This is a little bit outside my area of expertise, which is focused on the purely legal issues.

Ms. Hélène LeBlanc: That's quite all right.

Mrs. Garland, I wanted to come back to you because you talked about double patenting. Could you elaborate on that? You were mentioning that we don't have that in Canada. What does it consist of and why do we not have it in Canada? How does it facilitate your business?

Ms. Gail Garland: I should inform you that I'm not a lawyer, so my reference to it was simply to make a point. I'm not qualified to comment on double patenting.

[*Translation*]

Ms. Hélène LeBlanc: Right. That is not a problem.

I want to go back to Mr. Keon and Mr. Gray now.

As we know, there are many differences between public policies that would like to see pharmaceutical research companies and brand-name manufacturers on the one hand, and those that would like to see companies that develop generic drugs, on the other.

Is common ground or a consensus with regard to intellectual property between the two providers of pharmaceutical products possible?

[*English*]

Mr. C. Benjamin Gray (Vice-President, Legal and General Counsel, Mylan Pharmaceuticals ULC, Canadian Generic Pharmaceutical Association): My apologies as well; I will answer the question in English.

I would hazard a guess that there would be agreement that improvement could be made to our system to provide greater business certainty. As it stands, the PMNOC regime, which is unique to our industry sector, has some faults. Its largest fault is a lack of certainty. You can proceed through the PMNOC regime hearing, get a result, and be subject to a subsequent patent infringement hearing. That uncertainty is a very difficult matter to deal with for businesses trying to figure out whether they're going to invest a dollar in Canada or not. That's probably an area where our brand colleagues could agree that some corrective measures could be taken.

● (1145)

[*Translation*]

Ms. Hélène LeBlanc: Fine.

[*English*]

The Chair: Would you just confirm that acronym, PMNOC?

Mr. C. Benjamin Gray: It's the patented medicines notice of compliance regulations. Forgive me for—

The Chair: Thank you for that. It's just for the record.

We live in a land of acronyms. Don't worry, we're flooded with them.

Mr. Lake, go ahead for seven minutes.

Hon. Mike Lake (Edmonton—Mill Woods—Beaumont, CPC): Thank you to all the witnesses for coming today. My head is already swimming.

I'm going to start with Mr. Dixon. The first observation that you made was that work suitable for protection should be disclosed within the university system, or something to that effect.

How would you explain that to a student just coming into the university? You're giving him an overview of what IP is and how it works within the university. How would you explain that to someone who didn't really understand it, but was going to be affected by it there?

Mr. George Dixon: The first comment I'll make has to do with whether or not it's disclosed within the university. That would imply that it would be the university that would be active in protecting it and commercializing it. That's not really what I mean. I just want to make sure that it's disclosed to someone, so that they can effectively move on it. It could be done within the university. If the student takes it to a lawyer, protects it himself, and commercializes it, that's perfectly fine by my view of the world as well, as long as we get it out.

How we start with an undergraduate student is that we effectively have a module on IP that explains what it is and what the opportunities are if you have something you think you're going to protect. At the undergraduate level, we often refer them to someone they can talk to in confidence about whether it is an idea to move forward with. At the undergraduate level, there is a lot of nurturing on what IP is. It's an educational process.

As you move further and further along the chain and into graduate students and post doctorates, etc., they are usually aware of it sufficiently that they know they have something and would make an appropriate disclosure. They just don't know how to go about doing it. It's more that I lead them in the right direction.

I don't want to take up too much of your time, so I'll stop there.

Hon. Mike Lake: No, I want you to take up time. This is good because what you have to say makes sense.

Less than a month ago I had a chance to visit the University of Waterloo and have this conversation. How does the University of Waterloo treat IP differently than other universities in Canada?

Mr. George Dixon: At the University of Waterloo, IP is inventor owned. The intellectual property belongs to the inventor, whether it be a graduate student, an undergraduate student, or a faculty member. There is often co-ownership, where there'll be two or three people involved. Individuals are free to take that IP to a patent lawyer, protect it, and commercialize it in their own right without involvement of the university.

There is also a second pathway within the university where they can work with the university. We will protect it and effectively assist in commercialization. Under those circumstances, the individual retains 75% of the revenues and the university takes 25%.

In truth, I actually don't think it matters who owns it. It's a matter of who controls it, and that they actually do something with it, as opposed to sitting on it.

Hon. Mike Lake: We had some witnesses here the other day who talked about Canada potentially using a system where universities treat IP the same across the board, that there needs to be a common approach to IP.

Why is it that different universities might make different decisions on IP? Do you think it would make sense for Canada to adopt a one-size-fits-all approach as it relates to IP?

Mr. George Dixon: I'm not particularly in favour of a one-size-fits-all approach, because if that happened, I suspect the approach that's used at the University of Waterloo, which is inventor owned, would not be the one that was picked.

Each university develops in a different climate. Waterloo was founded in 1957 by Gerry Hagey and Ira Needles, who were senior executives at B. F. Goodrich. The university was put together with a very specific mandate to train engineers, and grew into a comprehensive university from there. I suspect that those policies of IP ownership by the individual came out of the philosophy of the original individuals who were on the board of governors of the university.

It's a method that's not tightly controlled. There's one thing I'm very worried about. I'm an ecologist, and if you look at how things work, I'm very much into diversity and, if you have a diversity of approaches, it tends to work better.

● (1150)

Hon. Mike Lake: Just to stay along the same line here, if there were a George Dixon university—and I'm sure there will be one day—what would you change?

Mr. George Dixon: If somebody names a university after me, then I'll really know I'm a has-been.

Voices: Oh, oh!

Mr. George Dixon: I would stick with the policy of inventor owned, because it's not just about the IP, it's who you attract to the university. We think the individuals we attract to the University of Waterloo, both the undergraduates and our faculty members, go there because they have an entrepreneurial bent by nature. The fact that they can own their own IP is a huge drawing power to attract the very best coming forward.

Hon. Mike Lake: All right.

Mr. George Dixon: It's about who you can attract. It's much easier to build a culture of innovation if you have the right people up front.

Hon. Mike Lake: For my last question I'm going to go to your third observation, the one about risk tolerance in the private sector. What would you change? What would you do to address that issue? You said you would be willing to elaborate on some things. This one is definitely of interest to the committee, so I would like you to elaborate on it, if you could.

Mr. George Dixon: The largest single organization that purchases goods and services in Canada is probably the federal government. Looking at some of these new technologies and the adaptation of new technologies in the purchases by government would be an area where you could probably make a significant impact.

I remember reading a study, and I apologize because I can't remember where it came from. It looked at the acceptance of technology in the private sector in the United States versus Canada. This was mostly information technology that would be useful business tools to move the agenda forward. The climate for acceptance was much greater in the United States.

How do you encourage industry to accept new technologies and risks? I don't know enough about government and the tax structure in order to figure out how to do that, but that would be something I would probably incent.

I will give you one very brief example. There was a company that was formed at the University of Waterloo that treated groundwater. I won't get into how they did it. It was innovative technology. That technology was in place in 80 sites outside Canada before it was in place anywhere in Canada.

The Chair: Thank you very much. You finished right at seven minutes. It's unbelievable.

Mr. Regan for seven minutes.

Mr. Mike Wallace: That will be unbelievable.

Some hon. members: Oh, oh!

Hon. Geoff Regan (Halifax West, Lib.): Mr. Siebrasse didn't hear that. Mike Wallace said, “That will be unbelievable.” I only will get seven minutes, I'm sure.

I first wanted to mention in regard to your comment about George Dixon university that I wish you the best of luck. I will look forward to that. The other possibility is what we had at Dalhousie University, George Munro day, a holiday. Mind you, he gave the equivalent of $8 million a long time ago to Dalhousie University. I don't know if you're going to manage that with your university or with the University of Waterloo. I will watch with interest to see.

Let me ask you, Mr. Dixon, whether you feel the patent system should be the same for all industries. Should it be the same, for instance, for pharmaceuticals as it is for information technology, or should we have different regimes?

Mr. George Dixon: You're getting into an area on which I'm not really the one to opine. I am not a patent lawyer. I'm an environmental toxicologist. I study the toxic impacts of chemicals. What I do is manage this initiative. For the actual nuts and bolts of different patenting policies I'm not the person to comment.

Hon. Geoff Regan: Okay. What I'm getting at is whether there should be different regimes for different kinds of activities.

I'll turn to Professor Siebrasse. It's nice to see you again, sir. What is your thought on that?

Prof. Norman Siebrasse: As I said in my remarks, it is very clear that industries experience the patent system differently. It has different importance in different industries. In that respect, yes, it would be a good idea in principle to tailor the patent regime and many aspects, potentially from patent term to breadth of patent and so on, to different industries.

The tough question is whether we can do that in any kind of coherent and sensible fashion. At this point, my suspicions are that yes, potentially with patent term, which is a fairly discrete kind of variable. In terms of tailoring other aspects, such as patent breadth, that's something that's talked about a lot academically, and I think it would be very difficult to do. It's a good idea in principle, but it would be difficult to carry out.

● (1155)

Hon. Geoff Regan: You talked about the patenting of business methods and the litigation going on in that regard. What, in your view, ought to be the legal framework for that? Are there best practices in other countries you would point to?

Prof. Norman Siebrasse: Let me start with the second part of your question regarding whether there are best practices in other countries. Unfortunately, I would say the answer is no.

The U.S. recently had very high-profile litigation over the same issue. Their law is just as confused as ours is. We have a recent Federal Court of Appeal decision that complains about how confused the law is. The U.S. is very much in the same boat we are, except they're having more actual litigation. Europe has specific exclusions for certain things, for business methods in particular, but the way their legislation is drafted, it has proven to be unclear what they actually mean by it. It's something we can look to, but I wouldn't call it a best practice.

In terms of what should the framework be, are you asking me whether or not in my view business methods should be patentable?

Hon. Geoff Regan: Yes.

Prof. Norman Siebrasse: Well, that's a question that I hate to answer because the answer is that I don't know. If you really pressed me, I think I would say probably not. My feeling is they're probably not good for innovation, but it really is a feeling and this is a question that, if you gave me more time to answer, I'd go out and consult stakeholders, the financial industry, banks. The financial industry would be heavily affected by business method patents, and that's why, mind you, it's a job for the legislature.

Hon. Geoff Regan: So, would you require us to hire you and pay you to do that, or are you prepared to do that on your own?

Voices: Oh, oh!

Hon. Geoff Regan: I'll leave that as a rhetorical question.

Do you have any views on how you might change the law regarding pharmaceutical patents?

Prof. Norman Siebrasse: Regarding pharmaceutical patents, there are many aspects of the law that could be changed. We've heard a fair bit already about the details of the notice of compliance system, that is, the patent linkage system. I think patent term extension is a good idea. I acknowledge there is uncertainty in this, but I would be in favour of it.

The linkage system, the notice of compliance system, probably is due for review. We could look at it and pick out things that don't make sense, but it is necessary to look at the system as a whole. There are a bunch of compromises in that system. It's not a matter of saying that the innovator companies are very upset about not having a right of appeal. It seems unfair, but they do get other advantages. Without getting into details, I would say we could make some improvements by an overall review of the system.

I mentioned some of these details of doctrine that I'm hoping the courts will straighten out. They might be addressed. I would echo Ms. Garland's comments that there are a number of technical doctrines, such as the double patenting doctrine, loss of patent rights, and failure to pay fees on time, that could be addressed relatively easily, and I hope in an uncontroversial way.

Hon. Geoff Regan: Being the only witness we have who's not from Ontario, or central Canada at least, you may have a strong knowledge of the research resulting in patents or patent-type activity in Atlantic Canada. One of the things we've heard from some people has to do with the lack of patent officers outside major centres. What are your thoughts on that, and what would you do about it?

Prof. Norman Siebrasse: I have to admit that I don't have a lot of familiarity with the Internet. I'm as central Canada focused as anyone. Part of the issue about not having patent officers outside of central Canada is that it's a very specialized practice.

Are there enough in New Brunswick? I know we have one patent agent here. Is there enough to have more activity? Would it really help innovation in this region? I'm not sure about that. I wouldn't say no, but I'm not sure.

● (1200)

The Chair: That's it, Mr. Regan. That concludes round one.

Now on to Mr. Wallace.

Mr. Mike Wallace (Burlington, CPC): I want to thank our guests for joining us today.

I'm going to start with you, Ms. Garland. Your final statement was that you wanted a patent system that's predictable, stable, and flexible. Isn't that a bit of a contradictory statement? If you want flexibility, the difficulty is having predictability and stability. Can you explain exactly what you mean?

Ms. Gail Garland: My view would be that a flexible intellectual property system in Canada is important to protect inventions and encourage inventors. Predictability is important because investors, multinationals, people looking to commercialize technologies here, need to know they will have market exclusivity for a period of time, and not waste important commercial time defending a patent and having their patent vulnerable and their market opportunity reduced. Consistency is important in the spirit of harmonization and our ability to be globally competitive.

Mr. Mike Wallace: In another statement you made—and I'm not picking on you; it's so I understand—you talked about Canada being a go-to nation potentially, but you also talked about a globalized patent system.

Maybe I'm misunderstanding. When somebody tells me they want a globalized whatever, it means that everybody around the world is playing by the same rules and regulations. Can a nation use the patent system as a means of attraction—let me just put it that way—or to drive innovation if everyone is following the same rules?

Is there a contradiction there, or am I missing the point? Are you saying that Canada should have a bare minimum that is a globalized piece and then do more? I'm not sure exactly what you're saying.

Ms. Gail Garland: There's a point in time element to the argument that's to be made. The IP regimes around the world are moving towards more harmonization. All patents are global from the perspective of a company looking to global markets to commercialize their technology.

Our opportunities to be a go-to nation are in some ways windows of opportunity to seek areas where we might have a competitive advantage. Frankly, as we move more and more to harmonization, some of those windows of opportunity close.

Mr. Mike Wallace: They close. Okay.

I'm going to ask Professor Dixon a question.

I could be wrong, but here's my thinking. We've had discussions before about commercialization in other committees, in this committee, and so on and so forth. I find that at universities in Canada, including the one my daughter attends—she's in the bachelor of commerce program at the University of Ottawa—we're not developing risk-takers. We're developing managers—

A voice: Yes.

Mr. Mike Wallace: —which is fine and good, but is that an issue the University of Waterloo is looking at?

Let's be honest. The University of Waterloo has a great reputation for its capacity to develop new products. On the science side and in engineering, it has a great reputation, but are we developing people who will just license it? Somebody else will actually bring it to market, commercialize it, and take the risk of using it in 80 other countries, but in terms of business management, no one here wants to take risks. They wait to see if somebody else does it.

Is that part of the responsibility of the educational system, including at the university level, in terms of developing better entrepreneurs and risk-takers?

● (1205)

Mr. George Dixon: Yes. That's what I speak to when I talk about a culture of innovation. You develop people with a solid undergraduate and graduate education in an area, but there is an opportunity for them to understand there are entrepreneurial opportunities out there.

When a company when is formed, it's very rare that an engineer will form that company in their own right. The engineer will be partnered up with someone from the commerce stream, and someone from sociology who knows a lot about market psychology. You put those together and do it. That is there. We actually have a graduate program that does that.

The Chair: Mr. Dixon—

Mr. George Dixon: It's the master of business, entrepreneurship and technology program.

The Chair: Mr. Dixon, I'm sorry. It's time again.

Mr. George Dixon: My apologies, I was ignoring you, sir.

Voices: Oh, oh!

Mr. Mike Wallace: I was ignoring him too—

The Chair: I'm glad you get a good night's sleep.

Voices: Oh, oh!

The Chair: I hope that doesn't trouble your conscience tonight.

Mr. Harris, for five minutes.

Mr. Dan Harris (Scarborough Southwest, NDP): I imagine that Mr. Dixon has a fair bit of experience in ignoring unruly students. That's not to say the chair is one, but that's a skill that would be useful in the House of Commons.

I'm going to start with Ms. Garland.

Earlier you were speaking about the Canada-Europe trade agreement and how it would be a benefit, that Canada would become the first country with preferred status both in the United States and in Europe.

There is certainly debate as to whether that favoured status with the United States has really helped Canada. As a total share of imports to the United States, Canada's percentage share of U.S. imports has actually dropped in that period of time. In terms of the actual contribution to our GDP, it has remained about stable.

Why do you think it would be helpful in that respect?

Ms. Gail Garland: The perspective I bring to this argument is that Canada must match global standards for intellectual property protection if technology is to be invented here, patented here, and commercialized here. My consideration is for the net benefit to our economy of having companies, whether they're indigenous or multinationals, commercialize their technologies here and give us, as Canadians, access to the latest technologies that are available around the world.

Mr. Dan Harris: In their prepared statement the generic industry mentioned that many of the investments by brand name drug companies are today directed to countries like Brazil, Russia, India, and China, which are not known for having strong intellectual property regimes. Why do you think we need that when currently development is going to countries that don't have it?

That was for Ms. Garland again.

Ms. Gail Garland: I'm sorry, I thought it was for him.

Mr. Dan Harris: I'll be asking them to follow up.

Ms. Gail Garland: In that case, could I ask you to rephrase the question for me?

Mr. Dan Harris: You're saying that we need strong intellectual property in order get that investment happening here, but currently the investment is going to countries that don't have strong protection in IP, such as Brazil, Russia, India, and China.

How do you square that circle?

Ms. Gail Garland: I would ask for clarification about what kind of investment you're referring to.

Mr. Dan Harris: The brand name pharmaceuticals are putting investments into those countries to develop their drugs.

Ms. Gail Garland: I'm not here on behalf of the multinational pharmaceutical industry, but Canada is a small market.

We want to have access to the latest technologies. If our patent regime delivers the right qualities of being predictable, stable, flexible, and consistent, then companies will be able to commercialize their technologies here and have a market here. They'll want to file their patents here so that they have access to the market.

There are many markets in the world that will always have tremendous attractiveness because they're just larger markets.

● (1210)

Mr. Dan Harris: I don't think I'll be able to ask the follow-up question, unfortunately, with only one minute.

I did want to ask a question to Mr. Keon and Mr. Gray, perhaps.

You might have a different approach on the Canada-Europe trade agreement. What impact do you think it's going to have on your industries if it goes through as envisioned?

Mr. Jim Keon: The first thing I would say is that we are a trading industry. We absolutely depend on trade. We want free trade. We support free trade.

Some of the proposals on the table on pharmaceutical IP are going to restrict trade and restrict our access to foreign markets that are absolutely critical for our companies to continue to invest here.

We are concerned about some of the pharmaceutical IP provisions. We support a Canada-European trade agreement strongly, but we would like to see those provisions amended or taken out.

Mr. Dan Harris: Thank you.

The Chair: Thank you very much.

Now on to Mr. McColeman, for five minutes.

Mr. Phil McColeman (Brant, CPC): Thank you to the witnesses for being here.

I'd like to direct my first question to Ms. Garland and Mr. Siebrasse to expand a bit further. Both of you have mentioned being in favour of patent term extensions. Can you fill in a little of the background as to how you see that as beneficial to a patent regime?

I'll start with you, Ms. Garland.

Ms. Gail Garland: Sure. My lens is always what is going to create the greatest commercial opportunity for companies that are inventing, developing, and patenting their technologies here. An indigenous company developing a therapeutic here needs to have the longest period of market exclusivity they can possibly have in order to recoup their costs.

The justification for requests for patent term extension lies in their ability to reap the commercial rewards of that period of market exclusivity. Time that's spent in the regulatory process eats away at that period of market exclusivity and puts companies at a competitive disadvantage if they're looking to market in Canada, if they're trying to partner or license a technology. A potential partner is looking at the market potential of that technology and calculating how many years of market exclusivity they'll have in Canada for that technology. If that technology spends a lot of time in the regulatory process, then the number of years available to recoup those costs is reduced. With market term extension, that time is recaptured.

Mr. Phil McColeman: Professor Siebrasse.

Prof. Norman Siebrasse: Yes. The argument in favour of patent term extension is fairly straightforward. The patent term runs from the time the patent application is filed. There's a certain amount of time, about three years maybe, until the patent is actually granted. In many industries, by that time the product can be commercialized and on the market, and you end up with 17 years of effective patent term.

In the pharmaceutical industry, the patenting always happens far before the clinical trials and before marketing approval, which can take many years. Therefore, the effective patent term in the pharmaceutical industry is much less than the 17 years. I don't have stats at hand, but it's eight years or sometimes five years, depending on the particular patent.

The argument is to compensate for this regulatory delay, the pharmaceutical industry needs term extension to give it the same effective patent life as every industry has. That's the basic argument in favour. The basic argument against it, what I call the principled argument against it, is how much time is really needed. The fact is that the term of 20 years from filing, and the 17 years from grant before that, all goes back to England and the time it took to train two apprentices.

We don't know that 17 years is optimal. Maybe five years is optimal. I don't think one year is optimal. Maybe 30 years is optimal, for all we know. It's a very difficult empirical question. We don't have good answers. We can say that one patent gets a less effective term than another, but nobody needs seventeen years, and five years is good enough. That's the principled objection.

The pragmatic objection to patent term extension is to say that we're going to get the benefits anyway. The U.S. and Europe are the big markets. The innovation is going to happen to serve those markets, and if they give patent term extensions, they'll get more innovation, and we'll get the benefits. The counter-argument to that is that we're free-riding, and that's likely to set off a trade war.

The very principled objection is if everybody thinks the same way, everybody says they shouldn't have patents and that everybody else should, then nobody will have patents and we'll be worse off. Apart from that, we might get into a trade war if other countries simply think we're free-riding.

More fundamentally from my perspective, I don't think we should free-ride. I have to say as a moral proposition that free riding on the investment of others for pharmaceuticals is a perfectly defensible position for a third world country, but we're not a third world country, and I don't see any reason that we shouldn't bear our fair share of the costs.

My view on this is that the best way to look at the issues is to ask —

● (1215)

The Chair: Thank you very much, but that's all the time we have for that round.

Now on to Mr. Stewart, for five minutes.

Mr. Kennedy Stewart (Burnaby—Douglas, NDP): Thanks to all the witnesses for coming today.

I have two questions on which I want to get comments from all of you.

One of the reasons we hear that we need patent term extensions, from a government perspective, is that we'll get more research and development out of the companies, more investments, essentially, in that area.

We had extended patents in the past. In the Mulroney government, we had quite an extension of patents, but our business enterprise investment, BERD, has been dropping. It's been pointed out in numerous reports that one of the biggest problems we have in innovation in Canada is the lack of investment by private companies in the R and D field. It does seem to be asking for more patents. Longer patent life may not accomplish the promise of increased research and development funding from the business sector.

I'm wondering if you can comment on that. Am I totally off base, or do you have something you can suggest?

Mr. Jim Keon: I can start.

Before I do, there has been a slight implication that Canada is free-riding in the pharmaceutical sector. Nothing could be further from the truth.

We have a very strong patent regime, a very strong data exclusivity regime. We provide eight years of data protection in Canada, far more than they do in the United States. We don't incent generics to come to market and challenge patents the way they do in the United States. In the United States if you're the first generic to challenge a patent, you get six months of exclusivity. They build it into their law that generics should challenge patents and make sure that only valid patents protect competition and keep prices high.

The last point I'd make is that patents are geographic neutral, but because of the nature of national treatment you will get the same protection in Canada whether you do the research in Mumbai, Munich, New York, or New Jersey. It doesn't incent you to come to Montreal, Toronto, or Vancouver to do the research. In Canada we've seen a decline in research and development. There are things Canada could do to attract more research and development. Simply increasing patent protection is going to increase profits of companies that are doing research out of Canada. That is going to be the primary impact.

Mr. Kennedy Stewart: Are there any other comments?

Mr. Gray.

Mr. C. Benjamin Gray: If you added on patent term extensions to the whole system today for the pharmaceutical industry, you would do real damage to our industry and the 12,000 jobs that we have across the country. You would damage the manufacturing sector, in particular, within our industry if you extended patents.

Mr. Kennedy Stewart: Professor Siebrasse.

Prof. Norman Siebrasse: We're talking about patent term extension in the pharmaceutical context here so I'm not sure if your remarks before about extension not leading to R and D.... That wouldn't surprise me at all in most other industries where patents don't play as big a role. That could be part of the answer. If patent term extension isn't a good idea across the board, it's really pharmaceuticals where the issue is.

To clarify on the free-riding issue, I agree in many respects that we have a very strong system. I take the point that we have to look at it as a whole. I would be worried that the patent term extension debate shouldn't turn on the idea that we'll get the benefits anyway. If we have a principled objection that says that we don't have patent term extension but we have all these other protections that are just as good as a package and we're doing our bit, that's a fair point. I'm not sure it's correct, but it's a reasonable argument.

● (1220)

Mr. Kennedy Stewart: Okay, thank you.

I have a second question.

Ms. Garland suggested that we move more towards the U.S. patent model. However, we've been hearing through testimony a bit of contradictory evidence. One of your colleagues, Mr. Scott Inwood from Waterloo, mentioned that there's quite a few murmurings in the U.S. about whether the Bayh-Dole act has outlived its purpose and about perhaps looking at moving towards more of a Canadian system.

Sylvain Laporte, the CEO of the Canadian Intellectual Property Office, said here that Canada has a number of aspects in our current patent system that they're aspiring to.

They're perhaps moving the changes in the American investment act more to a Canadian model of investing. It seems to be a bizarre situation if we're moving closer to the U.S. model and they're moving closer to ours, and we just switch positions.

Maybe you could help me understand that a bit more.

The Chair: You're actually over time.

Perhaps somebody has something they can say very quickly for me to be fair. Does somebody have a quick comment?

Mr. George Dixon: I have no comment.

The Chair: All right.

Thank you very much.

I'm sorry, Mr. Stewart, but we are well over time.

We'll move to Madam Gallant for five minutes.

Mrs. Cheryl Gallant (Renfrew—Nipissing—Pembroke, CPC): Thank you, Mr. Chairman.

Mr. Keon, in your remarks you alluded to the fact that brand name pharmaceuticals are taking on a larger share of ownership of the generic companies. To what extent are these companies controlling the generic companies as well?

Mr. Jim Keon: I'm not sure I made that specific point, but there is some overlap. One of our member companies, Sandoz, is part of the Novartis family, which is a brand name pharmaceutical company. Some of our companies have arms that also do research into new products, so there is some overlap between the two sectors. When the system is operating properly, brand name companies produce new, innovative medicines that improve therapies. When patents expire, generics come on the market at much lower prices. In Ontario and Quebec, for example, generic prices are capped at 25% of the brand name price. We provide head room for the health care system. We can fill four prescriptions for the price of one when a generic is available on the market. We each have a role to play. What we need are fair, equitable patent laws that allow that.

Mrs. Cheryl Gallant: The trend with drug benefit companies is to insure at the cost of the generic. What constituents often say is that when they go to have their prescription filled, the generic is not there and they have to buy the brand name pharmaceutical.

My question is whether these brand name pharmaceuticals are taking greater ownership in the generics, then holding back production of the generics so that the brand name pharmaceuticals will have to be bought by the patients.

Mr. Jim Keon: When patents expire and generics come on the market, I think you would find that in virtually all pharmacies in Canada, the generic would be available to the patient.

I will use an example in the area of cholesterol. A drug called Lipitor came off patent and instead of generic prescriptions for Lipitor increasing as you might expect as the prices came down, the promotion to the medical community was for a different drug, Crestor, and sales of Crestor went up. Patients were often prescribed Crestor, when in the past they might have been prescribed Lipitor. Crestor was still being sold at a very high brand price, and the generic Lipitor was available at a low price. The problem was that Lipitor was not being used properly. Some insurance plans will require that as well. It's called "therapeutic substitution", to ensure that the best-priced product is available. When the actual product, such as Lipitor, goes generic, I think you will find that pharmacies have it. The problem may be that it's not being prescribed.

● (1225)

Mrs. Cheryl Gallant: How do our prices for generic pharmaceuticals compare to those of other countries?

Mr. Jim Keon: The prices in Canada have come down dramatically over the last five years. We are a regulated market at the provincial level.

I'll use Ontario as an example since it's the largest. It used to regulate generics effectively at 63% of the brand name price. That was until 2008. In Ontario now, if you want to be listed on their formulary, you can price your product effectively at 25% or you won't get on.

At the new lower levels, our prices are essentially comparable to prices abroad. In the past when the prices were higher—and this has been shown in studies done by the Competition Bureau and others—much of that money was going to the pharmacy community to support pharmacy services and was being competed away to provide that. We have a very strong pharmacy sector in Canada. Provincial governments have decided to lower generic prices, and in return they are looking at alternate ways of funding the pharmacy community.

Mrs. Cheryl Gallant: With respect to personalized medicine, which was broached here, where the selection of a particular therapeutic or its dosage is individually tailored for scientific patient populations based on shared genetic characteristics, does your organization see the patentability thereof as another means of evergreening?

The Chair: A very brief response, please.

Mr. Jim Keon: If the medication is new, novel, useful, an improvement, we would support the patenting of it.

The Chair: Thank you very much, Mr. Keon.

Mr. Keon, did you say that with Crestor and Lipitor, there's no substantive therapeutic difference between the two?

Mr. Jim Keon: I think they're both in the same therapeutic class. What we found was the sales of Lipitor decreased dramatically and the sales of Crestor increased dramatically after Lipitor went off patent, indicating that there was something happening in the marketplace beyond an improvement in the therapeutic applicability of either product.

The Chair: I got that, but you know the point I'm trying to make here.

Mr. Jim Keon: They're not exact replicas, but they are both in the same therapeutic class.

The Chair: Are they substantially the same?

Mr. Jim Keon: They're substantially the same. They treat the same illnesses, yes.

The Chair: Thank you very much.

Mr. Jim Keon: They're both statin products.

The Chair: Now on to Mr. Harris for five minutes.

Mr. Dan Harris: I want to touch on another statement that you made, Ms. Garland, but I don't want you to think that I disagree with everything you said. I don't want to come off as not being very nice.

You spoke about the necessity for an online searchable database for patents. Maybe you could elaborate on why you think that would be useful. Then I'll ask Mr. Dixon if that would be helpful to students at Waterloo, and then ask Mr. Siebrasse if that would help with respect to litigation.

Ms. Gail Garland: An online searchable database, in my view, is just a quick win to help companies that are going through the patent filing process, so that they can keep track of how their application is proceeding through the system and what the deadlines are and so on. It's just an opportunity for us to join the 21st century in terms of access to information over the Internet.

Mr. Dan Harris: I apologize about the whole Western and Waterloo thing.

Mr. George Dixon: That's fine.

I'm not too sure I understand the question.

Mr. Dan Harris: If we were to have an online searchable database of patents and applications, would it help students at Waterloo who are at the very start of their careers and not familiar with the system? Do you think that approach would help them?

● (1230)

Mr. George Dixon: Anything that increases the availability of data and allows people to get it in real time and use it is going to be helpful.

Mr. Dan Harris: I think I could use that quote in a lot of areas to do with government.

Mr. Siebrasse?

Prof. Norman Siebrasse: Yes. I would just repeat that anything that increases the availability of information and increases the ease of searching is good. I'm not sure exactly what the nature of the database we're talking about is, but it's certainly very important to be able to find information on issued patents in particular, but also patents in the process, so that the public can be aware of this information, for example, what's being patented, what they have to watch out for. The more easily this is available the better. Searchability isn't just about Internet access, but about how it's classified. How easy it is to find patents that will affect your business is very important.

Mr. Dan Harris: Great.

How much time do I have?

The Chair: You have about two minutes.

Mr. Dan Harris: Oh, I have lots of time.

Ms. Garland, you also spoke about “terminal disclaimer”. I'd like to hear more on that, about being able to bring a patent out before all the work is done and how this could improve our IP regime.

Ms. Gail Garland: The point about a terminal disclaimer is that this is possible in the U.S. and not possible in Canada.

One of the Canadian inventors who belongs to my organization files his patents in the U.S. because he can make use of this terminal disclaimer opportunity. It allows him to continue to add embodiments to the patent.

It doesn't extend the term. It's an effective way of continuing to do the work on your patent as part of your filing and to advance the embodiments that are included in it as part of a single filing, whereas in Canada you have to have all of those embodiments thought through and completely documented as part of your application. That's just a more onerous process. It's easier to use the terminal disclaimer in the U.S..

Mr. Dan Harris: I understand that. I'm asking because we have heard already from many witnesses at the committee that in many cases the United States, or in other cases Europe, is the point of primary filing because that's where the markets are.

We've mentioned that Canada is a very small part of the market, so I'm not sure how much adding this in Canada would result in more primary rather than secondary filings. Often what businesses are doing is filing in the U.S., where the large share of the market is going to be. They can make use of that provision, and then they make their secondary filing in Canada when the product is further along the development line.

I'm just not sure how one would actually help the other.

Ms. Gail Garland: If I could answer—

Mr. Dan Harris: Unfortunately you can't, but it's not my fault.

The Chair: I'll take the blame totally. We're well over time again.

We will go on to Mr. Braid for five minutes.

Mr. Peter Braid: Professor Siebrasse, at the very end of your opening remarks you talked about patent trolls. I want to pursue that. You indicated, if I recollect correctly, that patent trolls are an issue in the U.S. that hasn't really affected Canada yet, and you hope that this continues to be the case.

Could you explain what patent trolls are? Also, what can we do or not do to ensure that it remains a non-issue in our jurisdiction?

Prof. Norman Siebrasse: I was hoping somebody would follow up on that.

It's rather difficult to define patent trolls. The broad definition of a troll is that it's a non-practising entity, that is, somebody who doesn't actually commercialize and implement the invention, but who instead has licensed it for excessive fees.

The reason it's difficult to define a troll is that trolling is an exaggerated form of behaviour that's common to many legitimate patentees, if I might put it that way.

What can we not do? I was reading the Canadian International Council report and listening to the testimony of Ms. Mazurkewich on Tuesday, and I must say that their chapter 4 sounds to me as if they want to set up a government-funded patent troll, which seems to be quite a bad idea. They say their fund wants, rather than to exclude terms, to see broader access, with large companies paying market rates—big fund managers—with a sliding scale.

Trolls don't want to exclude any firms. Real inventors, real innovators, do exclude other firms, because they're actually commercializing their innovation themselves. If trolls exclude somebody, that somebody is not paying them rent.

Sure they charge a sliding scale, because they charge what the market will bear. They say the fund could salvage IT when tech firms go bankrupt and provide equity to cash-strapped entrepreneurs who have licensing rights to trade. That's where trolls get their patents. They get them from bankrupt firms and then assert them against other practising entities. I don't want to take up the entire answer by going into these details.

Maybe there is something I am missing here, but from everything I read in the report and everything I heard on Tuesday, it sounds to me as though she is proposing setting up a government-funded patent troll. Are you going to troll Canadian companies? That's a bad idea. Are you going to troll U.S. companies? That sounds to me like a bad idea.

That's what we shouldn't do. What should we do to address trolls?

In the short term, much of the patent trolling comes from somebody out to shut down a company.

I'll try to give a quick explanation. Let's say you're going to retire and you are going to sell your tiny condo in Vancouver and take the $3 million you get for it and buy a beautiful dream property in a remote area. You find a property that looks great, but you need to access it across somebody else's property. You would negotiate the access right then to go through the back entrance of their lot with a $10,000 licence. Now instead of negotiating the licence, let's say you build your million-dollar dream home and then you go to the neighbour and say that you need access across his property. Well, you are not going to get it for $10,000. It may be $100,000. What are you going to pay? Your house is there.

That's what trolls do. They don't license at the outset. They license once the business is set up and then they pop out of the woodwork. The patentee has a hard time finding them, because they're not out there practising.

That's what happened to RIM. Somebody popped up. Sure, the idea was good, and there's no suggestion that RIM actually took the idea from NTP or the patentee that NTP acquired it from. This is an aspect of the patent system. Independent creation is not a defence. RIM comes up with this idea. They take the idea, which is valuable in itself, and they put a fortune into commercializing it. They grow a big company, and then somebody says that they need access.

There are reasons why sometimes this happens: you tried to commercialize and weren't able to, or maybe somebody stole your idea. The aspects of the patent system that allow you to do this aren't bad. They're good in the right context, but they can be abused, so patents are dangerous in this respect.

The most straightforward response that we've seen in the U.S., which I think is appropriate in Canada, is to say to the troll that it cannot get an injunction, that it cannot stop the person from running their business. RIM had $25 million in damages awarded against it. That's the value of the patent. They had settled for $623 million. That's the value of their business. To say that you can't shut down a business and that all you get is your $23 million in damages is a step in the right direction.

I think I am over time, so I'll stop there.

● (1235)

The Chair: There were about 20 seconds left.

Mr. Peter Braid: That was very good. Thank you.

The Chair: We have a couple of minutes left. We normally don't have this luxury. I can ask the witnesses to make any closing remarks they may have from everything that's been asked, or if there was a question they couldn't respond to and they were dying to say something, now would be the time.

I will start with you, Mr. Keon, for 90 seconds.

Mr. Jim Keon: I think we made most of our points in our opening remarks or in answering questions.

I would like to ask the committee to focus on the suggestions we have for looking at the patented medicine notice of compliance regulations. They are unique to pharmaceuticals. They block a generic from getting approval at Health Canada until it litigates patents. It encourages, almost demands, litigation. The biggest problem right now is that it doesn't settle the issue and there's ongoing litigation.

We have made proposals to Industry Canada. We would urge the committee to look at that. I think it is generating excessive litigation and business uncertainty. It could be improved and still provide good protection.

● (1240)

The Chair: Thank you, Mr. Keon.

Madam Garland.

Ms. Gail Garland: I'll first of all respond to Mr. Harrison's question, which I wasn't able to respond to before.

The sole purpose for filing a U.S. provisional as a first step for an inventor is simply to establish a priority date. It's the formal application that is actually driven by market size.

The second point I would like to make is that we need the IP regime in Canada to allow Canadians to get the benefit of technologies developed here and to give them a reason to stay here and grow here.

Further, without a predictable patent regime, investments won't happen and investors will not invest in our Canadian companies.

The Chair: Thank you, Madam Garland.

Mr. Dixon.

Mr. George Dixon: Thank you very kindly. I have no further comment other than to thank the committee for its time and attention.

The Chair: Mr. Dixon, thank you very much, and by the way, I forgive you.

Some hon. members: Oh, oh!

The Chair: Mr. Siebrasse.

Prof. Norman Siebrasse: I'll follow up on Mr. Keon's remarks on the linkage system, the patented medicine notice of compliance system. It's not a perfect system from either the generic or the brand perspective, but I will agree that it's a strong system. I must say I'm a bit annoyed that we're on the U.S. watch list on the patent side because of that. This has been such an issue with the Europeans. Arguably, this aspect of our patent system is stronger than the corresponding aspect in the U.S. or Europe.

It's difficult because the details matter. It's difficult to say, but it is important that we look at the NOC system, the patent system as a whole, and decide whether we have a strong system or a weak system. Can we improve it in the details? For sure, but at the trade negotiation level it's not really fair for anyone to be saying they don't like this or that and therefore the whole system is wrong. We have to look at the system as a whole.

The Chair: Thank you very much, Mr. Siebrasse.

On behalf of the committee, thank you all very much. Your testimony has been very illuminating.

Yes, Madam LeBlanc?

Ms. Hélène LeBlanc: Mr. Keon, you talked about recommendations made previously to the industry committee. Would it be possible for you to provide them to the committee?

Mr. Jim Keon: Yes, we would be pleased to do that. We'll follow up and send the recommendations.

Ms. Hélène LeBlanc: Thank you very much.

The Chair: Thank you, Madam LeBlanc.

We have a couple of minutes to clear out the room and then we'll be going in camera for committee business.

[*Proceedings continue in camera*]

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