

Interview: Alain Leclerc, Co-Managing Partner, Goudreau Gage Dubuc, Canada

01.09.2013

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The co-managing partner of one of Canada's leading IP law firms discusses the landscape for intellectual property in the pharmaceutical industry in Canada today, the legislative challenges facing his clients, and the incentive schemes in place to bring innovation to Canada.



What have you seen as the key trends of the IP regime in Canada over the years?

The first trend, in relation to the pharmaceutical industry, is the growing importance of patent protection for improvements on existing products. There is increasingly more of this, as opposed to brand new molecules, which are very expensive to develop. Patent protection on product improvements such as new formulations, new crystal forms, and generally better products but on the same backbone of molecules has filled the gap for many pharmaceutical companies. The second key trend, as a result of the economic challenges of the late 2000s, has been a move towards organizing, culling and getting more from existing patent portfolios. Companies have abandoned many patent applications with no commercial value to focus more financial resources on forward-looking IP strategies.

How has being in the position of co-managing partner helped you in organizing and directing GGD in terms of positioning the firm in Canada as you would like?

I think you have to be humble in whatever position you occupy, especially if you are in a leadership position. Positioning a firm in a marketplace is more important than ever. In a sense, it is more difficult to position GGD than a few years ago. Clients expect more value than ever. We are currently working on consolidating GGD's positioning as a Canadian leader in life sciences patents. Since our firm is mainly known by word of mouth, this is a long process. In my position as a partner of the firm I have had the opportunity to travel and participate in international meetings. I think that GGD and Canadians in general are having more of a voice now than they did in the past. After all, Canada is the eight largest pharmaceutical market in the world and we have strong patent professionals.

What are the best perks that Canada needs to offer to ensure that ideas stay in Canada?

Pharma R&D spending has decreased slightly in recent years, according to statistics provided by the Canadian government. This is worrisome. I suspect it may have something to do with the current tax incentives or IP regimes. International clients will shop around for the most attractive tax incentives

in conjunction with R&D spending. Also, recent legal decisions have struck down important patents and this may have given investors cold feet. I agree with comments from others in the industry that we need to have an IP regime that is friendly to patentees. That would probably start with patent-term extensions that are available in most other industrialized countries: for example, the US and EU have allowed up to five years of patent term extension. That is one thing the Canada could do to attract further investments. There would also be a need for a number of technical changes in the Canada's IP regimes. I am talking about legislation or regulations to allow more flexibility in the way that patent applications are presented and examined and also to allow for applicants to restore patent applications that have been inadvertently abandoned.

The cessation of BAP-15 created huge losses for many pharmaceutical companies. Is there a way that the authorities could help better prepare for such changes in public policy?

I think companies are well aware of the regulatory landscape and the effect of loss of exclusivity on their bottom line. While the 15-year exclusivity in the Province of Quebec for new chemical entities has ceased to apply, the Federal Government regime of data exclusivity for innovative drugs has improved matters since 2006. Whenever a pharmaceutical company brings in a new molecule for regulatory approval in Canada, they are given up to eight years of data exclusivity, which simply means that generic companies cannot present bioequivalent drugs for regulatory approval for up to eight years. That has been a welcomed change by brand companies. In some situations, it allowed this particular protection to go beyond the expiry date of the patent. These are two parallel and independent tracks. If a patent protection falls, data exclusivity will continue and vice versa. That has been good. Otherwise, companies are well aware of the patent cliff that is in front of them.

What tends to be the most important advice you are giving your clients today?

I think that given legal challenges and the scrutiny that patents are being subjected to, the most important advice is to dot your i's and cross your t's. Be very detail-oriented and ensure that the note keeping and work leading up to IP protection is impeccable. We also work very closely with our clients when drafting or amending patent applications. The company really teams up with clients to ensure the best possible patent protection.

To what extent is the firm actively involved in lobbying with institutions like the PMPRB, with regulatory or market access issues?

GGD, as a firm, is not involved in lobbying activities. The firm provides legal advice and advice on the patenting process to its clients. We canvass all possibilities within the given legislative and regulatory framework. GGD will often provide customized and creative advice to clients. This is what we are known for. We make sure clients are made aware of every possibility. For example, GGD looks for regulatory solutions with PMPRB issues, and represents clients before these authorities. Most members of GGD are also members of professional practice committees and professional associations. For example, I am the current president of the Canadian chapter of the International Federation of Intellectual Property Attorneys (FICPI) a worldwide organization of IP lawyers in private practice. FICPI has over a hundred members in Canada and thousands worldwide. The federation represents a key voice for the IP community in Canada and regularly meets with the Canadian Intellectual Property Office to provide suggestions and ideas for change. GGD is also very active in responding to any calls for suggestions or comments on draft legislation guidelines. As far as GGD influencing the process in Canada, it is done through professional associations.

Is the challenge of IP different according to the clients you have?

It is always different. Every client is unique and there is no recipe or formula for the best IP protection. I often sit down with clients who may want to patent a particular feature of their innovation

process and in talking with them I realize that perhaps it is not the best way to go in view of the entire environment and in view of their commercial goals. So we end up focusing patent protection or other forms of IP protection on other features of their innovation process. For example, using a mix of trade secrets for certain parts of their innovation and perhaps using trademarks, designs or patents for other parts. It is truly a customized approach.

Are there general differences that you see between biotech and pharma?

I think that they are quite similar, since both industries are trying to develop and protect new therapeutic cures for diseases. But the biotech industry has a particular focus towards diagnosis that pharma may not have. That makes it a different challenge. Market entry is often more difficult for biotech companies that tend to be smaller than pharmaceutical companies. This is an added challenge.

Where would you say GGD fits on the innovation map of Canada?

That is a question that we always ask ourselves. How can we help? GGD is a professional service provider, so I see our job as making sure that our clients are supported in the way they create, innovate and take risks in conducting R&D. At GGD, we want to make sure that clients are given the best possible professional advice, counseling and work output. This is where we fit in. Failure for us would be not obtaining proper IP protection for great innovation. We deploy all efforts to make sure that our role is fulfilled by using everything within our experience and our power. At the moment, GGD is within the top ten patent firms as far as volume of work done in Canada. However, that is not really the company's focus; GGD's focus is on quality. It is a slow-growing firm in that it is very selective in its hiring and training processes and therefore strives for quality, not quantity.

GGD was recently selected for the Canadian IP Rising Star award. Could you tell our readers a little more about this honor?

I understand that the jury for this award was composed of general counsels from companies all over the world. It was really a pleasant surprise to be recognized by clients without any prompting on GGD's part. GGD is very pleased and honored to receive this award because the firm's theme in its latest strategic plan was to be recognized as the rising star of IP in Canada. Getting an award with this particular designation is perhaps a coincidence but for GGD is very telling.

GGD's motto is "a home for your ideas". How does GGD actively promote its welcome mat? What makes GGD the partner of choice?

GGD is the partner of choice because of our customized approach. Client files are treated with much care. The professional and support staff in the firm are very experienced, and they really care about their work and how they do it. "A home for your ideas" conjures up the notion that it is a safe harbor for our client's ideas; it is a place for nurturing and growing ideas, and eventually letting them out into the big world and commercializing those ideas. GGD is home base for maximizing the commercial value of innovation.

If we were to return to Canada in another 4-5 years, what is your vision by that point?

GGD is a rising star in Canada. The vision is to become the go-to firm for life sciences and the pharma industry and in general a high quality boutique IP firm. Being the largest is not important. However, GGD wants to be immediately known and recognized as a top notch Canadian IP firm.

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