

Sands shift for pharma patents

Pharmaceutical patents are at the forefront of litigation in Canada. **Andrew Bernstein** and **Grant Worden** of Torys LLP in Toronto explain why, and consider proposed changes to rules on generic drugs

In Canada, a substantial proportion of intellectual property litigation relates to patent disputes generally, and to patent disputes concerning pharmaceutical products in particular. Many of these pharmaceutical patent cases occur under a specialized regime designed to prevent market entry by generic firms, by linking regulatory approval with patent compliance. Following Canada's last meaningful patent reforms in the 1980s, there is widespread acceptance of the structure and operation of the current Patent Act.

However, in the context of the specialized regime of pharmaceutical patent litigation, the situation is rather different. Since the 1993 introduction of the Patented Medicine (Notice of Compliance) Regulations (PM(NOC) Regulations), the regime that controls market access to generic firms, there has already been one significant round of amendments. Moreover, the federal Department of Industry, which is responsible for this regime, is undergoing significant consultation with industry stakeholders in an attempt to satisfy both generic and innovative companies' widespread concern about the operation of the Regulations.

In this article, we provide a brief of overview of the framework for intellectual property litigation in Canada. Then we focus on describing the procedure for pharmaceutical patent litigation in more detail.

Patent litigation in Canada

Patent infringement litigation in Canada has changed little since the enactment, in 1989, of the new Patent Act. The new Act moved from the first-to-invent to the first-to-file rule, thereby eliminating conflict proceedings. As a result, most litigation under the Patent Act (other than that relating to pharmaceuticals) looks much like it always has. First, it is typically heard in Federal Court, notwithstanding the fact that most civil cases in Canada are tried in the provincial superior courts. Second, it proceeds like a regular civil enforcement action: the parties

exchange pleadings and make full disclosure of relevant, non-privileged documents; then the parties are entitled to examine one another for discovery (which is analogous, but not identical, to an American-style deposition). If the matter remains unresolved after discoveries, a trial takes place before a single judge, based on oral evidence from witnesses. As there are no *Markman*-style hearings in Canada, issues of patent construction are determined at trial. Remedies for patent infringement in Canada include permanent injunctions, damages or an accounting of profits, legal costs, delivery of infringing goods and, on very rare occasions, punitive damages. Given the expense of a full civil trial, it is not surprising that most patent infringement cases are settled before trial.

Regulatory approval of pharmaceutical products

While numerous civil patent infringement suits are still brought in Canada every year, a substantial amount of patent litigation occurs under an entirely different regime, with a different purpose, practice and procedure. In the pharmaceutical industry, innovator companies have specialized remedies that not only redress patent infringement after it occurs, but can affirmatively prevent generic companies from entering the market while patents that protect innovators' products remain unexpired. In particular, the PM(NOC) Regulations prevent the health protection authorities from granting regulatory approval for generic drugs when unexpired patents protect an innovator's product.

It should be noted that generic firms are not prevented from conducting their own formulation work while patents subsist. The Canadian Patent Act contains a limited early-working exception to permit generic companies to conduct formulation work and prepare their regulatory submission during the period of patent protection, so that generic drugs can be introduced as soon as patents expire. Of course, one of the purposes of the

PM(NOC) Regulations is to ensure that early working does not result in early competition.

The scheme of the PM(NOC) Regulations

Before a drug can be sold in Canada, a drug manufacturer must obtain regulatory approval for its proposed product in the form of a Notice of Compliance. An application for a Notice of Compliance for new medicinal ingredients (that is, where the active ingredient is an

restriction on the types of patents that may be listed on the patent register; (2) a modification of a generic drug company's obligation to challenge newly listed patents; and (3) an expansion of the types of allegations that a generic drug company may make to circumvent listed patents. Although these amendments are not yet finalized, if accepted as proposed, they have the potential to significantly curtail the protection available to innovative pharmaceutical companies.

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entirely new chemical compound) is called a New Drug Submission. Generic drug applicants who wish to rely on and refer to an existing active ingredient in order to demonstrate bioequivalence file an Abbreviated New Drug Submission (ANDS).

The Minister of Health maintains a patent register that lists eligible patents that relate to drugs for which Notices of Compliance have been issued. If a generic drug company files an ANDS that refers to a drug in respect of which a patent is listed on the patent register, the generic company must explain to the Minister how it proposes to deal with that patent. The company has two choices: it can either accept that it will not receive regulatory approval until the patent expires or it can serve a letter called a Notice of Allegation on the patentee alleging either that the patent is invalid or that it will not be infringed if the Minister issues a Notice of Compliance to the generic company.

If the generic drug company serves a Notice of Allegation, the patentee has 45 days to commence an

serve a Notice of Allegation on the patentee. In most cases the patentee will commence an application in Federal Court to litigate the issue whether the generic drug company is entitled to receive regulatory approval for its product. Given that there is a significant advantage to the first generic drug manufacturer to come to market after the expiry of a patent, generic challenges to existing patents (in the form of a Notice of Allegation) beget more generic challenges to those patents. The result is that a patentee may at any one time be prosecuting multiple applications against competing generic drug companies who are seeking to enter the Canadian marketplace at the same time. In some cases, the innovator drug company may have to bring as many as four or five lawsuits against different generic companies to protect its intellectual property rights.

Another idiosyncrasy of the PM(NOC) Regulations is the possibility of multiple stays. A generic drug manufacturer is required to address each and every patent listed in respect of a drug marketed in Canada for which patents are listed on the patent register. Multiple and overlapping

stays can therefore result from a single application for a Notice of Compliance. Not surprisingly, generic drug manufacturers support the implementation of a rule that limits the innovator pharmaceutical companies

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application to prohibit the Minister of Health from issuing a Notice of Compliance to the generic company. This application creates a mandatory 24-month period in which a Notice of Compliance cannot be issued to the generic drug company unless the proceeding is resolved in favour of that company.

In December 2004, the government of Canada published proposed amendments to the PM(NOC) Regulations. The proposed changes include (1) a

to a single stay per Notice of Compliance application. It is likely that this issue will be dealt with in the next review of the Regulations.

Since pharmaceutical patent litigation involves high stakes, most provisions of the PM(NOC) Regulations, and in particular the rules regarding which patents are eligible for inclusion in the overall scheme, have been heavily litigated and have been the subject of considerable lobbying from all interested parties.

The Jean Chrétien Pledge to Africa Act

Given the stakes involved, all areas of Canadian pharmaceutical patent litigation tend to be contentious. Litigation involving the scope of the Jean Chrétien Pledge to Africa Act (JCPA) (which came into force in July 2005) is unlikely to be different. This Act allows compulsory patent licences (termed “authorizations”) to be granted so that companies other than the patentee can manufacture certain patented pharmaceutical products for export to specified countries in need of those products.

Certain conditions must be met for a generic drug manufacturer to obtain a compulsory licence under the JCPA. The pharmaceutical product must be specifically identified in the JCPA, and the country to receive the pharmaceutical product must be an “eligible recipient”. In addition, the patentee of a pharmaceutical product for which a compulsory licence is granted is entitled to a royalty whenever a compulsory licence is granted by the federal government for that product.

The authorization specifies the amount of product that may be exported. The recipient of the authorization must maintain a website listing certain information relevant to the authorization. The recipient must also give notice to the patentee whenever a shipment is being made under the authorization. That notice must identify every party that will be handling the product while in transit from Canada to the recipient country.

A patentee may apply to have a compulsory licence terminated. The circumstances under which a licence may be terminated include, among other things, inaccuracies in the materials contained in the application for the authorization; failure to maintain the required information on a website; and failure to make timely royalty payments to the patentee. In addition, if the average price of the pharmaceutical product being exported is equal to or greater than 25% of the average price in Canada or the equivalent product sold by or with the consent of the patentee, the patentee can also request that the compulsory licence be terminated on the basis that it is “commercial in nature”.

A patentee may also commence proceedings in Federal Court to obtain a higher royalty than that determined in accordance with the Act. The Court may order a higher royalty if “it is satisfied that the royalty otherwise required to be paid is not adequate ... taking into account (a) the humanitarian and non-commercial reasons underlying the issuance of the authorization, and (b) the economic value of the use of the invention”. The Court may either fix a royalty or specify how it is to be determined.

Leaving questions of policy aside, it is likely that any legislation that (1) provides for the grant of a compulsory licence, (2) establishes a mechanism by which a patentee can commence legal proceedings to terminate that licence, and (3) allows patentees to commence proceedings to obtain an increased royalty rate will lead to litigation if and when a compulsory licence is granted.

More litigation expected

Changes to the legislative landscape invariably result in litigation because courts must interpret what the legislature has enacted. Although overall patent reform is not likely in the next decade, the steady stream of amendments and new legislation in the pharmaceutical patent area will ensure that pharma patents continue to be the most active area of intellectual property litigation in Canada.

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