More effective protection for pharmaceuticals

Smart & Biggar/Fetherstonhaugh's **Steven B Garland** and **Daphne C Lainson** explore if greater protection for innovative pharmaceuticals in Canada is on the horizon

Innovators and generics, neither are wholly satisfied with the current Canadian system of intellectual property and related rights (IPRs). Ongoing trade negotiations between Canada and the European Union (EU) has fuelled the debate over effective IPR for innovative pharmaceutical products.

CETA negotiations

In 2009, Canada and the EU began closed door negotiations towards a Comprehensive Economic and Trade Agreement (CETA). Since then, there have been multiple rounds of negotiations, with both sides working towards a conclusion this year.

The CETA negotiations encompass many aspects of trade between Canada and the EU with IPRs being but one. Although the meetings are secret, there have been the usual leaks. Many report that a sticking point in the negotiations is the EU's proposal for greater protections for innovative pharmaceutical products, including:

- Supplementary Protection Certificates (SPCs);
- Heightened data protection; and
- Innovator right of appeal in proceedings under the Patented Medicines (Notice of Compliance[1]) Regulations ("NOC Regulations").

SPCs

Canada currently does not permit any extensions to patent term. Under the Patent Act, all patent applications filed on or after 1 October 1989, have a 20 year term measured from the Canadian filing date[2]. For those applications filed prior to 1 October 1989 (of which there remain patents and applications pending), the term is the longer of 17 years from date of grant and 20 years from filing[3].

SPCs in Europe address regulatory delays in the approval of pharmaceutical and plant protection products, and not surprisingly, the EU is negotiating for SPCs in Canada. The EU is not alone in providing patent term restoration (PTR) – the US, Japan, Australia, South Korea and Israel also have PTR to address regulatory delays.

An SPC recognises that the period between the filing of a patent application and the first authorisation permitting sale of the product in the marketplace, may shorten the period of effective patent protection. An SPC would recoup some of that lost term, and if the EU system is adopted, provide up to five years of additional protection on the patent, with the possibility of a further six-month paediatric extension.

In order to provide SPCs, the Patent Act would need to be amended. There has not been a major amendment to the Patent Act since 1996, and while the amending legislation could be narrowly directed to only SPCs, opening the Patent Act to amendments may create an opportunity to clarify the law in a number of other areas, including on the law of double patenting, the utility standard in Canada and statutory subject matter.

Double patenting

A second issuing patent may be invalidated as same-invention or obviousness double patenting over an earlier issued patent[4]. Canada does not have a US-style terminal disclaimer practice or any other means to effectively address double patenting. A specific double patenting provision in the Patent Act may clarify whether there is double patenting and how to fix it.

Utility

A patent claim may be invalidated if the patentee cannot establish that, as of the Canadian application filing date, there was (a) a demonstrated utility, or (b) a sound prediction of utility for the subject matter claimed for each utility promised in the patent[5]. While data obtained pre-filing may be relevant to showing a demonstrated utility, any argument for a sound prediction of utility may be limited to what is actually disclosed in the patent. The law thus raises questions as to what a patent must disclose, distinct from the support/enablement requirements in the Patent Act. A provision in the Patent Act specifically defining what is required for utility could greatly clarify the law.

Statutory subject matter

The Patent Act has a very broad definition of invention, with only a single exclusion prohibiting a patent claim for a mere scientific principle or abstract theorem[6]. Despite the broad definition, methods of medical treatment and higher life forms have been excluded from patentability[7], as have business methods until recently[8]. Given the developing law in the US, questions of the proper scope of statutory subject matter will likely persist absent a clarifying amendment to the Patent Act.

Heightened data protection

Data protection for pharmaceutical and human biologic products is covered by the Food and Drug Regulations. Prior to 1 October 2006, Canada's data protection provisions were largely ineffective, such that they were rarely (if ever) applied.

Effective data protection was introduced with amendments to the Food and Drug Regulations that came into force on 1 October 2006[9]. The amendments introduced a six year period of data exclusivity for innovative drugs measured from the date of the first NOC, with a further two years of market exclusivity or two and a half years if the paediatric extension applies, for a total exclusivity period of eight-years (or eight and a half years if the paediatric extension applies) from the first NOC. During the data exclusivity period, a subsequent entry manufacturer ("SEM") is prohibited from filing a submission that makes a direct or indirect comparison to a previously approved innovative drug. The minister of health is prohibited from approving the subsequent entry product until the market exclusivity period expires. The provisions apply equally to pharmaceuticals and human biologics. Under the current system, extensions of term are not possible for new therapeutic indications.

It has been reported that the EU is negotiating for a longer data protection term, such that the data exclusivity period would be at least eight years from the first NOC, with a further two years of market exclusivity, and the possibility of an additional year of market exclusivity for new indications. The total exclusivity period could then be 10 or 11 years from the first NOC.

The extension of a data protection term would only require amendment to the Food

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and Drug Regulations. However, Health Canada (the federal department responsible for national public health) is conducting a broader review of the entire drug approval system, including the Food and Drugs Act in order to modernise the process. While broader amendments might not occur for some time, more modest regulatory changes are expected soon, such as introduction of orphan drug provisions.

Innovator right of appeal

An unsuccessful party in a patent infringement or invalidity (impeachment) trial under the Patent Act has a right of appeal. However, most pharmaceutical litigation in Canada does not proceed on this track at first instance. Rather, the first proceeding for a pharmaceutical litigant is usually one under the NOC Regulations, the operation of which often does not permit an innovator the ability to appeal a negative decision.

The NOC Regulations were enacted in response to an amendment to the Patent Act that introduced a broad Bolar-type exemption to patent infringement[10].

Under the NOC Regulations, an innovator or its licensee has the ability to list patents that are relevant to its pharmaceutical or human biologic drug on a "patent register" maintained by Health Canada. If a SEM directly or indirectly compares its drug with, or makes reference to, the innovator drug against which patents are listed, then Health Canada places a patent hold on its submission. The submission will be reviewed for safety and efficacy, but a NOC will not grant until all relevant listed patents are addressed.

The SEM can wait until all relevant listed patents expire before obtaining approval, or it can make an allegation that, for instance, its drug does not infringe any relevant listed patent or the listed patents are invalid. If the patent hold is to continue, the innovator must commence a court proceeding pursuant to the NOC Regulations to assess the merits of the allegations. The commencement of the proceeding creates an automatic stay of up to 24 months, during which time Health Canada is prohibited from issuing a NOC to the SEM.

If the allegations are found unjustified, the court will issue an order prohibiting the minister of health from issuing a NOC to the SEM until the applicable patents expire. The SEM can appeal this decision.

If the allegations are found to be justified, the minister of health is free to issue a NOC (provided the submission meets the requirements of the Food and Drug Regulations). The innovator can only pursue an appeal if a NOC has not been issued to the SEM. In many cases, the NOC issues to the SEM quickly – often within a day or two – following the lower level decision such that the innovator cannot pursue an appeal. It is this situation that the EU negotiators are seeking to address, permitting both parties to have a right of appeal.

A proceeding under the NOC Regulations does not finally determine rights. The innovator's patent is not invalidated/declared not infringed. Thus, even if the SEM launches its drug following grant of the NOC, the innovator could still start a patent infringement action. Likewise, if the SEM is unsuccessful in a proceeding under the NOC Regulations, it could start an impeachment action.

Introducing a right of appeal for an innovator into the NOC Regulations would be administratively easy, since no statutory amendment is required. Whether any other amendments would be made at the same time is uncertain. Significant amendments to the NOC Regulations were introduced in 2006, addressing many of the issues that had arisen since their inception in 1993.

Other IPR provisions

In addition to greater protection for pharmaceutical innovation, CETA may also materially affect other aspects of IPRs. Canada may need to amend its laws for greater compliance with the Patent Law Treaty (Geneva, 2000), the World Intellectual Property Organization (WIPO) Copyright Treaty (Geneva, 1996) and the WIPO Performances and Phonograms Treaty (Geneva, 1996). It may also accede to the protocol related to the Madrid Agreement concerning the International Registration of Marks, the Singapore Treaty on the Law of Trademarks (2006), and to the Geneva Act of the Hague Agreement Concerning the International Registration of Industrial Designs (1999). Canada may also need to amend its laws for greater protection for geographical indications.

If CETA does conclude, it is obvious from the previously mentioned that the impact on IPRs in Canada may be significant. This is not the first time that a trade agreement has impacted on Canadian intellectual property laws, with strong precedents being set by Canada's accession to the North American Free Trade Agreement in 1992 and the Marrakesh Agreement establishing the World Trade Organization in 1995. It may not be the last since Canada has joined the Trans-Pacific Partnership of Asia-Pacific economies.

Footnotes

1. A Notice of Compliance (NOC) is the marketing authorisation from Health Canada permitting a manufacturer to sell a new drug in Canada following a safety and efficacy review of a regulatory submission. Health Canada is the federal department responsible for national public health.
2. Patent Act, s 44.
3. Patent Act, s 45.
4. *Whirlpool Corp v Camco Inc*, 2000 SCC 67, [2000] 2 SCR 1067.
5. See *Apotex Inc v Wellcome Foundation Ltd*, 2002 SCC 77, [2002] 4 SCR 153. *Eli Lilly Canada Inc v Apotex Inc* 2009 FCA 97, leave to appeal to Supreme Court of Canada dismissed. *Novopharm Limited v Pfizer Canada Inc* 2010 FCA 242, appeal pending before Supreme Court of Canada. *Eli Lilly and Company v Teva Canada Limited* 2011 FCA 220, leave to appeal to Supreme Court of Canada dismissed.
6. Patent Act, Section 2; Patent Act, Subsection 27(8).
7. *Harvard College v Canada (Commissioner of Patents)*, 2002 SCC 76, [2002] 4 SCR 45.
8. *Canada (Attorney General) v Amazon.com, Inc* 2011 FCA 328.
9. Food and Drug Regulations, Section C.08.004.1.
10. Patent Act, s 55.2. Canada's Bolar exemption permits a party to practise a patented invention for uses reasonably related to regulatory approval of a product, and this activity is exempt from patent infringement.

Authors

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