Regulatory context for patented pharmaceuticals and biotechnology drugs in Canada

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Canada has a number of regulations that intersect with the Patent Act and the drug approval process. These regulations inform the business decisions that innovative companies must make when bringing a new drug to market in Canada.

In this insight, we highlight the importance of communication between a company's patent and regulatory groups at each step of the drug development process, and how the engagement of a Canadian patent agent well versed in these systems, or with access to a lawyer who practices in this area, can help companies make the most informed decisions.

Data protection

Pursuant to Canada's *Food and Drug Regulations*, a generic or biosimilar manufacturer **cannot** file a drug submission with Health Canada or receive regulatory approval, for a set period of time if that submission contains a direct or indirect comparison to an innovative drug. Unlike in the U.S., the biologic and small molecule drugs both have the same length of data protection.

An innovative drug is defined as a drug containing "a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph."

A generic or biosimilar drug submission cannot be filed for six years after the issuance of the first Notice of Compliance (NOC) or regulatory approval for the innovative drug. The generic or biosimilar drug submission cannot be approved by Health Canada for a further two-year period. The innovative drug must be marketed in Canada in order to be eligible for this data protection.

Therefore, this regime provides a total of eight years of market exclusivity to the marketed innovative drug. A further six months can be obtained if the results of pediatric clinical trials are submitted to Health Canada within five years of the first NOC.

Linkage regulations

Canada has regulations linking generic and biosimilar regulatory approval to the clearance of certain patent hurdles, namely, the *Patented Medicines (Notice of Compliance) Regulations (NOC Regulations)*. These *NOC Regulations* are similar to the U.S. Hatch-Waxman system, however they apply to both biologic and small molecule drugs.

These regulations provide that patents containing at least one claim to the medicinal ingredient, a formulation containing the medicinal ingredient, the use of the medicinal ingredient, or the dosage form of the medicine, can be listed on the Patent Register (the rough Canadian equivalent of the U.S. Orange Book). The patent claim must match the commercial product. A Patent List (Form IV) must be filed at the time the regulatory submission for drug approval is submitted to Health Canada or, if a relevant patent application(s) is still pending at that time, within 30 days of patent issuance.

Once a drug has at least one patent listed on the Patent Register, Health Canada will not issue regulatory approval to a generic or biosimilar drug that makes direct or indirect comparison to the drug that is the subject of a Patent List until those patents have been addressed through the *NOC Regulations*. The generic or biosimilar filer can agree to await patent expiry, or can allege a number of things including non-infringement and/or invalidity of the patent. For more information on the specifics of litigating under this scheme, please see our bulletin here.

If the innovator chooses to start a proceeding in response to the generic or biosimilar allegation, Health Canada cannot issue an NOC to the generic or biosimilar filer until either the action is dismissed or two years have passed, whichever is sooner. Furthermore, if the innovator is successful in the action, there can be no regulatory approval until the patent expires.

This linkage of generic or biosimilar regulatory approval to the patent infringement/validity outcome has the effect of providing an interlocutory injunction until the decision issues and a permanent injunction if the action is successful. As interlocutory injunctions are difficult to obtain in IP cases in Canada, this regulatory system provides a benefit to the innovator. However, before this benefit can be used, the innovator must meet both the strict timing and the eligibility requirements for listing the patent on the Patent Register.

As a result, **it is important that the patent prosecution division of a company communicate with the regulatory team making the new drug submission filing in Canada**. This collaboration allows the timing restrictions to be met and protection under the various regulations maximized. Furthermore, the subject matter of the claims must be related to the commercial product, and thus, close communication amongst the relevant teams is critical.

Patent term restoration

Canada now has a patent term restoration period meant to restore time lost due to delays in drug approval at Health Canada. This system is governed through the *Patent Act* and the *Certificate of Supplementary Protection Regulations (CSP Regulations)*. Up

to two years of time can be “restored” to the patent through the issuance of a Certificate of Supplementary Protection (CSP). One CSP can be issued per drug and the choice of patent to which the CSP is applied is up to the company.

For the purposes of the regulatory systems discussed in this article, the CSP will have essentially the same effect as the patent does for the original term of the patent, albeit its scope is limited to the medicine in question. CSPs can be listed on the Patent Register. They also must be reported to the Patented Medicines Prices Review Board (PMPRB).

The eligibility requirements for a CSP are strict. Find details of the requirements in our previous article. From a patent prosecution standpoint, two things are important.

1. The **patent must pertain to a medicinal ingredient or combination of medicinal ingredients in a drug for which the NOC was issued** , and contain a claim for: the medicinal ingredient or combination; the medicinal ingredient or combination as obtained by a specified process; or the use of the medicinal ingredient or combination.
2. If Canada is not the first country for which an application for marketing approval for that medicinal ingredient or combination has been submitted, **the application in Canada must have been filed within 12 months of the earliest foreign application** for marketing approval in: the European Union (EU) and any country that is a member of the EU; the United States of America; Australia; Switzerland; the United Kingdom; and Japan.

For this reason, communication between teams is critical to ensure the patent contains the necessary claims, and to ensure that if a CSP is desired, the regulatory filing is made in time to be eligible.

Price controls

The PMPRB oversees a regime designed to ensure patented medicines are not sold at an excessive price in Canada. Under this regime, the PMPRB determines the maximum price at which a patented medicine can be sold.

Patentees are obligated to report relevant patents to the PMRPB under the *Patent Act*.

Importantly, the reporting obligations encompass a much broader range of patents than those that are eligible for a CSP or for listing on the Patent Register. The oft-used test is that if the patent relates to the medicine by the ‘merest slender thread’, it must be reported. For example, this reporting requirement includes patents to processes and intermediates, which are not eligible for listing. Furthermore, the PMRPB requires reporting whether or not the patent is actually used in relation to the commercial product.

The PMPRB only takes jurisdiction over the price of a drug once a relevant patent has issued. However, once a patent issues, the PMPRB takes jurisdiction back to the publication date of the patent.

If a patent issues for a drug that has been on the market, yet 'off patent' for some time and therefore not within the purview of the PMPRB, the newly created pricing jurisdiction may cause problems. Accordingly, business decisions need to be made with respect to all ongoing innovation. A perceptive innovator should ask themselves whether the additional protection from this patent worth the additional price control. Often it is, however, an informed decision is a better decision.

Conclusions

As we have demonstrated, it is critical that patent and regulatory groups at pharmaceutical and biotechnology companies communicate and co-ordinate in order to position the company to best strategize with respect to the various regulatory systems in Canada.

Working with a Canadian patent agent familiar with the regulatory requirements and timelines can be invaluable when developing strategies for Canada. Even more valuable is a team of patent agents who work closely with litigation colleagues who have dealt with the associated regulatory challenges, and can be called upon for additional strategic guidance.

For questions or additional support on how to best position and align the patent and regulatory groups at your company at each step of the drug development process, please reach out to any of the authors or key contacts listed below.

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