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THE PATENT ACT: NOTICE OF COMPLIANCE LINKAGE REGULATIONS

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THE *PATENT ACT*: NOTICE OF COMPLIANCE LINKAGE REGULATIONS

INTRODUCTION

Prior to the passage of the *Patent Act Amendment Act, 1992*,(1) Canadian patent law permitted the issuance of compulsory licences(2) in relation to patents pertaining to pharmaceutical products. This allowed generic drug manufacturers to produce and sell copies of patented medicines before the expiration of the relevant patents. The *Patent Act Amendment Act, 1992* eliminated compulsory licensing, thereby ensuring that the owners of pharmaceutical patents would be protected from generic competition until their patents expired.

Although generic manufacturers are now prohibited from selling copies of a medicine until the relevant patents expire, the Act allows them to take the necessary steps to obtain

regulatory approval for their products before the expiration of the patents. These measures are designed to facilitate the entry of generic products to the market.

When the bill to enact the *Patent Act Amendment Act, 1992* (Bill C-91) came before Parliament, the brand-name drug manufacturers expressed concern that the generic sector might use the provisions of the Act that allow for early development ("early working") of generic products to sell these products before the relevant patents expired. The brand-name manufacturers therefore called for measures to link the granting of marketing approval for generic medicines to the expiration of the relevant patents.

These notes will review section 55.2 of the *Patent Act*(3) as enacted by the *Patent Act Amendment Act, 1992* as well as the relevant regulations with respect to the use of patents by generic manufacturers and the infringement of patent rights.

EXCEPTIONS TO INFRINGEMENT

A person owning a patent for a product has the exclusive right to make, use and sell the product for a specified period of time. Under Canadian law, a patent has a term of 20 years from the date on which the application for the patent is filed. Anyone who uses a patent or makes a product to which a patent relates without permission of the patent owner and before the patent expires risks an action for patent infringement.

Subsections 55.2(1) and (2) of the *Patent Act*, as enacted by section 4 of the *Patent Act Amendment Act, 1992*, create an exception to an action for infringement by permitting generic manufacturers to use a patented product for certain purposes prior to patent expiration.

Section 55.2(1) provides that it is not an infringement of a patent for a person to "make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information" required under federal or provincial law or the law of another country that regulates the manufacture, use or sale of the product. Thus, generic drug manufacturers are allowed to develop a generic copy of a patented medicine and to take whatever steps are necessary to meet the regulatory requirements pertaining to its sale before the expiration of the relevant patents for the brand-name equivalent drug. Among other things, generic manufacturers are permitted to formulate and test the drug and present it to provincial authorities for the purpose of having it accepted for subsequent coverage under provincial drug benefit plans.

Section 55.2(2) provides that it will not be an infringement of a patent for a person to use a patented invention during a period prescribed by regulation in order to manufacture and store a product intended for sale after the patent expires ("stockpiling").(4) This permits a manufacturer to make use of a patentee's invention to stockpile generic copies of a patented medicine before patent expiry so that the drug will be ready for sale immediately after expiry. Without this provision and that in section 55.2(1), a patentee could prohibit a generic manufacturer from manufacturing a product under patent until the patent expires. Such a prohibition would effectively bar the generic manufacturer from the market for a period beyond the end of the patent term because the manufacturer would require time to obtain regulatory approval to market the drug and manufacture it for sale.

These provisions, however, do not give generic manufacturers free rein to use a patented product. The Act is clear that such use is limited to the situations outlined in section 55.2 (1) and (2). Nevertheless, at the time Bill C-91 was before the House of Commons, brand-name drug manufacturers expressed concern that generic producers might abuse these exceptions to patent infringement and begin to sell generic products before the relevant patents had expired. Should this occur, brand-name manufacturers would have to pursue generic manufacturers in the courts for patent infringement.

LINKAGE REGULATIONS

Section 55.2(4) of the *Patent Act* was enacted to allay the concerns of the brand-name manufacturers in this regard. It authorizes the Governor in Council to make regulations to prevent the infringement of a patent by generic drug manufacturers using a patented invention in accordance with section 55.2(1) and (2). More particularly, such regulations can specify:

> (a) the conditions that must be fulfilled before a notice, certificate or permit pertaining to a patented product can be issued to a patentee or to any other person pursuant to any Act regulating the product;
>
> (b) the earliest date on which a notice, certificate or permit issued to a person, other than a patentee, is to take effect;
>
> (c) how disputes between a patentee and a generic manufacturers as to the effective date of a notice, certificate or permit are to be resolved; and
>
> (d) the right of a patentee to pursue a court action with respect to disputes concerning the effective date of a notice, certificate or permit.

Before a new drug can be sold to the Canadian public, it must be approved by the federal Department of Health. The document evidencing this approval is called a Notice of Compliance (NOC). The NOC certifies that a drug meets the requisite standards for safety, efficacy and quality.

The primary purpose of section 55.2(4) is to ensure that a generic drug manufacturer is not granted an NOC by the Minister of Health (Minister) until it can be shown that the drug does not infringe existing patent rights. In most cases, an NOC for a generic drug will not be issued until after expiry of the patent or patents for the brand-name equivalent product.

The *Patented Medicines (Notice of Compliance) Regulations*(5) (Linkage Regulations) establish how the granting of an NOC for a generic version of a patented medicine is to be linked to the expiration of patent rights. Essentially, the regulations provide that, unless a patentee has consented to the making of a generic drug, the relevant patent is invalid, or there has been no infringement of any patent rights, the Minister cannot issue an NOC to a generic manufacturer until the patent has expired.

Under the Linkage Regulations, patentees submit to the Minister a patent list that sets out the Canadian patents for a particular medicine. A generic manufacturer filing an application for the Minister to issue an NOC for a generic product must certify the status of the patents issued for the brand-name equivalent drug. Under section 5 of the Linkage Regulations, the generic manufacturer must:

> (a) accept that the NOC for the generic drug will not be issued until the relevant products expire; or
>
> (b) allege that
>
> (i) the patentee does not own the patent,
> (ii) the patent has expired,
> (iii) the patent is not valid, or
> (iv) the generic manufacturer is not infringing any patent.

If a generic manufacturer makes any of the allegations listed above, it must provide a detailed statement of the legal and factual basis of its allegation and serve notice of the allegation on the patentee.

Within 45 days after being served with notice of an allegation, a patentee can apply for a court order prohibiting the Minister from issuing an NOC for the generic drug until after the expiration of the relevant patent.(6) Among other things, the Linkage Regulations provide that the Minister cannot issue an NOC to a generic manufacturer until 30 months after the patentee has applied for a court order unless the patent expires, a court declares that the patent is invalid or that it has not been infringed, or the parties reach an agreement.(7)

The contentious aspect of the Linkage Regulations is the 30-month delay. The generic industry claims that the brand-name companies have used the Regulations to block non-infringing products from entering the market. The brand-name companies, on the other hand, claim that the delay is critical, since traditional injunctive relief in Canada cannot adequately address the infringement of pharmaceutical patents.(8)

The Linkage Regulations have generated substantial litigation, with some 100 cases having been commenced in the last four years.

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(1) Statutes of Canada, 1993, c. 2.

(2) A compulsory licence is a statutory licence that gives the licensee the right to manufacture, sell or distribute a patented invention.

(3) R.S.C. 1985, c. P-4, as amended.

(4) SOR/93-134, 12 March 1993, *Canada Gazette Part II*, Vol. 127, No. 6, p. 1390. The *Manufacturing and Storage of Patented Medicines Regulations* provide that the applicable period is six months immediately prior to the date on which the patent expires.

(5) SOR/93-133, 12 March 1993, *Canada Gazette Part II*, Vol. 127, No. 6, p. 1383.

(6) *Ibid*., s. 6(1).

(7) *Ibid*., s. 7(1), (2).

(8) Minister of Industry, Speaking Notes to the House of Commons Standing Committee on Industry, 17 February 1997, p. 5.