a) Overview

Canadian Health Law Practice Manual

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CHAPTER 10 REGULATION OF PHARMACEUTICALS

III. FEDERAL REGULATION

B. INTELLECTUAL PROPERTY PROTECTION FOR PHARMACEUTICALS

2. *Patented Medicines (Notice of Compliance) Regulations*

a) Overview

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The NOC Regulations were enacted under s. 55.2(4) of the *Patent Act*.[1] The NOC Regulations came into force on March 13, 1993, shortly after the enactment of Bill C-91. The NOC Regulations, which are administered by the Office of Patented Medicines and Liaison (within the Therapeutic Products Directorate), create a scheme ostensibly to prevent infringement of certain patents pertaining to medicines. Specifically, the NOC Regulations were designed to prevent abuse of the "early working" exception.

The NOC Regulations are referred to as the "linkage" regulations because they link two otherwise unrelated legislative schemes: the *Patent Act* (the purpose of which is the protection of private patent rights) and the *Food and Drugs Act*[2] (the purpose of which is the protection of public health and safety). Essentially, the NOC Regulations prohibit the Minister of Health from issuing a NOC for a generic drug until the relevant patents expire, or the Court makes a determination that the generic company's allegation of non-infringement or invalidity of the patent in question is justified.[3] The NOC Regulations were amended in 1998, 1999, 2006, 2008, 2010 and 2011.

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As discussed earlier in the chapter, when a generic manufacturer seeks to obtain approval to market a generic version of an approved innovator drug, it must submit a NDS. However, where the generic manufacturer can show that its product is the pharmaceutical equivalent, is bioequivalent, uses the same route of administration and the same conditions of use as a "Canadian Reference Product" for which approval in the form of a NOC has already been granted, the generic manufacturer may file an ANDS, comparing the generic product to the approved

Canadian Reference Product, and relying on the safety and efficacy data of the innovator drug to obtain its own approval.[4] Thus, in filing an ANDS, the generic manufacturer may forgo the costly and time-consuming generation of original test data.

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Prior to the 2006 amendments of the NOC Regulations, the Patented Medicines (Notice of Compliance) (PMNOC) regime was triggered when a generic manufacturer filed an ANDS — for the "purpose of demonstrating bioequivalence" of the proposed generic product with an approved innovator product. It was unclear whether the protection afforded to the patentees under the regime would still be triggered if the generic manufacturer instead filed a NDS for the drug — relying on its own original safety and efficacy data. A 2005 decision of the Supreme Court of Canada held that where a generic manufacturer files a NDS with original test data (thus not demonstrating "bioequivalence"), the NOC Regulations do not apply, and there is no protection afforded to the patentee.[5]

The 2006 amendments to the NOC Regulations removed the requirement of demonstrating bioequivalence. Specifically, the NOC Regulations are triggered when a generic manufacturer files a drug submission that "directly or indirectly compares the drug with, or makes reference to another drug marketed in Canada under a notice of compliance."[6] The trigger is a comparison to a drug that is marketed in Canada under a NOC. Therefore, withdrawal of an approved product from the market could result in loss of protection under the NOC Regulations.

Footnote(s)

1 R.S.C. 1985, c. P-4, s. 55.2(4).

2 R.S.C. 1985, c. F-27.

3 SOR/93-133, s. 7.

4 *Food and Drug Regulations*, C.R.C., c. 870, s. C.08.002.1.

5 *Bristol-Myers Squibb Co. v. Canada (A.G)*, [2005] S.C.J. No. 26, 39 C.P.R. (4th) 449 (S.C.C.).

6 SOR/93-133, s. 5(1). Courts have since clarified that this section refers to the drugs themselves, and not the uses of said drugs. See, *e.g.*, *Janssen Inc. v. Celltrion Healthcare Co.*, [2016] F.C.J. No. 609, 2016 FC 525.