

Blakes Bulletin

Intellectual Property

Canadian Court Determines Scope of Financial Recovery for Delayed Generic Entry

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A judge of Canada's Federal Court has issued the first trial decision on a claim made by a generic manufacturer under section 8 of the *Patented Medicines (Notice of Compliance) Regulations* (the Regulations) for damages suffered as a result of being kept off the market due to an innovator's assertion of its patent rights under the Regulations.

BACKGROUND TO THE REGULATIONS

The Regulations were initially implemented by the Canadian government in 1993, at the same time that the government abolished the compulsory licensing scheme that had been in place for patented pharmaceuticals for many years.

The Regulations link the ability of the Minister of Health (the Minister) to approve the marketing of a generic drug through the issuance of a Notice of Compliance (NOC) with the patent status of the equivalent innovative drug product.

A generic manufacturer which compares its product with a patented, innovative drug must either await the expiry of the innovator's patent(s) before obtaining its NOC or, alternatively, make an allegation of non-infringement or invalidity that is either not disputed by the innovator or is upheld by a court.

If the innovator commences court proceedings for an order prohibiting the Minister from issuing a NOC to the generic manufacturer ("NOC proceedings" or "prohibition proceedings"), the Regulations provide for a stay of up to 24 months, which can be extended or abridged by court order, before the Minister can issue a NOC.

The purpose of this stay is to allow sufficient time for the innovator's prohibition proceeding to be heard by the court.

The Canadian government's stated goal in implementing the Regulations was to strike a balance between the prevention of patent infringement and the facilitation of entry of generic drugs into the marketplace where no infringement exists.

SECTION 8

As part of this attempted balance, section 8 of the Regulations enables a generic manufacturer to obtain recovery for losses that it suffers as a result of a prohibition proceeding where the prohibition proceeding is withdrawn or discontinued by the innovator or dismissed by a court.

Section 8 provides that, in such circumstances, the innovator is liable to the generic manufacturer for any loss suffered during the period beginning on the date that a NOC would have been issued but for the Regulations and ending on the date of the withdrawal, discontinuance or dismissal of the prohibition proceeding.

APOTEX V. MERCK

In *Apotex v. Merck*, the first trial decision on a section 8 claim, Justice Hughes of the Federal Court had to decide the following three issues: (a) whether section 8 was validly enacted; (b) whether the section limits a generic manufacturer to recovering its lost profits or, alternatively, allows it to elect recovery of the innovator's profits; and (c) whether a generic manufacturer can obtain recovery for events occurring beyond the date on which a NOC proceeding is dismissed or withdrawn.

VALIDITY OF SECTION 8

Merck raised several attacks on the validity of section 8. First, Merck argued that the *Patent Act* (the Act) did not give the Federal Court jurisdiction to hear section 8 claims. Hughes J. disagreed, holding that the Regulations, including section 8, were properly authorized under the Act and conferred jurisdiction on the Federal Court to hear a section 8 claim.

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Second, Merck argued that section 8 was not enabled under the regulation-making power granted in the Act. In this regard, Merck relied upon the wording of subsection 55.2(4) of the Act which permits the making of regulations "necessary for the preventing of the infringement of a patent". Merck argued that section 8 of the Regulations was not enabled since it punished an unsuccessful innovator rather than prevented infringement. Justice Hughes dismissed this argument, holding that the Regulations had to be viewed as a whole and that section 8 was an important part of the balance being sought by Parliament under the Regulations. In this regard, Hughes J. analogized section 8 to the undertaking that a party seeking an interlocutory injunction must provide to the court to compensate the defendant for damages that it may suffer through the wrongful granting of an injunction.

Third, Merck argued that section 8 creates a civil cause of action between individuals and as such is a matter respecting property and civil rights and thus a matter within exclusive provincial jurisdiction under Canada's constitution. In dismissing this argument, Hughes J. held that section 8 was an integral part of the scheme set out in the Regulations, authorized by the *Patent Act*, and which was directed to the enforcement of patent rights, a matter falling within exclusive federal jurisdiction under the constitution.

There are other arguments that can be made to attack section 8 and so it is likely that the Federal Court and the Federal Court of Appeal will be called upon to determine the validity of this section in future cases.

RECOVERY OF INNOVATOR'S PROFITS

One of the arguments raised by Apotex was that it was entitled to its election of the greater of its damages or Merck's profits.

In recent years, there has been a series of interlocutory skirmishes over whether subsection 8(4) of the Regulations permits a court to award a generic manufacturer an election of either its damages or the innovator's profits. Subsection 8(4) formerly read "The court may make such order for relief by way of damages or profits as the circumstances require in respect of any loss referred to in subsection (1)". As a result of amendments to the Regulations made in 2006, section 8 now provides that the court can only make an award of damages to a successful generic

manufacturer. This amendment does not, however, apply to any action commenced under section 8 prior to the coming into force of the amended Regulations on October 5, 2006. In the Regulatory Impact Analysis Statement accompanying the 2006 amendments, the Canadian government noted that it was reserving comment on the proper interpretation of the word "profits" in the former subsection 8(4), presumably since it did not wish to influence the outcome of litigation between innovators and generic manufacturers on this very issue.

Apotex relied upon the inclusion of the wording "relief by way of damages or profits" in the former subsection 8(4) as allowing its claim for Merck's profits. In response, Merck noted that under the wording of subsection 8(1) an innovator "is liable to the second person (i.e., the generic manufacturer) for any loss suffered", thus mandating that recovery is limited to losses suffered by the generic manufacturer, not profits made by the innovator.

Hughes J. agreed with Merck's argument, holding that the purpose of section 8 was to "compensate" a generic manufacturer for its losses suffered as a result of its delayed entry into the marketplace and that unless the Regulations expressly granted an equitable remedy (such as an accounting of profits) to a generic manufacturer, the court had no jurisdiction to go beyond a damages award.

This finding will substantially reduce the financial risk faced by innovators who have been unsuccessful in NOC proceedings since the profits earned by them during the period that the generic manufacturer was kept off the market will typically exceed the profits lost by the generic manufacturer during the same period.

RECOVERY FOR PERIOD BEYOND DISMISSAL OF NOC PROCEEDING

As noted above, section 8 provides that a generic manufacturer is entitled to claim for losses suffered during the period between the date on which its abbreviated new drug submission (ANDS) was approvable and the date on which the NOC proceeding was withdrawn, discontinued or dismissed. In this case, there was nearly a 16-month gap between February 3, 2004 when Apotex' ANDS became approvable and May 26, 2005 when Merck's NOC proceeding was dismissed.

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Apotex argued that part of the loss that it suffered during this 16-month period was its permanent loss of market share attributable to the fact that instead of being the first generic to enter the marketplace, two other generic manufacturers were able to enter the market at about the same time as Apotex.

In very brief reasons, Justice Hughes agreed with Apotex' interpretation. Hughes J. held that Apotex is entitled to claim damages for this permanent loss of market share as long as it was not a matter that Apotex rectified or could have rectified before the NOC proceeding was dismissed.

SUMMARY

Justice Hughes' decision, like the Regulations themselves and the periodic amendments to them, is unlikely to entirely please either the innovators or the generic manufacturers. Although the innovators will be pleased with Hughes J.'s decision that their profits are not at stake in section 8 proceedings, they will be disappointed by his holding that section 8 is valid. Perhaps more important than either finding, however, is Hughes J.'s ruling on the recovery of damages for the period after the dismissal of an NOC proceeding. Not only will it be difficult in many cases to quantify such damages but the permanent nature of these damages could make for some large awards.

In view of the consequences, it is unlikely that *Apotex v. Merck* will constitute the last word on section 8. There are other section 8 cases pending and several of them are likely to make their way to the Federal Court of Appeal, if not the Supreme Court of Canada, before the scope of section 8 is conclusively determined.

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