TORYS LLP

NEW YORK TORONTO

No. 2006-3
November 8, 2006

INTELLECTUAL PROPERTY BULLETIN

Supreme Court Decision May Seriously Affect Innovator Pharmaceutical Companies

On November 3, 2006, a unanimous Supreme Court of Canada released a decision (*AstraZeneca Canada Inc. v. Canada (Minister of Health)*[1]) that may have significant implications for innovator pharmaceutical companies. It suggests that generic manufacturers may no longer be required to address every patent listed on the Patent Register in respect of a particular *drug*, but only those patents that are relevant to the *product* cited as the Canadian reference product. The Court departed from the broad interpretation of section 5(1) of the *Patented Medicines (Notice of Compliance) Regulations* (*Regulations*) that was previously adopted by the Federal Court of Canada. Although the facts of this case are unique and it was decided under the pre-amendment *Regulations*, it is likely to be held out by generic manufacturers as a case of general application.

Facts

AstraZeneca began marketing omeprazole in Canada in 1989 under the brand name Losec. In 1993, Apotex filed an Abbreviated New Drug Submission (ANDS) seeking approval for a generic version of Losec omeprazole 20 mg capsules (Losec 20). Apotex's ANDS compared its proposed product to Losec 20. In September 1996, AstraZeneca voluntarily withdrew Losec 20 from the Canadian market.

Despite the absence of Losec 20 from the market in Canada, AstraZeneca continued to list patents against it on the Patent Register maintained by the Minister of Health. In 2002 and 2003, AstraZeneca listed two additional patents on the Patent Register in relation to two Supplemental New Drug Submissions for which additional Notices of Compliance (NOCs) were issued to AstraZeneca.

In 2004, the Minister of Health granted Apotex an NOC for its generic omeprazole product even though Apotex had not delivered notices of allegation for the two additional patents. The Minister's position was that a generic manufacturer should not be required to address patents listed for a Supplemental New Drug Submission introducing a change to a drug that was no longer marketed because the generic product could not have been compared with the drug as changed. AstraZeneca commenced a judicial review of the Minister's decision to issue an NOC to Apotex.

The Supreme Court's Decision

The Court agreed with Apotex that the *Regulations* are concerned only with patents relevant to the innovator product actually copied and not with listed patents from which a generic manufacturer could receive no benefit. In other words, relevant patents are those that the generic has relied on in making its copycat product. As AstraZeneca added the additional patents to the register after Apotex filed its ANDS and these patents were not incorporated in the Canadian reference product cited by Apotex, Apotex was not required to address them.

The particular facts of this case gave rise to the Court's concern about innovator companies evergreening their products by "adding bells and whistles to a pioneering product … after the original patent for that pioneering patent has expired." The Court's solution was to require Apotex to address only the "cluster of patents listed against submissions relevant to the NOC that gave rise to the comparator drug."

---

[1] 2006 SCC 49.

© 2006 by Torys LLP. All rights reserved.

Implications

Recognizing the uniqueness of the facts of this case, the lower court observed that "no other brand name company has attempted to list patents in this manner in Canada, making this a novel situation." The Court found it would have been impossible for Apotex to demonstrate bioequivalence on the basis of the subsequent patents for which no product was marketed in Canada. The Court held that if AstraZeneca had marketed a version of Losec 20 under the later NOCs, and Apotex had referred to the new product for the purpose of demonstrating bioequivalence, Apotex would have been required to file a notice of allegation regarding the new patents.

As stated above, it is important to note that this case was decided under the *Regulations* as they existed before the recent October 5, 2006 amendments (for a discussion of these amendments please see the Food & Drug Regulatory Bulletin No. 2006-2 dated October 10, 2006 on Torys' website). It could thus be argued that this case is of limited application to the *Regulations* presently in force.

Nonetheless, the Supreme Court's narrow construction of section 5(1) may be potentially problematic for innovator pharmaceutical companies if, as it may be asserted this decision suggests, generic manufacturers no longer need to address every patent listed on the Patent Register in respect of the drug that they seek to copy.

The potential significance of this decision will depend on the facts of each particular case. We encourage a review of your company's relevant patent portfolios to determine the impact of this case on your patent strategy and scope of protection under the *Regulations*.

* * * * * * * *

Andrew Shaughnessy
416.865.8171
ashaughnessy@torys.com

Peter Wilcox
416.865.7327
pwilcox@torys.com

Grant Worden
416.865.7698
gworden@torys.com

To contact us, to change your mailing options or to unsubscribe, please email us at info@torys.com or call us at 416.865.7500, extension 8500. If you are calling long distance from anywhere in the continental United States and Canada, you may use the toll-free number 1.800.505.TORY (8679), extension 8500. Torys' client memos and bulletins are available on our website at www.torys.com, under Publications. Our privacy policy is also available on our website.

This bulletin is a general discussion of certain legal and related developments and should not be relied upon as legal advice. If you require legal advice, we would be pleased to discuss with you the issues raised in this bulletin in the context of your particular circumstances.

© 2006 by Torys LLP. All rights reserved.