April 23, 2015

No Debate on Section 8 – Supreme Court dismisses patent appeal from the bench

In a rare and surprising turn of events, a full panel of the Supreme Court of Canada unanimously dismissed Sanofi-Aventis' appeal of its "Section 8" liability at the conclusion of oral argument on April 20. (*Sanofi-Aventis v. Apotex Inc*., 2015 SCC 20).

Section 8 of the *Patented Medicines (Notice of Compliance) Regulations* (known in patent litigation circles simply as "Section 8") has been a hotly contested area of litigation resulting in several substantial damage awards. One of those awards (exceeding $215 million) was at issue in the Sanofi-Aventis matter, which marked the Supreme Court's first hearing of a Section 8 case after dismissing numerous leave applications.

The underlying decision was split, with Justice Sharlow writing the majority ruling at the Federal Court of Appeal, upholding the trial decision of Justice Snider (2014 FCA 68, affirming 2012 FC 553). The biggest issue in the case, and the one of most interest, was the scope of the "but for" world in Section 8 cases.

Section 8 is intended to compensate generic companies for being held off the market due to applications brought by innovator companies under the *PM(NOC) Regulations* that are ultimately dismissed. In Section 8 cases, the Court creates a "but for" scenario to calculate what generic sales would have been, but for the applications. It awards damages in the amount of the profits the plaintiff generic company would have made on those sales.

As there can be multiple cases and multiple generic companies, the question before the Court was whether there would be one "but for" scenario, in which where generics would each get their share of the generic sales that would have been made in a free market during the period, or whether each case would get its own "but for" scenario. The latter raises the possibility that damage awards over multiple cases would exceed the size of the generic market that would have existed in the real world.

Justice Snider chose the latter path of multiple "but for" worlds and was upheld in that conclusion by the majority of the

Federal Court of Appeal. Given the significance of this issue to the scope of potential Section 8 liability (present and future), the pharmaceutical industry was watching the appeal with great interest. While the outcome was obviously unknown, it was at least expected that the Court would not render a decision for many months. The dismissal from the bench came as a major surprise.

The hopes of the innovator pharmaceutical industry that the Supreme Court would reverse the Federal Court of Appeal on the issue of the approach to the "but for" concept are now gone. Unless the Supreme Court grants leave again, which seems remote given the dismissal from the bench, it appears that this case has effectively settled the debate on Section 8.