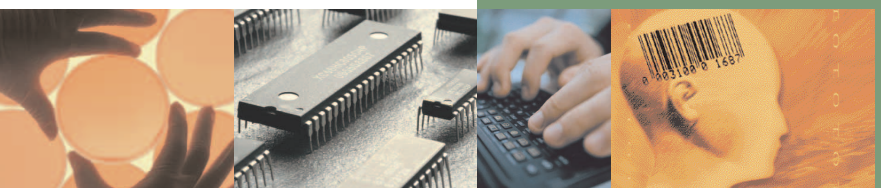

# IP Alert

INTELLECTUAL PROPERTY GROUP

## Recent Federal Court of Appeal Decision on The Scope of Damage Claims under Section 8 of the *Patented Medicines* (*Notice of Compliance*) *Regulations*

*By Jonathan Stainsby*

In a decision released May 2, 2011, the Federal Court of Appeal has demonstrated that it is not of a single mind with respect to the scope of the damages recoverable under section 8 of the *Patented Medicines (Notice of Compliance) Regulations* (the "*Regulations*") *(Teva Canada Limited v. Sanofi-Aventis Canada Inc. et al,* 2011 FCA 149). The *Regulations* provide that a "second person" (a generic manufacturer) who successfully resists an application brought thereunder is entitled to recover damages for "any loss suffered" during the period which commences on the date "on which a Notice of Compliance would have been issued in the absence of [these] *Regulations"* and ending on "the date of the withdrawal, the discontinuance, the dismissal or the reversal [of the application]" (the so-called "statutory period").

In *Apotex Inc. v. Merck & Co.* (2009 FCA 187 ("*Merck*")) the Federal Court of Appeal (Noel, Layden-Stevenson and Ryer JJA) interpreted this provision narrowly, restricting potential recovery to losses realized within the "statutory period." It did so by contrasting the word "suffered" with the word "caused", concluding that the two have different meanings. In doing so, the Federal Court of Appeal granted an appeal from the prior decision of Justice Hughes, who had allowed recovery for losses caused by the imposition of the automatic statutory stay, but realized (and therefore "quantified") only after the "statutory period" (*Apotex Inc. v. Merck & Co*, 2008 FC 1185). Justice Hughes analogized these losses to damages caused by tortious conduct which are manifested, and therefore quantified, after the date of the tortious conduct.

The Federal Court of Appeal's recent decision considers the issue, first reviewed in *Merck*, in the context of Teva Canada's appeal from prior decisions striking out portions of its statement of claim for section 8 damages that it "suffered" as a result of two applications commenced by Sanofi-Aventis Canada and others ("Sanofi") relating to the drug ramipril. Each of these applications was dismissed as an abuse of process, enabling Teva Canada to enter the Canadian ramipril market. Sanofi then sued for patent infringement; Teva Canada's counterclaim for a declaration of patent invalidity was allowed and Teva Canada proceeded to pursue recovery of its section 8 damages. This recent decision arises from Sanofi having succeeded in having portions of Teva Canada's statement of claim struck – those relating to losses allegedly outside the "statutory period."

The majority (Noel and Dawson, JJA) dismissed Teva Canada's appeal from a decision of the Federal Court which had upheld a Prothonotary's decision to strike claims for permanent loss of market share that extended beyond the so-called "statutory period." The majority reaffirmed the Federal Court of Appeal's decision in *Merck*.

However, in a very strongly worded dissent, Madam Justice Sharlow disagreed with the majority's position. In Justice Sharlow's view, the purpose of damages under section 8 of the *Regulations* is to balance the impact of the "statutory freeze" available under the *Regulations* (the automatic statutory stay which prevents the Minister from granting the generic manufacturer marketing authorization in the form of a "Notice of Compliance" while the litigation commenced by the brand company plays out). This "statutory freeze" is available as of right to a brand company who chooses to commence the prescribed proceedings, and the Court lacks the jurisdiction to relieve against it. Justice Sharlow analogized the "statutory freeze" to a "mandatory injunction" and further analogized section 8 damages to the undertaking in damages required to be given to obtain an interlocutory injunction. Noting that interlocutory injunctions are extraordinary remedies (and, therefore, broadly comparable to the unusual and draconian "statutory freeze" under the *Regulations*), Justice Sharlow further noted that the undertaking is "normally broad enough to cover all losses resulting from the injunction, in the event it is determined that the injunction should never have been imposed."

On this basis, Justice Sharlow observed that "section 8 of the *Regulations* was intended to be similarly broad, and should be so interpreted. Nothing within section 8 or in the associated Regulatory Impact Analysis Statements discloses an intention on the part of the Governor in Council to impose ***an artificial limitation on the normal method of computing damages that would result from the analogous situation of an interlocutory injunction imposed without justification.***" (emphasis added)

Justice Sharlow would have allowed the appeal, noting that she was "not persuaded that the narrow interpretation of section 8 adopted in *Merck*, which turns on a literal interpretation of the word "suffered", is correct, or that *Miller* [*Miller v. Canada (Attorney General)*, 2002, FCA 370] should preclude [the Federal] Court [of Appeal] from permitting the interpretation of section 8 adopted in *Merck* to be reconsidered in the context of Teva's claim."

A further point of interest arises from this decision. In the underlying decisions of the Prothonotary and the Federal Court Judge, it had been found that it was plain and obvious that the claim for damages outside of the "statutory period" could not succeed. However, given Justice Sharlow's strong dissent it will be much more difficult to argue successfully that a claim for damages outside the period is, as expressed in the case law, "doomed to fail" or "hopeless with the outcome beyond doubt." In future cases, this decision will likely be relied upon to argue that the proposition that such claims cannot possibly succeed is unsustainable. ■

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