HOW TO CLAIM REAL DAMAGES IN A HYPOTHETICAL MARKET: A GUIDE FOR GENERIC DRUG MANUFACTURERS IN CANADA

JASON MOSCOVICI*
ROBIC, LLP
LAWYERS, PATENT AND TRADE-MARK AGENTS

On March 14th 2014, a hot trio of highly anticipated patent decisions were rendered by the Canadian Federal Court of Appeal, clarifying the environment under which a Generic Drug Manufacturer ("Generic") can claim the profits it would have made had it not suffered the delays brought on by a Notice of Compliance proceeding taken by the innovator drug company ("Innovator"). More particularly, these decisions related to claims for losses following the dismissal of prohibition proceedings taken by SANOFI-AVENTIS ("Sanofi"), where TEVA Canada Limited ("TEVA") and APOTEX Inc. ("APOTEX") were seeking to market generic versions of RAMIPRIL, using Sanofi's ALTACE® brand Ramipril drug as a reference (collectively "Ramipril proceedings"). Sanofi filed for applications seeking to prohibit the Minister of Health from granting market approvals to TEVA and APOTEX, alleging infringement of patents covering this subject matter that were listed on Health Canada's patent register. [*Apotex Inc.* v. *Sanofi-Aventis*, 2014 FCA 68; *Teva Canada Limited* v. *Sanofi-Aventis et al*, 2014 FCA 67; *Teva Canada Limited* v. *Sanofi-Aventis et al*, 2014 FCA 69].

NOC Proceedings

In order to market a drug in Canada, a notice of compliance ("NOC") must first be obtained from the Minister of Health, in compliance with the *Food and Drug Regulations*[1]. However, if the drug has a patent listed against it on Health Canada's patent register, the Generic would need to address this patent before obtaining its approval, by way of a "Notice of Allegation" ("NOA"), alleging either non-infringement or invalidity of the listed patent. The Innovator who owns the listed patent can then take an action by filing a Notice of Application, seeking a prohibition order prohibiting the Minister of Health from issuing an NOC to the Generic, until expiry of the listed patent.

*From ROBIC, LLP, a multidisciplinary firm of Lawyers, and Patent and Trade-mark Agents. Published in [2014] *Intellectual Property* (Federated Press). Publication 173.030.
[1] C.R.C., c. 870

If such a request for a prohibition order is dismissed, the Innovator becomes liable for the losses the Generic suffered by not being able to bring a drug to market during the prohibition proceedings.

Sanofi had filed such applications to obtain prohibition orders against TEVA and APOTEX, prohibiting the Minister of Health from issuing market approvals for generic versions of RAMIPRIL**,** under the basis of patents that were listed against this active ingredient on Health Canada's patent register. At trial, the Court ultimately dismissed Sanofi's applications; APOTEX AND TEVA both filed subsequent motions to be granted damages for the loss of profit and delay caused by these proceedings. These decisions were appealed and are be discussed below.

Section 8 Damages: A general Overview

Section 8 of the Patented Medicines (Notice of Compliance) Regulations[2] NOC regulations provides a mechanism by which monetary losses can be claimed by a party who was impeded from entering the market following an unsuccessful NOC proceeding. A Generic is therefore entitled to be compensated for any losses starting from the period where it would have received its NOC from the Minister of Health, ending on the period where the innovator company's NOC prohibition proceeding was either withdrawn, discontinued or dismissed, ("Liability Period").

In one of the first cases to award such damages[3], the Court noted that a Generic could not claim damages for future losses caused by erosion of market share. Only compensations for damages suffered during the relevant period, could be granted.

The awarding of damages under this provision is relatively new in Canada and the Courts have had little guidance to help them with the quantification of these losses, or the identification of the Liability Period.

Subsequent cases[4] allowed a party to claim damages resulting from a loss of market share, but only if they are within the Liability Period. No compensation for losses during a Generic's "ramping up" phase could therefore be awarded if this ramping up occurred after the liability period, nor any other such permanent or residual losses.

It was unclear what damages were eligible for compensation. Much of this uncertainty was based on the assessment of the "potential" profits that the Generic may have lost. To calculate potential profits, the Court creates a "hypothetical world" in which the generic company was granted an NOC, unimpeded. However, the components of this hypothetical world were open to interpretation (does this world also comprise the Innovator and/or other competitors?).

[2] SOR/93-133
[3] *Apotex Inc.* v. *Merck & Co. Inc* 2008 FC 1185
[4] *Sanofi-Aventis Canada Inc.* v. *Novapharm Ltd* 2011 FCA 149.

As such, these RAMIPRIL decisions shed a light on the framework for establishing these losses and provide guidance with regards to the construction of this “hypothetical world”.

RAMIPRIL DECISIONS

A) Apotex Inc. v. Sanofi-Aventis et al., 2014 FCA 68

The Court had to study the “liability period” of the claim in this appeal. Summarily, Apotex seemed to have had two kicks at the can with regards to obtaining an NOC for RAMIPRIL. During a first NOC proceeding, Apotex alleged non-infringement of the listed patent, and was unsuccessful. A prohibition order was subsequently granted. Parallel to this, Apotex served a new NOA, alleging invalidity and was successful; the first prohibition order was never reversed. As such, Sanofi alleged that the liability period should only start after the initial prohibition order expires, as Apotex would not have gone to market before then. The Court was not in agreement and considered both files as a whole. The "net effect" was that Apotex was not impeded from going to market and the liability period should therefore not be delayed until the expiry of the first prohibition order.

Regarding the end date of this liability period, multiple patents were listed on Health Canada's patent register by Sanofi. Each proceeding relating to these patents also had different dismissal dates. The question therefore was which of these dismissal dates should be considered to calculate the end date of liability. The Court chose the earlier date: "once […] issued, all pending prohibition proceedings respecting the HOPE patents became moot, and the withdrawal […] of those proceedings under the meaning of [section 8] of the NOC regulations was concomitant to the issuance of the NOC to Apotex"[5].

In addition to the debate surrounding the start and end dates of the Liability Period, the Court considered the characteristics of the "hypothetical world", and gave guidance as to what factors must be taken into account for a "hypothetical market". A Court assessing a hypothetical market needs to consider when competing generic manufacturers also enter the market. In this context, the Court overturned the trial judge's findings with regards to the date when Teva, another Generic, would have entered the market with Apotex. In its assessment, the Court determined that Teva, also involved in NOC proceedings, would have likely a sought summary dismissal of these prohibition proceedings, as soon as it would have determined that it had a fair chance of success. Factually however, Teva would not have been able to obtain summary dismissal any sooner than it had in the real world, and Teva would only have entered the market after Apotex’s Liability Period.

[5] *Apotex Inc.* v. *Sanofi-Aventis et al.*, *2014 FCA 68*, par 97

B) *Teva Canada Limited* v. *Sanofi-Aventis Canada Inc*., 2014 FCA 67

This appeal relates to Teva Canada's claim for damages, after an unsuccessful attempt by Sanofi at obtaining a prohibition order under a previous NOC proceeding. The trial judge assessed the damages awarded to Teva by examining a hypothetical scenario, where Sanofi had not requested a prohibition order against Teva.

On appeal, the Court considered the following series of questions:

1) ***Period for calculating damages***: the Court considered the duration of the period that Teva could have sold the drug had it not been for the prohibition proceedings, as well as the generic drug's hypothetical market share. Teva argued that the start date of the Liability Period (when it would have received an NOC from the Minister of Health) was before the "statutory stay period" (once an NOC proceeding is taken , the Minister of Health cannot issue an NOC for a period of 24 months, this is known as the "statutory stay period"). The Court confirmed that the liability period begins on the date an NOC would have been issued in the absence of an NOC proceeding, and that nothing prevents this period from starting before the statutory stay.

2) ***Hypothetical Market:*** In the Court's consideration of the attributes of the hypothetical market, it was agreed that the market share of other Generics should be considered, as well as their market entry date. The evaluation of Teva's entry into the hypothetical market should be without consideration of the regulations; however, for the other Generics comprising this hypothetical world, the delays brought on by the regulations should apply.

3) ***Authorized Generics:*** the Court assessed if the hypothetical market should account for the presence of generics that were authorized by the Innovator itself. As Sanofi had launched an authorized generic one year before a "real world" generic was authorized to do so, the Court concluded that the hypothetical market must take this into consideration in its assessment.

4) ***Unapproved Indications***: The Court had to consider if compensation could be granted for losses associated with an unapproved indication. Teva had not included any reference to alternative uses of the drug in its application for an NOC, except for use in the treatment of hypertension, which was the subject of the patent held by Sanofi. However, Sanofi had registered several other patents relating to the use of Ramipril in preventing other heart diseases. Given that Teva had not included these other uses in its NOC application, it could not sell the drug for those uses without infringing Sanofi's other patents. The Court rejected Sanofi's argument and concluded that Teva would have been able to sell its generic version of Ramipril for the unapproved indications, without any serious objections from Sanofi as, in the "real world", Sanofi was not enforcing those patents.

The Court added that a Generic cannot always be compensated in such a manner. This is depends on the measures taken by the innovator to prevent such sales and to protect its other patents in the real world market.

5) ***Loss of business value:*** the Court agreed that a company's loss of value is a future injury that cannot be compensated, as only compensation for losses incurred during the liability period is allowed. Similarly, the loss of indirect profits, or the loss of opportunity to reinvest profits, is adequately compensated by pre-judgment interests.

6) ***Ramp-Up***: On the issue of doubling the assessment of the time required to penetrate the market to its full potential (one in the "real world", one in the "hypothetical world": double "ramp-up"), Teva alleged that when it was finally allowed to sell the generic version of Ramipril, it had experienced a ramp-up period and should therefore be compensated. According to Teva, it would be unfair to reduce the number of potential sales during the entry into the hypothetical market without compensating for losses in the real-world market during that same time frame. The Court did not agree. Compensating the generic manufacturer for losses during the ramp-up period is contrary to the established notion that only losses incurred during the liability period can be compensated.

C) *Sanofi-Aventis Canada Inc. v. Teva Canada Limited*, 2014 FCA 69

Summarily, this appeal also addressed the question if compensation for losses of sales for unapproved indications can be granted. Teva sought damages for sales it would have made in connection with other uses of the drug than what was found on the product monograph.

The trial Court found that even if the monograph made no reference to purposes other than for the treatment of hypertension, sales would have been made anyway for other uses of this drug, since in the real market, Sanofi had not objected to the interchange of generic version of Ramipril for each of the other uses.

The Court reiterated that the validity of section 8 was already established by caselaw and further stated that it permits the granting of losses related to unapproved indications. A decision granting damages on such sales depends on the circumstances of each case.

Conclusion

Following the Ramipril decisions, the Courts now have more guidance with regards to the evaluation of the losses that can be claimed by a Generic manufacturer in the context of a section 8 proceeding. While each of these cases can surely be the

subject of further detailed discussions, some of the more relevant teachings can nevertheless be resumed as follows:

1) in a “hypothetical world”, the NOC regulations apply equally to the Generic, and to the competition. When quantifying losses, the NOC regulations are only set aside for the determination of the liability period. The court needs to take into account the administrative delays that each generic company will have when trying to enter the market under the regulations.

As such, the Court determines when the generic manufacturer would have entered the market during the liability period, and what competition it would have faced. It is not presumed that the competition receives its NOC unimpeded. A Generic's market share is also not automatically split with other generics.

2) Since Generic’s must still serve NOAs in the assessment of a “hypothetical world”, the Innovator will still receive notice that a Generic is seeking market approval. The innovator can react and bring its own generic to market sooner. The Court therefore takes the innovator's strategies, as well as the competition’s (for example: if competing generics were trying to enter the market), into account in this hypothetical world. Since the presence of other generics must be considered in the hypothetical market and also the presence of generics authorized by the innovator, the Court may conclude that in the hypothetical market, the innovator would have launched an authorized generic before it actually did in the real world.

2) A Generic is subject to a “ramp-up” in the hypothetical world. This reduces losses, as they would not have been making their “full potential” profits right out of the gate. This reiterates the prior dogma: damages can only be awarded for losses suffered *during* the liability period. The real world ramp-up constitutes damages sustained *after* the prohibition proceedings are completed, and are thus outside the liability period. The fact that the generic will also be facing a ramp-up in the real world is not cause to disregard the ramp-up in the hypothetical world.

3) The period for calculating of losses begins when a notice of compliance would have been issued to a generic in the absence of the NOC proceeding. Nothing prevents this period from beginning before the imposition of a “statutory stay” under the Rules, subject to the discretion of the Court to choose a more appropriate time.

4) Loss of profits can be recovered for sales related to unapproved indications. The decision as to whether or not to grant damages for such sales depends on the circumstances of each case.

ROBIC + LAW + BUSINESS + SCIENCE + ART

ROBIC, LLP
www.robic.ca
info@robic.com

MONTREAL
1001 Square-Victoria - Bloc E - 8th Floor
Montreal, Quebec, Canada H2Z 2B7
Tel.: +1 514 987-6242 Fax: +1 514 845-7874

QUEBEC
2828 Laurier Boulevard, Tower 1, Suite 925
Quebec, Quebec, Canada G1V 0B9
Tel.: +1 418 653-1888 Fax.: +1 418 653-0006

ROBIC, LLP
www.robic.ca
info@robic.com

MONTREAL
1001 Square-Victoria - Bloc E - 8th Floor
Montreal, Quebec, Canada H2Z 2B7
Tel.: +1 514 987-6242 Fax: +1 514 845-7874

QUEBEC
2828 Laurier Boulevard, Tower 1, Suite 925
Quebec, Quebec, Canada G1V 0B9
Tel.: +1 418 653-1888 Fax.: +1 418 653-0006

ROBIC, LLP
www.robic.ca
info@robic.com

MONTREAL
1001 Square-Victoria - Bloc E - 8th Floor
Montreal, Quebec, Canada H2Z 2B7
Tel.: +1 514 987-6242 Fax: +1 514 845-7874

QUEBEC
2828 Laurier Boulevard, Tower 1, Suite 925
Quebec, Quebec, Canada G1V 0B9
Tel.: +1 418 653-1888 Fax.: +1 418 653-0006

ROBIC, LLP
www.robic.ca
info@robic.com

MONTREAL
1001 Square-Victoria - Bloc E - 8th Floor
Montreal, Quebec, Canada H2Z 2B7
Tel.: +1 514 987-6242 Fax: +1 514 845-7874

QUEBEC
2828 Laurier Boulevard, Tower 1, Suite 925
Quebec, Quebec, Canada G1V 0B9
Tel.: +1 418 653-1888 Fax.: +1 418 653-0006

ROBIC, LLP
www.robic.ca
info@robic.com

MONTREAL
1001 Square-Victoria - Bloc E - 8th Floor
Montreal, Quebec, Canada H2Z 2B7
Tel.: +1 514 987-6242 Fax: +1 514 845-7874

QUEBEC
2828 Laurier Boulevard, Tower 1, Suite 925
Quebec, Quebec, Canada G1V 0B9
Tel.: +1 418 653-1888 Fax.: +1 418 653-0006