



## QUANTIFYING DAMAGES AND PROFITS: RECENT TRENDS IN PATENT DISPUTES

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**ABSTRACT.** Calculating the appropriate compensation for a successful plaintiff in a patent dispute is not an easy task. Depending on the context, the plaintiff may be entitled to receive reparation for damages suffered, or recuperate an infringer's profits. In both cases, there is often disagreement as to the appropriate methodology for calculating what the plaintiff is owed.

This conference will provide an overview of the remedies available to plaintiffs in patent disputes, and will review recent case law highlighting the methods used by the courts to quantify damages and profits. Topics covered will include: non-infringing alternatives, price suppression, apportionment, springboard profits, deductible costs, pipefill and tradespend.

**RÉSUMÉ.** Le calcul d'une compensation appropriée pour un demandeur ayant gagné sa cause dans un litige en matière de brevets n'est pas une tâche facile. Selon le contexte, le demandeur peut avoir droit à une réparation pour les dommages subis ou à récupérer les profits d'un contrevenant. Dans les deux cas, la méthode appropriée pour calculer ce qui est dû au demandeur est fréquemment une cause de désaccord.

Cette conférence vise à donner un aperçu des recours offerts aux demandeurs dans les litiges en matière de brevets, et examinera la jurisprudence récente mettant en évidence les méthodes utilisées par les tribunaux pour quantifier les dommages et les bénéfices. Les sujets couverts comprendront: les alternatives non-contrefactrices, la suppression des prix, la répartition, les bénéfices « springboard », les coûts déductibles, le « pipefill » et les dépenses de commercialisation.

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## 1. Patent Infringement Remedies

The *Patent Act* grants patentees the exclusive right to make, use and sell an invention throughout the term of a patent. There is no doubt that patents provide significant commercial value; they are an exception to free competition, and allow patentees to enjoy monopoly for a limited period. As a result, a patentee can profit substantially by receiving proceeds of all sales during the patent period, and by being able to fully establish themselves in the market place before any competitors come along.

Of course, the value of a patent hinges on others respecting the exclusivity granted by the government. When a third party engages in activities which infringe on a patent right, the patentee can suffer significant losses, including loss of potential sales and reduced profits due to competition. Meanwhile, the third-party infringer can see significant profits by making, using or selling a product, which they would not otherwise have the right to do.

Several recourses are available to patentees who are victims of infringement. The patentee can seek an injunction ordering the infringer to cease infringing activities. The patentee can further obtain a court order allowing the seizure and/or destruction of infringing goods. While such recourses can prevent future acts of infringement, in most cases the infringer has already profited from the infringement and/or the patentee has already suffered damages. Fortunately, there are monetary remedies available allowing the patentee to deprive the infringer of its profits or compensate the patentee for the damages suffered.

In most cases, there are two types of monetary remedies available to patentees: damages and an accounting of profits. Damages seek to return the patentee to the position it would have been in had the infringement not occurred by compensating the patentee for the loss suffered due to infringing activities. Accounting of profits, on the other hand, seek to return the infringer to the position it would have been in had the infringement had not occurred, by taking away the benefits it received due to the infringing activities.

As can be appreciated, these two remedies can overlap to a certain extent. Therefore, when taking action against an infringer, the patentee will have to elect one or the other. Deciding which remedy is the most appropriate is very much a strategic question, and will depend on factors such as the type of convincing evidence available to the patentee, and which remedy is expected to result in a more lucrative payout, among others.

### 1.1 Damages

Section 55(1) of the *Patent Act* provides that an infringer is liable for all damage sustained by a patentee due to infringing activities while a patent is in force. The

ways in which a patentee suffers damages can be very different from one case to another, as it depends on how the patentee chooses to exploit their invention. For example, patentees who manufacture and sell products incorporating their patented technology may suffer from lost sales or forced price reduction due to the existence of a competitor. On the other hand, patentees who license their technology to others may miss out on potential royalties.

Even once the nature of the damage has been determined, it can be very difficult to accurately quantify the amount of damage actually sustained. The usual method adopted by the courts is to determine the difference between the patentee's actual financial situation and the financial situation the patentee would have been in if not for the infringement. As can be appreciated, determining the financial situation *but for* the infringement requires courts to essentially make an educated guess. Moreover, there are a variety of secondary factors which the court will have to consider which may have an impact on the patentee's actual financial situation.

In addition to damages sustained while a patent is in force, the *Patent Act* also provides a mechanism for patentees to seek compensation retroactively for acts which took place before the patent was in force. In effect, patents may be pending for several months to several years before they are actually granted, and a patentee will only have a legal recourse against infringers once the patent has actually been granted. During this time, a third party can make, sell and/or use the invention described in a patent application without technically infringing. In order to deter such activities, section 55(2) of the *Patent Act* provides that an infringer is liable to pay reasonable compensation for activities which occurred between the time when the patent was published and when it issued, i.e. the pre-grant period.

Section 55(2) of the *Patent Act* does not award damages *per se*, but rather "reasonable compensation". Generally, reasonable compensation is less than the actual damages suffered by the patentee. The courts have generally equated reasonable compensation with a "reasonable royalty"<sup>1</sup>, and thus instead of calculating the damages suffered, the courts determine an appropriate royalty that the infringer should have paid.

## 1.2 Accounting of Profits

In some cases, awarding damages may not be the most appropriate remedy. For example, a patentee may only suffer minor damages while an infringer profits substantially through their infringing activities. If damages were the only remedy available, an infringer might decide to intentionally infringe with the knowledge that it would still profit even if it is ordered to pay damages to the patentee.

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<sup>1</sup> *Jay-Lor International Inc. v. Penta Farm Systems Ltd.*, 2007 FC 358 at para. 122; *Bauer Hockey Corp. v. Easton Sports Canada Inc.*, 2010 FC 361 at paras. 337, 338, aff'd 2011 FCA 83.

Fortunately, an alternate remedy exists, allowing the patentee to recover the profits gained by the infringer, essentially preventing the infringer from unjust enrichment through their infringing activities. This remedy is known as an accounting of profits. It essentially involves calculating the profits gained by the infringer due to the infringing activities, and ordering the calculated amount to be paid to the patentee as compensation. In some cases, this can amount to more than damages, and would thus be preferable to the patentee.

An accounting of profits is an equitable remedy and is thus made available at the discretion of the court. There are many cases in which the court has refused to allow an accounting of profits as a remedy. Such refusal has been based on the conduct of the patentee (e.g. due to an excessive delay in commencing proceedings, or failure to work the invention in Canada)<sup>2</sup>. In some cases, the courts have refused to award an accounting of profits due to the prohibitive complexity in determining the profits gained.

There are two different approaches as to how profits can be quantified. The first approach is referred to as the “actual profits” approach and involves simply subtracting the costs associated with manufacturing and selling the article from the revenue obtained from the selling the article. This approach is factually based, and the plaintiff has the burden of proving the defendant’s revenue, while the defendant has the burden of proving all costs and apportionment to deduct from this amount.<sup>3</sup> The second approach is referred to as the “differential approach” and involves determining the difference between the defendant’s actual profits and the profits it would have received by using the best non-infringing alternative. Generally speaking, the differential profits approach is preferred.<sup>4</sup>

## 2. Remedies in Patent Infringement: Recent Cases

Once patent infringement has been determined, the matter of quantifying monetary remedies is an important issue in its own right. In practice, there are many contextual and financial factors which can be taken into consideration when calculating profits and/or damages. How the court chooses to treat these factors can be the difference between a plaintiff receiving a large windfall and receiving next to nothing as compensation for infringement. Both parties will therefore bring up every accounting trick in the book so that the court calculates the remedies in their favor.

Due to the complexity and the importance of calculating monetary remedies, patent disputes are often bifurcated into two separate proceedings. A first proceeding

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<sup>2</sup> *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*, (1978), 39 C.P.R. (2d) 191 (F.C.), Collier, J., rev'd 1979 CarswellNat 206 (F.C.A.), rev'd [1981] S.C.R. 504 (S.C.C.); *Invacare Corp. v. Everest & Jennings Canadian Ltd.* (1987), 14 C.P.R. (3d) 156 (F.C.), Collier, J.

<sup>3</sup> *Teledyne Industries Inc. v. Lido Industrial Products Ltd.*, 1979 CarswellNat 781, 45 C.P.R. (2d) 18 (F.C.), varied 1981 CarswellNat 561 (F.C.A.), leave to appeal refused 1981 CarswellNat 813 (S.C.C.).

<sup>4</sup> *Monsanto Canada Inc. v. Schmeiser*, 2004 SCC 34, part D, “Remedy,” at paras 98-105.

focuses on determining whether or not there is infringement (the liability phase), and if necessary, a second proceeding focuses on determining how much the infringer must pay as compensation to the patentee (the remedies phase).

In the past year, there have been several judgements arising out of the remedies phase of patent infringement suits. These judgements highlight some of the complex issues which must be addressed when quantifying monetary compensation, and provide insight as to how different contextual and financial factors are considered by the courts.

## 2.1 *Janssen v. Teva Canada*, 2016 FC 593

In a previous judgement<sup>5</sup>, the Federal Court upheld the validity of Canadian patent no. 1,304,080 (hereafter “CA’080”) to which the plaintiff Janssen Inc. (previously Janssen-Ortho Inc., hereafter “Janssen”) holds a license, and found that the defendant Teva Canada Limited (formerly Novopharm Limited, hereafter “Teva”) was infringing on claim 4 of said patent through the sale of products containing levofloxacin (LEVAQUIN), a drug used to treat a variety of bacterial infections. The court granted an injunction and damages, but decided not to award an accounting of profits, noting that since it is an equitable remedy, the plaintiff has the burden of demonstrating a basis for the exercise of equity, which it did not do in this case<sup>6</sup>.

### 2.1.1 Quantification of Damages – General Principles

The Court was now tasked with determining the type and quantity of damages to award Janssen due to Teva’s infringing activities. To tackle this matter, the Court applied an over 100-year-old doctrine which instructs the exercise of a “sound imagination” and the practice of a “broad axe” to restore the plaintiff to a condition it would have been had the infringement not occurred<sup>7</sup>. This doctrine is particularly appropriate for restoration in patent cases, because not all damages suffered by the plaintiff are accurately quantifiable, and it can be nearly impossible to consider all factors which may have contributed to the damages. It is thus inherently very difficult to attribute a number to the damages suffered by the plaintiff, calling for the Court to do “the best one can” without professing to have been completely accurate and have considered every possible circumstance in a case<sup>8</sup>.

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<sup>5</sup> *Janssen-Ortho Inc. v. Novopharm Ltd.*, 2006 FC 1234, affirmed by the Federal Court of Appeal on June 7, 2007 (Docket No. A-500-06, Reasons cited as 2007 FCA 217). Leave to appeal refused by the Supreme Court of Canada on December 6, 2007 (Docket No. 32200).

<sup>6</sup> *Ibid* at para. 132.

<sup>7</sup> *Janssen v. Teva Canada*, 2016 FC 593 at para. 69. Cited The words of Lord Shaw in *Watson, Laidlaw & Co. Ltd. v Pott Cassels, and Williamson* (1914), 31 R.P.C. 104, pages 117 to 118.

<sup>8</sup> *Ibid* at para. 71.; Cited *Meters Ltd. v. Metropolitan Gas Meters Ltd* (1911), 28 RPC 157 (Eng CA) at page 161.



The Court followed a standard practice for calculating damages in IP disputes, and sought to quantify damages by comparing Janssen's current position with the position Janssen would have been in *but for* the infringement. This comparison would require the court to exercise its sound imagination, as it involved considering theories and predictions provided by expert witnesses from both parties in an attempt to construct a fictional marketplace as it would have existed if Teva had not entered the Canadian marketplace with a generic LEVAQUIN product during the relevant period.

### 2.1.2 Construction of the Fictional Marketplace

As a first step in this assessment, the court examined the marketplace as it existed in fact before and after the respective entry of LEVAQUIN and the corresponding generics. The court took into consideration that there were two other similar products (AVELOX and TEQUIN) which were competitive in the marketplace around the same time that LEVAQUIN was introduced. The court also noted that Teva was the only generic to launch a generic on the market for LEVAQUIN, and that it did so for the 250mg and 500mg strength tablets, but not for the 750mg which were also being sold by Janssen.<sup>9</sup>

As a second step, the court turned to the expert witnesses of both parties to determine what the market might have looked like *but for* the entry of Teva's generic product. The experts on both sides provided several possible scenarios for the court to consider. Unsurprisingly, the experts on both sides diverged from one another quite a bit. Teva's expert submitted that Janssen actually benefited by Teva entering the marketplace by over \$4 million (due to avoiding additional spending), whereas Janssen's expert argued that Janssen actually suffered a loss of \$20 million.<sup>10</sup>

The Court expressed that it had trouble comprehending how Teva would have actually benefitted from Teva being in the market earlier<sup>11</sup>. Ultimately, the Court determined that a scenario presented by Janssen's expert witness was the most likely to have occurred. In this scenario, the expert put forth that LEVAQUIN would have had sales efforts during the Damages Period which were similar to those immediately preceding the Damages Period, and that the market share of LEVAQUIN during those two periods would be essentially the same, i.e. at about 51.8% of the combined levofloxacin and AVELOX market<sup>12</sup>. Although the Court retained the scenario presented by Janssen's expert, it noted that certain changes would have to be made to some assumptions which the expert relied on for his calculations, particularly with respect to the damage period and price suppression.

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<sup>9</sup> *Ibid* at paras 75 to 88.

<sup>10</sup> *Ibid* at paras. 89 to 96.

<sup>11</sup> *Ibid* at para. 95.

<sup>12</sup> *Ibid* at paras. 89 and 106.

### 2.1.3 Damage Period

With respect to the damage period, the court noted that, as previously held in *Merck & Co., Inc. v Apotex Inc.*<sup>13</sup>, a claimant is entitled to damages sustained after a patent has expired, inasmuch as those losses were incurred as a result of infringement during the period the patent was in force. The Court noted that in the present case, even after the patent expires, prescriptions would have to be filled, contracts complied with, and other existing obligations incurred during a period when the patent was in force would have to be fulfilled. The damage period must therefore extend beyond the expiry of the patent.

In the present case, the court noted that customers of levofloxacin can be divided into at least two different groups, and that the damage period would be different for each of these groups. More particularly, a first group corresponds to direct sales to hospitals, and a second group corresponds to retail sales through direct or indirect sales to drug stores. It was determined that the damage period for retail losses would extend two months beyond the expiry of the patent, whereas hospital losses would extend one year after the patent expired.

### 2.1.4 Price Suppression

Another factor in the adjustment related to price suppression. In effect, once Teva had entered the marketplace, Janssen was forced to reduce its price to hospitals to compete. Moreover, Janssen was unable to raise the prices after Teva was forced to withdraw due to the injunction. Citing *AlliedSignal*<sup>14</sup>, the Court noted that price suppression is indeed a type of damage which can be claimed if it can be established that the price reduction was necessary because of the competition of the infringer. The Court was satisfied with the evidence provided by Janssen to this effect, and thus factored price suppression into the awarded damages.

After taking all factors into consideration, about \$19 million in total damages were awarded, including pre-judgement interest. The matter of costs would be determined in a subsequent judgement.

## 2.2 *Apotex Inc. v. ADIR, 2017 FCA 23*

This case is an appeal of a 2015 Federal Court judgement<sup>15</sup> on remedies, in which the defendants, Apotex Inc. and Apotex Pharmachem Inc. (hereafter collectively “Apotex”), were ordered to pay over \$60 million in damages, plus interest to the plaintiffs, ADIR and its affiliate Servier Canada Inc. (hereafter collectively “Servier”).

<sup>13</sup> *Merck & Co. v. Apotex Inc.*, 2013 FC 751 at para. 183.

<sup>14</sup> *AlliedSignal Inc. v. Du Pont Canada Inc.* (1998), 1998 CanLII 7464 (FC), 78 C.P.R. (3d) 129 (FCTD), aff'd 1999 CanLII 7409 (FCA), 86 CPR (3d) 324 (FCA) at para. 23.

<sup>15</sup> *ADIR v. Apotex Inc.*, 2015 FC 721.



In 2008, the Federal Court issued a first judgement on liability<sup>16</sup>, confirming the validity of Servier's Canadian patent no. 1,341,196 (hereafter "CA'196"), and finding that Apotex had infringed this patent through the manufacture and sale of products containing perindopril (COVERSYL), a drug used to treat high blood pressure and heart failure. In this first judgement, the Court allowed Servier to elect between recovering damages or an accounting of profit as a remedy.

During the subsequent trial on remedies, Servier elected an accounting of profits, and the Federal Court was tasked with determining the amount of Apotex's profits which were attributable to the infringing activity. The Federal Court subsequently issued the 2015 judgement ordering Apotex to pay over \$60 million, accounting for Apotex's profits from the sale of perindopril tablets in Canada, as well as the sale of tablets manufactured in Canada to foreign affiliates.

In calculating the profits, the Federal Court had to consider a number of issues, including the relevancy of non-infringing alternatives, and whether a portion of Apotex's revenue was attributable to non-infringing services. These issues are now the subject of the present appeal.

### 2.2.1 Non-Infringing Alternatives – Relevancy for Export Sales

At trial, Apotex acknowledged that there were no non-infringing alternatives available in Canada. Apotex was therefore required to completely disgorge its Canadian profits. However, with respect to export sales, Apotex argued that non-infringing alternatives were available. More particularly, Apotex argued that the perindopril tablets could have been manufactured in countries where it was not protected by patent, and those tablets could have instead been sold to the foreign affiliates. The trial judge rejected this argument as a matter of law, stating that a non-infringing alternative cannot be the product covered by the patent, and further stating that allowing such a defense would provide Apotex with perfect shelter against the consequences of any future patent infringement in Canada.<sup>17</sup>

In the present decision, the Court of Appeal reversed the trial judge's ruling, and decided that the foreign manufactured perindopril is in fact a relevant non-infringing alternative. The Court of Appeal reiterated the importance that a patentee should only receive a portion of the infringer's profits which are causally attributable to the invention, and that this principle cannot be trumped by policy issues such as the desire to avoid providing "a perfect shelter" to infringers. The value of a patent lies in

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<sup>16</sup> *Laboratoires Servier v. Apotex Inc.*, 2008 FC 82, aff'd 2009 FCA 222. Leave to appeal refused by the Supreme Court of Canada on March 25, 2010 (Docket No. 33357).

<sup>17</sup> *Supra note 15* at paras. 119 to 121.

its ability to exclude competitors, therefore quantifying the value of a patent requires the Court to consider all non-infringing alternatives<sup>18</sup>.

In reversing the trial judge's ruling, the Court of Appeal also clarified that the foreign manufactured perindopril should not be categorically excluded as a relevant non-infringing alternative. While the Court of Appeal did not disagree that a non-infringing alternative cannot be the patented product itself, it implied that foreign-manufactured perindopril is not in fact the patented product. In effect, the CA'196 patent has no extraterritorial reach, so it could not prevent Apotex from legally manufacturing the perindopril in jurisdictions where it was not patented. If the foreign-manufactured perindopril were to be considered the patented product, the CA'196 patent would effectively be given extraterritorial reach<sup>19</sup>.

The matter was thus remitted to the Federal Court to recalculate the profits while taking into account the availability of non-infringing alternatives. In remitting this matter to the Federal Court, the Federal Court of Appeal provided guidance as to how to determine the availability of non-infringing alternatives. More particularly, it must be demonstrated that Apotex could have and would have obtained sufficient quantities of non-infringing perindopril, and further that Apotex could have and would have sold these non-infringing quantities to their foreign affiliates<sup>20</sup>.

### 2.2.2 Apportionment

At trial, Apotex argued that its profits should be reduced because a significant portion of its gross revenue for foreign sales of perindopril was not attributed to the perindopril itself, but rather to non-infringing services which Apotex provided as part of the sale. In effect, Apotex was selling the perindopril manufactured in Canada to its affiliates in Australia and the UK. Since perindopril was classified as a "Patent Challenged Product" in these countries (i.e. it presented a high risk of litigation), Apotex agreed to pay an indemnity and provide litigation services if ever its affiliates were faced with litigation. These additional services were accounted for in the price of the perindopril which Apotex sold to its affiliates, as it attempted to demonstrate in its price transfer agreement.<sup>21</sup>

The trial judge acknowledged that apportionment is relevant, in that it allows identifying what profits are causally attributable to the invention. In the present case, the judge was in agreement that the indemnity and litigation offered by Apotex did not constitute an infringement of the CA'916. Therefore, if it could be proven that a part of the price paid by Apotex's affiliates was paid on account of those services, then the revenues should be apportioned accordingly<sup>22</sup>. However, the trial judge was

<sup>18</sup> *Apotex Inc. v. ADIR*, 2017 FCA 23 at paras. 28 and 34

<sup>19</sup> *Ibid* at paras. 32 and 33

<sup>20</sup> *Ibid* at paras. 67 and 68.

<sup>21</sup> *Supra note 15* at paras. 26 and 27.

<sup>22</sup> *Ibid* at paras. 29 and 30.

not convinced that there was enough evidence to prove the link between the higher price and the non-infringing services, and therefore denied apportionment<sup>23</sup>.

The Court of Appeal upheld the decision not to apportion. This decision was primarily based on a causality analysis. In effect, the Court noted that without the infringing perindopril, Apotex would not have been able to make a sale at all. Therefore, the entirety of the profits of the sale were causally attributable to the infringing perindopril.<sup>24</sup>

### **2.3 Airbus Helicopters S.A.S. v. Bell Helicopter Textron Canada Limitée, 2017 FC 170**

Following a previous finding<sup>25</sup> that the defendant, Bell Helicopter Textron Canada Limitée (hereafter “Bell”), infringed on Canadian patent No. 2,207,787 (hereafter “CA’787”) belonging to the plaintiff, Airbus Helicopter S.A.S. (hereafter “Airbus”), the Court has been seized with determining the amount of damages to award to Airbus for the infringement.

The CA’787 patent relates to a skid-type landing gear for helicopters. In 2004, Bell began development of its Bell 429 helicopter, incorporating a “legacy” landing gear which closely resembled the invention covered by the CA’787 patent. Despite being aware of the close resemblance, Bell instructed its engineers to “carry on” with the development<sup>26</sup>. The legacy gear was later modified and replaced with another version of the landing gear which came to be known as the “production” landing gear.

During the liability phase, the Court determined that only the legacy gear had infringed on the CA’787 patent. Bell was thus ordered to destroy all legacy gears still in its possession (save one, for use in foreign litigation), and forbidden from manufacturing, using or selling the legacy landing gear until the CA’787 patent expires. The Court further ruled that Airbus was entitled to damages, both compensatory and punitive, as a result of Bell’s infringement<sup>27</sup>. Now, during the damages phase, the court is tasked with determining the quantum of the damages to which Airbus is entitled.

#### **2.3.1 Compensatory Damages**

The extent of the infringement was not in dispute. Both parties were in agreement that 21 legacy gears were manufactured and used by Bell for a variety of purposes. However, a particularity in this case lies in the fact that the legacy gears were never

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<sup>23</sup> *Ibid* at para. 51.

<sup>24</sup> *Supra note 18* at para. 71

<sup>25</sup> *Eurocopter v. Bell Helicopter Textron Canada Limitée*, 2012 FC 113, aff’d 2013 FCA 219

<sup>26</sup> *Ibid* at para. 10

<sup>27</sup> *Ibid*, Judgement points 1 to 7

actually sold by Bell. Instead, they were used for other purposes, including demonstrations, which allowed Bell to secure sales and effectively realize a significant economic through the use of the infringing gears without selling the gears themselves.

### 2.3.2 Reasonable Royalty

Because no sales were made, Airbus was not in a position to prove it had actually sustained damages through lost profits. The Court therefore found it appropriate to compensate Airbus via a reasonable royalty for Bell's use of the infringing gears<sup>28</sup>. This reasonable royalty would have to be determined by creating a hypothetical negotiation between the parties, and determining what royalty would have been agreed upon on the eve of the first infringement. Of course, the hypothetical negotiation would have to be based on reliable evidence.

Proceeding with a hypothetical negotiation required the court to determine the bargaining power of each of the parties on the eve of the infringement. In following the sample principles applied in previous cases, the court considered a number of contextual factors for this purpose, including: (1) transfer of technology; (2) differences in the practice of the invention; (3) non-exclusive license; (4) territorial limitations; (5) term of the license; (6) competitive technology; (7) competition between the licensor and licensee; (8) demand for the product; (9) risk; (10) novelty of the invention; (11) compensation for research and development costs; (12) displacement of business; and (13) capacity to meet market demand<sup>29</sup>. These factors would ultimately aid the court in assessing the minimum royalty Airbus would have been willing to accept ("minimum willingness to accept", hereafter "MWA") and the maximum royalty Bell would have been willing to pay ("maximum willingness to pay", hereafter "MWP").

### 2.3.3 Non-Infringing alternatives

The court considered the "competitive technology" factor separately from the others. As part of this factor, the Court had to consider the existence and relevance of non-infringing alternatives, and their impact on the negotiating power of the parties and/or on the potential damage suffered by the patentee.

With respect to negotiating power, the existence of non-infringing alternatives may weaken the position of the patentee. When negotiating a license, it is unlikely that a licensee would agree to pay an amount which exceeds the expected benefit he

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<sup>28</sup> *Airbus Helicopters S.A.S. v. Bell Helicopter Textron Canada Limitée*, 2017 FC 170 at para. 112 (citing *Jay-Lor International Inc. v. Penta Farms Systems Ltd*, 2007 FC 358 at para. 123 and *Merck & Co Inc v Apotex Inc*, 2013 FC 751 at para. 41)

<sup>29</sup> *Ibid* at para. 119 (citing factors mentioned in *AlliedSignal Inc v. Du Pont Canada Inc*, 1998 CanLII 7464 (FC), [1998] FCJ No 190, 78 CPR (3d) 129 (FCTD))

would gain from the patent. If there are non-infringing alternatives available, the licensee would benefit less from the patent and would negotiate a lower royalty.

With respect to potential damages, the existence of non-infringing alternatives may reduce the damage attributable to the infringing activities. Without any non-infringing alternatives, every sale made by the infringer could be a potential lost sale for the patentee. However, when a non-infringing alternative exists, the patentee may not be able to claim every sale as a lost sale, as some of those sales may have been lost to lawful competition.

To properly assess the effect of legitimate competition on the negotiations and damages, the Court followed the *Lovastatin* test which was previously laid out by the Federal Court of Appeal<sup>30</sup>. The test directs the Court to answer the following four questions:

1. Is the alleged non-infringing alternative a true substitute and thus a real alternative?
2. Is the alleged non-infringing alternative a true alternative in the sense of being economically viable?
3. At the time of infringement, does the infringer have a sufficient supply of the non-infringing alternative to replace the non-infringing sales? Another way of framing this inquiry is could the infringer have sold the non-infringing alternative?
4. Would the infringer actually have sold the non-infringing alternative?

The court considered several potential non-infringing alternatives, including conventional gear, wheel landing gear, and I-beam cross section gear. However, the court concluded that none of these were true alternatives, as none were found to be economically viable. The only option which was determined to be a true alternative and economically viable was the production gear which Bell had developed. However, the court did not consider the production gear to be a true non-infringing alternative as it was not available on the eve of the infringement, and Bell therefore could not have used it.

Although the production gear did not actually exist on the eve of the infringement, Bell attempted to argue that it had the necessary knowledge and tools at the time to create said gear. Therefore, Bell argued that in a *but for* world, it could have developed the production gear earlier to avoid infringement. The Court did not accept this argument, noting that Bell had not demonstrated that it could have developed the production landing gear from scratch. Moreover, the Court noted that the creation of the production gear was only made possible through the illicit use of the legacy gear. Since Airbus had not granted Bell a license to use the legacy gear for developing a non-infringing alternative, this avenue for obtaining a non-infringing alternative would not have been possible.<sup>31</sup>

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<sup>30</sup> *Merck & Co Inc v Apotex Inc*, 2015 FCA 171

<sup>31</sup> *Supra* note 28 at para. 213

### 2.3.4 Determining the royalty fee

After considering the various factors, the Court determined that Airbus would have been in a much stronger position in a hypothetical license negotiation. The agreed royalty would therefore have been close to Bell's MWP, which was estimated as \$525,000, corresponding to the actual unit price of all the legacy gears that were manufactured for the development of the Bell 429. Moreover, having considered that Airbus would have reasonably requested a minimum of \$250,000 for the costs Bell would have saved from having to develop the production gear from scratch, that Airbus would sought to recover a portion of economic benefits realized from the promotion of the legacy gear, and that the parties would have agreed upon a reasonable risk premium for Airbus to allow its competitor to commercialize its patent, the Court concluded that that Airbus' MWA would be roughly \$475,000. By applying the "broad axe principle" between Bell's MWP and Airbus's MWA, the Court found that an appropriate lump sum for the agreed royalty resulting from the hypothetical negotiation would be \$500,000<sup>32</sup>.

### 2.3.5 Punitive Damages

The Court considered that the awarded damages of 500,000\$ would not be sufficient to achieve the goal of punishment and deterrence. Accordingly, the court ordered Bell to pay an additional 1,000,000\$ in punitive damage. This amount awarded in proportion to the blameworthiness of Bell's actions, to the degree of Airbus's vulnerability, to the harm directed to Airbus, to the need to sufficiently deter infringement, and to the economic advantage wrongfully gained by Bell.

In the present case, the blameworthiness of Bell's action had the most significant impact on the award of punitive damages. During the liability proceedings, the Court had found that Bell's misconduct was planned and deliberate – Bell intentionally imported a helicopter having the patented gear for the purposes of copying it, and subsequently promoted the infringing legacy gear as its own invention. Moreover, Bell is a sophisticated company with an IP department, and had the means to prevent infringement. Despite this, Bell willingly continued its infringing activities for several years.

The need for deterrence was also an important factor for the award of punitive damages. The Court could not accept that Bell intentionally copied Airbus and subsequently claim the invention as its own. The Court wanted to send a message that Bell's conduct would not be tolerated as it went against the core purpose of patent law. An amount no less than \$1,000,000 was necessary to achieve this purpose.

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<sup>32</sup> *Ibid* at paras. 376 to 379



## 2.4 *Dow Chemical Company v. Nova Chemicals Corporation*, 2017 FC 350

This case involves Dow Chemical Company's (hereafter "Dow") Canadian Patent no. 2,160,705 (hereafter "CA'705"), which covers a specific type of polyethylene plastic used to make "film" products, such as plastics bags and food wrapping. In an initial judgement<sup>33</sup>, the patent was held valid and infringed by the defendant, Nova Chemicals Corporation (hereafter "Nova"), due to the manufacture and sale in Canada of its SURPASS brand polyethylene film-grade copolymers. Pursuant to the judgement, Dow was entitled to compensation by electing between damages and an accounting of Nova's profits. Moreover, since Nova's infringing activities took place during the pendency period of Dow's patent, Dow was also entitled to seek reasonable compensation for infringing activities which took place during the pre-grant period.

As part of the present judgement, the Federal Court has been tasked with determining how to appropriately quantify the damages and reasonable compensation owed to Dow.

### 2.4.1 Reasonable Royalty

In the judgement, the Court first addressed the matter of reasonable compensation. Both parties agreed that the proper measure of this compensation would be to calculate a reasonable royalty for Nova's use of Dow's patent during the pre-grant period. The relevant time period was determined to extend between December 9, 2004 and August 21, 2006, i.e. starting on the date Dow had acquired the still pending CA'705 patent application, and ending on the date the CA'705 was granted.<sup>34</sup>

#### i) Hypothetical Negotiation

To determine the appropriate royalty rate, the Court applied the practice laid out in *Allied Signal*<sup>35</sup>, and sought to conduct a hypothetical negotiation between the parties, with the ultimate goal of identifying the royalty rate that would result from a negotiation between a willing licensor and a willing licensee. To conduct this hypothetical negotiation, the Court considered evidence present by expert witnesses on both sides to determine the minimum rate Dow would have been willing to accept (referred to as "minimum willingness to accept" or MWTA), and to weigh this against the maximum rate Nova would have been willing to pay (referred to as "maximum willing to pay" or MWTP).

<sup>33</sup> *Dow Chemical Company v. NOVA Chemicals Corporation*, 2014 FC 844, aff'd 2016 FCA 216

<sup>34</sup> *Dow Chemical Company v. Nova Chemicals Corporation*, 2017 FC 350 at para. 64.

<sup>35</sup> *AlliedSignal Inc. v. DuPont Canada Inc.*, 1998 CanLII 7464 (FC), [1998] FCJ No 190 (TD) at para 199, aff'd [1999] FCJ No 38 (CA)

## ii) MWA vs. MWTP

In calculating Dow's MWTA, the Court considered that it would correspond to the profits Dow expected to lose from licensing its technology to Nova, i.e. the proportion of Nova's sales of SURPASS that would be diverted from Dow's sales of its corresponding ELITE product.<sup>36</sup> Similarly, in calculating Nova's MWTP, the Court considered that it would correspond to the profit that Nova would expect to earn on SURPASS compared to the next best non-infringing alternative.<sup>37</sup>

After reviewing the evidence, the Court found that Dow's MWTA was actually higher than Nova's MWTP. In other words, there would have been no bargaining range between the parties, and it would not have been possible to come to an agreement. However, since the bargaining is compulsory for the purposes of establishing the reasonable royalty, the Court simply accepted Dow's MWTA as the appropriate rate, and set the royalty at 8.8% of Nova's net revenue from sales of the infringing products.<sup>38</sup>

### 2.4.2 Accounting of profits

The next matter addressed by the court was compensation for the period during which the patent was in force. Dow elected compensation by way of an accounting of Nova's profits rather than restitution for damages suffered. Dow therefore bore the burden of proving Nova's sales revenue which were attributable to the infringing activities which took place between when the patent was granted on August 22, 2006, and when the patent expired on April 19, 2014.

## i) Springboard Profits

An important issue under contention was whether Dow should be entitled to "springboard profits". Dow argued that by infringing the CA'705 patent, Nova was able to enter the market early (i.e. "springboard" into the market). As a result, by the time the patent expired, Nova was able to enjoy a higher level of sales than it would have had it waited for the patent to expire before entering the market. Dow therefore argued that Nova continued to profit from its infringing activities even after the patent expired, and should thus be entitled to receive these "springboard profits".

The Court agreed that it was indeed appropriate to award springboard profits to Dow. The Court noted that the purpose of an accounting of profits is simply to give to the plaintiff the profits made by the defendant from the wrongful infringement.<sup>39</sup> The

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<sup>36</sup> *Supra* note 34 at para. 68

<sup>37</sup> *Ibid* at para. 82.

<sup>38</sup> *Ibid* at paras. 87 to 89.

<sup>39</sup> *Ibid* at para. 120.

accounting of profits must be assessed in a *but for* world in which Nova had not yet produced an infringing product at the time of the CA'705 patent's expiry, and springboard profits are a type of gain realized through the infringement which can be proven with evidence.<sup>40</sup>

To calculate the springboard profits, the Court held that the appropriate model in this case would be to consider that Nova would have had to have gone through a progressive ramp-up period after the patent expired to attain the same level of real world sales.<sup>41</sup>

## ii) Deductible Costs

Once revenues have been established, the defendant must prove the appropriate costs to deduct to arrive at the actual profits. In the present case, a significant portion of the costs would be associated with acquiring ethylene, a key ingredient in the manufacture of the plastic protected by the CA'705 patent. However, instead of acquiring ethylene from third parties, Nova produced its own ethylene at its facilities located in Alberta. This enabled Nova to benefit from a significant discount compared to the market price of ethylene.

The Court noted that Nova enjoyed an economic advantage with respect to the cost of ethylene, and that this benefit should be passed on to Dow. Therefore, instead of deducting the cost of ethylene at market price, the Court ruled that it was appropriate to deduct the actual cost Nova incurred to produce the ethylene that was used to make the infringing SURPASS products.<sup>42</sup>

In addition to deducting the cost of producing ethylene, the Court also allowed Nova to deduct several other costs associated with manufacturing the infringing SURPASS products at its plants, including: (i) capital depreciation expenses; (ii) salaries; (iii) overhead; (iv) ongoing capital costs; and (v) plant, distribution, sales & marketing, technical, administration and research and development costs, excluding costs related to research and development. The court opted for this "full costs" approach, as there were no viable non-infringing alternatives available. It was therefore more appropriate to calculate Nova's profits by subtracting its full costs from its revenues, rather than calculating the difference between the profits Nova earned from the infringement less the profits it would have earned had it produced a non-infringing alternative (the "differential costs" approach).<sup>43</sup>

### 2.4.3 Quantum

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<sup>40</sup> *Ibid* at para. 124.

<sup>41</sup> *Ibid* at para. 130.

<sup>42</sup> *Ibid* at paras. 139 and 140.

<sup>43</sup> *Ibid* at paras. 142, 143, 146 and 165.

In subsequent decisions on the quantum, Nova was ultimately ordered to pay \$644.6 million, plus interest, to Dow in damages<sup>44</sup>, and \$4.4 million legal fees and disbursements<sup>45</sup>. This constitutes the largest reported award in a Canadian patent infringement case.

### 3. Remedies Under the Patented Medicines (Notice of Compliance) Regulations

Infringement proceedings are not the only patent disputes which involve a monetary remedy. A recourse for damages also exists under the Patented Medicines (Notice of Compliance) Regulations (hereafter “PM(NOC)”).

In Canada, when an innovator wants to market a new drug, it must first have it approved by Health Canada. In order to do so, the innovator must submit a New Drug Submission (hereafter “NDS”) which sets out the safety and efficacy of the drug as evaluated through thorough testing. Health Canada will review the NDS, and if the drug is approved, it will assign a drug identification number (hereafter “DIN”) to the drug, and will issue a Notice of Compliance (hereafter “NOC”) effectively authorizing the innovator to market the drug. Any subsequent company wishing to sell the same drug must apply for their own NOC. If the drug has already been approved, they need simply file an Abbreviated New Drug Submission (hereafter “ANDS”) claiming bioequivalence to the drug which has already been approved.

The procedure for issuing a NOC is governed by the PM(NOC) regulations, which are designed to promote the protection of patent rights of the innovator. When filing an NDS, the innovator also submits a list of patents which protect the drug in question, and these patents can subsequently be listed on a register. When a generic manufacturer files an ANDS for a drug which has patents listed on the register, the NOC regulations are triggered. Under section 5 of the NOC Regulations, before a NOC can be issued, the generic must address each of the patents listed on the register for the drug in question, and either accept that a NOC will only issue after the patent has expired, or file a Notice of Allegation (NOA) in which it alleges that the patent has expired, that the patent is invalid, or that the patent will not be infringed.

Upon receiving a NOA, section 6 of the NOA Regulations allow the innovator to apply to the Federal Court for an order prohibiting the Minister of Health from issuing a NOC to the generic. Once such an application has been filed, section 7(2) of the NOA regulations provide that a NOC cannot issue for a period of up to 24 months. During this period, the allegations in the NOA can be evaluated by the Federal Court, but the generic will effectively be held off the market. If the Federal Court rules in favor of the generic, the generic will have been unjustly held off the market during the 24 month period. Section 8 of the NOC regulations therefore allow the generic to recover damages sustained from having been held off the market by the innovator.

<sup>44</sup> *Dow Chemical Company v. Nova Chemical Corporation*, 2017 FC 637.

<sup>45</sup> *Dow Chemical Company v. Nova Chemicals Corporation*, 2017 FC 759.

## 4. Recent PM(NOC) Cases

Much like damages in patent infringement, damages under section 8 of the PM(NOC) are restorative in nature. In this case, the recourse seeks to return the generic manufacturer to a position that it would have been in if it had not been held off the market. Damages are therefore calculated in a similar way as in cases of patent infringement, and requires the Court to create a hypothetical *but for* world to assess the extent of the damage. In this case, instead of determining what a patentee's position would have been *but for* the actions of an infringer, the Court must determine what a generic's position would have been *but for* being held off the market. This can involve considering what the generic's profits would have been during the appropriate period.

Given the similarities between the recourses, the manner in which the courts consider factors when assessing damages under section 8 of the PM(NOC) regulations can inform how similar factors could be considered during infringement proceedings, and vice-versa. Two judgements issued this year have helped clarify the factors which the courts will consider when assessing damages under section 8 of the PM(NOC) regulations.

### 4.1 *Eli Lilly v. Teva Canada, 2017 FC 88*

In 2006, Eli Lilly Canada Inc. (hereafter "Lilly") attempted to prevent Teva Canada Ltd (formerly Novopharm Ltd, hereafter "Teva") from coming to market with a generic version of ZYPREXA (olanzapine), a drug primarily used in the treatment of schizophrenia, by filing an application for an order to prohibit the Minister of Health from issuing a Notice of Compliance to Teva. Teva was subsequently held off the market until 2007, pursuant to the regulatory stay in the PM(NOC) regulations. In 2007, Teva was finally able to enter the market after the proceedings under the PM(NOC) regulations concluded with a ruling in Teva's favor<sup>46</sup>.

Lilly subsequently brought an action against Teva alleging infringement of its patent for olanzapine<sup>47</sup>. The Court ultimately concluded that Lilly's patent was invalid, and confirmed that Teva was entitled to damages under section 8 of the PM(NOC) regulations for the period of time during which it was unjustly held off the market. In the present judgement, the Court has been tasked with determining how to calculate the amount of damages to which Teva is entitled.

#### 4.1.1 Quantum of Damages – Overview

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<sup>46</sup> *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2007 FC 596

<sup>47</sup> *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2009 FC 1018.

The Court sought to tackle this issue by creating a hypothetical world which would have existed *but for* Teva being held off the market. The damages could then be quantified by comparing Teva's situation in the *but for* world with its actual situation in the real world. In constructing the hypothetical world, the court relied on opinions provided by expert witnesses, noting that testimony provided by fact witnesses would be inadmissible for this purpose.<sup>48</sup>

During this exercise, there were a number of elements which the court would have to take into consideration, including the duration of the liability period, Teva's hypothetical market share *but for* the infringement, and finally any factors which may have varied Teva's actual losses.

#### 4.1.2 Liability Period

With respect to the liability period, there was no disagreement between the parties that the end date should correspond to the date on which a decision dismissing Lilly's application under the PM(NOC) proceedings was rendered, i.e. on June 5, 2007. However, there was some contention as to when the liability date should have been considered to have started.

As a first position, Lilly tried to argue that Teva had effectively abandoned its claim to damages under section 8 of the PM(NOC) regulations, and that there should be no liability period. In effect, Teva had filed a first NOA alleging the invalidity of Lilly's olanzapine patent on August 5, 2004. Lilly responded to the NOA by applying for a prohibition order, and filed evidence to this effect. Teva subsequently withdrew its NOA and subsequently served a new one. After Lilly tried to recover costs, Teva claimed it was prejudiced from the delay resulting from the withdrawal, partially because it had "abandoned its claim to s. 8 damages".

Lilly thus put forth that Teva was estopped from subsequently claiming s. 8 damages. However, the court disagreed with this position, and was of the opinion that this abandonment related only to s. 8 damages relating to the first proceeding, and that it would have no bearing on whether or not Teva could seek s. 8 damages in the second proceeding.

As an alternative position, Lilly attempted to argue that although Teva would have received its NOC on March 3, 2006 in the *but for* world, it would not have been able to enter the market right away. According to Lilly, it would have taken Teva up to a year to actually make it into the market following the issuance of the NOC.

After reviewing the evidence, the Court disagreed with Lilly, and found that Teva would not have had any trouble entering the market upon receiving the NOC. The

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<sup>48</sup> *Eli Lilly v. Teva Canada*, 2017 FC 88 at para. 11



court thus ruled that the start date of the liability period was the date on which Teva would have received the NOC, i.e. on March 3, 2006.<sup>49</sup>

#### 4.1.3 Teva's share of the olanzapine market

In order to properly quantify the damages, an important question which the Court had to answer is what would Teva's share of the olanzapine market have been *but for* being held off the market during the liability period. The Court took a systematic approach to answer this question, and broke the problem down into three distinct steps: first, determining the overall size of the olanzapine market in the *but for* world, second, determining the generic's share of the overall market in the *but for* world, and finally, determining what Teva's share of the generic olanzapine market would have been in the *but for* world.

In regard to the overall size of the olanzapine market in the *but for* world, both parties agreed that it would have been the same as the real-world market. In other words, the size of the market would not have been affected by the introduction of a generic version of the drug.

Next, in regard to the generic's share of the olanzapine market, the parties were in dispute as to the speed with which a generic company could have entered the market in each province. In order to resolve this issue, the court looked at how long it took Teva to enter the market in each province following receipt of a NOA in the real world. The Court noted that there were some factors which slowed down Teva's entry into some provinces, and that these factors would not have been applicable in the hypothetical world.<sup>50</sup>

Finally, in determining Teva's share of the generic olanzapine market, the Court had to consider whether there were any generic competitors during the liability period, and if so, how they would stack up against Teva. Lilly attempted to argue that Teva would have had to share the generic market with Apotex, another generic company. However, the Court noted that Apotex was also held off the market due to prohibition proceedings, and that in the *but for* world, Lilly would have proceeded with the prohibition proceedings against Apotex even if Teva had obtained its NOC. As a result, Apotex would have been kept off the market in the *but for* world, at least during the liability period, and that Teva would therefore be the only generic on the market. The Court thus determined that Teva would have the full share of the generic olanzapine market during the liability period.<sup>51</sup>

With Teva's share of the generic market being determinable, the losses suffered would essentially be tied to the sale price of the generic olanzapine in the hypothetical world. In the present case, the Court determined that the appropriate

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<sup>49</sup> *Ibid* at para. 43.

<sup>50</sup> *Ibid* at paras 45 to 83.

<sup>51</sup> *Ibid* at paras 84 to 88.

sale price would be 70% of the brand price in each province. However, Teva's potential profits in the hypothetical world are not solely based on sales revenue during the liability period, and other factors such as costs and/or non-immediate losses would have to be considered to assess Teva's actual damage suffered. In the present case, the Court addressed two issues to this effect: pipefill and trade-spend.

#### 4.1.4 Pipefill

Pipefill refers to the quantity of sales Teva would have made to distributors in the *but-for* world that would not be included in retail sales figures. In practice, before a product can be sold to consumers, the product must make its way through the appropriate channels. For example, a manufactured product may sit in a factory's inventory for a while before being shipped to wholesalers, and may sit in inventory at the wholesaler before being sent to retailer, and finally may sit on a pharmacy shelf before ultimately being dispensed to a consumer.

Teva argued that it would be appropriate to include an amount for pipefill in calculating their losses in this case, and that an adjustment for pipefill was awarded in the past<sup>52</sup>. However, the Court noted that the issue of pipefill was not seriously addressed in past proceedings, and its quantum was never specifically calculated. The Court ultimately denied compensation for pipefill, reasoning that any discrepancy between retail sales and the amount of product leaving the manufacturer's factories would represent future sales. Such sales cannot be compensated under section 8 of the PM(NOC) Regulations, as they are sales which would take place after the end of the liability period.<sup>53</sup>

#### 4.1.5 Trade-spend

Trade-spend represents additional costs paid by generics to build relationships with retailers. Such costs can include rebates, trade allowances, educational subsidies, purchasing incentives, etc. In multi source markets where several generics are manufacturing the same product, generics will generally compete with one another through the amount of trade-spend they are willing to provide. Generally, retailers will have a greater incentive to sell the generic product from a manufacturer from which they receive the most trade-spend. Trade-spend is generally considered a normal expense, and would be factored in when assessing a generic's profits.

In the present case, Lilly attempted to argue that Teva's trade-spend in the *but for* world would be the same or higher as the average for all products in the real world, and that Teva's hypothetical profits should be discounted by a corresponding

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<sup>52</sup> See *Apotex Inc. v. Sanofi-Aventis*, 2012 FC 553 (CanLII) at paras 221-226, *aff'd* 2014 FCA 68 (CanLII); *Teva Canada Limited v. Pfizer Canada Inc.*, 2014 FC 248 (CanLII) at paras. 186-190; and *Apotex Inc. v. Takeda Canada Inc.*, 2013 FC 1237 (CanLII) at paras. 119-120.

<sup>53</sup> *Supra note 48* at paras. 102 and 103.

amount. The Court disagreed with Lilly's position, noting that Teva would have been the only generic on the market during the liability period. As a result, Teva's trade-spend would be relatively low. To arrive at an appropriate figure, the Court used an analogous drug, venlafaxine, as a model, as it is a sole-source product in the same therapeutic class that was marketed during the relevant time frame. Based on the trade-spend calculated for venlafaxine, the court arrived at a figure of 29.4% of trade-spend for olanzapine.<sup>54</sup>

## 4.2 *Teva Canada v. Pfizer, 2017 FC 332*

Shortly after the olanzapine decision, the Federal Court issued another decision relating to section 8 damages which also involved Teva. This time, the dispute was between Teva and Pfizer Canada Inc. (hereafter "Pfizer"), and was related to the sale of product containing pregabalin (LYRICA), a popular drug used to treat epilepsy, neuropathic pain, fibromyalgia, and generalized anxiety disorder. Teva sought damages under section 8 for having been held off the market while Pfizer commenced prohibition proceedings. Pfizer ultimately discontinued the proceedings on February 14, 2013, at which point Teva was finally able to enter the market.

### 4.2.1 Quantum of Damages – Overview

The court followed the same steps as *Eli Lilly v. Teva Canada* to construct the *but for* world and assess the damages, i.e. determine the duration of the liability period, determine the overall size of the pregabalin market during the liability period, determine the generic's share of the overall pregabalin market during the liability period, determine Teva's portion of the generic market during the liability period, and finally quantify the actual damages that Teva would have suffered. Citing a recent judgement<sup>55</sup>, the Court noted that in constructing the *but for* world, it would have to consider both what *could* have happened, and what *would* have happened. *Could have* requires proof that nothing made it impossible for Teva to be in a certain position, and *would have* requires proof that events would transpire to put Teva in that position.<sup>56</sup>

### 4.2.2 Liability Period

In determining the liability period, there was no disagreement that the end date would correspond to the date on which Pfizer discontinued its prohibition proceedings, i.e. on February 14, 2013. However, the parties were in disagreement as to the appropriate start date. In particular, both parties had a different view as to the date which Teva would have been able to obtain its NOC and enter into the market.

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<sup>54</sup> *Ibid* at para. 120.

<sup>55</sup> *Pfizer Canada Inc. v. Teva Canada Limited*, 2016 FCA 161.

<sup>56</sup> *Supra note 48* at para. 12.

In order to settle this disagreement, the Court attributed a significant importance to events which took place in the real world in order to predict what Teva's actions might have been in the *but for* world. Teva had argued that in the *but for* world, it would have acted expeditiously to obtain an NOC to allow it to launch as soon as possible. However, in the real world, Teva did not act expeditiously in responding to the patent hold letter it had received.

Generally speaking, if a generic is serious about bringing a product to market, it will act very quickly upon receiving a patent hold letter such that the two year stay period which is initiated thereafter will end as soon as possible. Since Teva did not act quickly in the real world, Teva's argument that it would have acted quickly in the *but for* world was not convincing. The Court ultimately decided that a start date of August 26, 2010 was appropriate, thus corresponding to the patent hold date.

#### 4.2.3 Teva's share of the pregabalin market

The Court relied on the evidence provided by Teva's expert witness in order to establish the total size of the pregabalin market and the generic's portion of the pregabalin market in the *but for* world, stating that it was more balanced and fair than that of Pfizer's expert. With respect to Teva's share of the generic pregabalin market, there was some dispute as to whether Teva would have faced delays entering the market, and whether Teva would have to share the market with other generic competitors. After considering the evidence, the Court concluded that Teva would have been able to launch the pregabalin without delays, and that there would not have been any third-party or authorized generics in the market during the liability period. Teva was thus considered to have the full share of the generic pregabalin market during the liability period.<sup>57</sup>

#### 4.2.4 Pipefill and Trade-spend

As with the *Eli Lilly v. Teva Canada* judgement, the Court considered the effect of trade-spend on Teva's profits. To estimate the appropriate trade-spend, the Court again considered the real-world trade-spend of another drug subject to similar market conditions, in this case risedronate. The trade-spend rate was ultimately set at 35%.

Unlike the *Eli Lilly v. Teva Canada* judgement, the Court accepted an adjustment in Teva's profits to account for pipefill. According to the Court, the Federal Court of Appeal made it clear in a previous decision<sup>58</sup> that section 8 damages are restricted to what would occur in the *but for* world during the liability period, thus precluding double ramp-up compensation. Said the Court: "To the extent that pipefill or inventory adjustments represent sales lost in the BFW, they are appropriate. To the

<sup>57</sup> *Ibid* at paras. 217, 244, and 258.

<sup>58</sup> *Apotex Inc. v. Sanofi-Aventis*, 2014 FCA 68 at paras. 156-159, aff'd 2015 SCC 20.

extent that they are a disguised method of compensating for double ramp-up, they are not.”<sup>59</sup>

## 5. Conclusion

Although not ground breaking, the recent judgements from the Federal Court and Federal Court of Appeal discussed above have shed light on the direction in which the courts are headed when calculating damages and profits in patent disputes. It appears that the courts are open to considering a wide range of factors, provided those factors can be demonstrated as being causally linked to the plaintiff’s damages and/or the defendant’s profits.

Most notably, non-infringing alternatives seem to have been cemented as a relevant consideration in calculating both damages and profits. Future cases may therefore see defendants rely more heavily on a non-infringing alternatives defense to reduce the compensation they will be required to pay. Such a defense is not always available, however, as the defendant must be able to demonstrate that it could have and would have been able to rely on the non-infringing alternative. When a non-infringing alternative is not available, the court can fall back on the less preferred actual profits approach, and calculate profits by deducting an infringer’s full costs from its revenue.

With respect to profits, the courts are willing to apportion between total profits and profits attributable to the invention. However, it appears that the bar is quite high for apportionment to apply in practice, as the defendant has the onus of demonstrating that the apportioned profits are not causally attributable to the invention.

It has also been confirmed that “springboard” advantages are a relevant consideration in an accounting of profits. It has already been well established that “springboard damages” can be awarded in the context of calculating damages. However, the *Dow Chemical* judgement effectively confirmed that this principle applies in the context of an accounting of profits as well. This allows a plaintiff to receive profits gained by an infringer after a patent has expired, provided those profits are attributable to the infringing activities which took place while the patent was in force.

Finally, with respect to damage calculations, the courts have confirmed that price suppression and trade-spend are relevant factors to consider. However, the relevancy of pipefill is still uncertain, as two recent Federal Court decisions had completely different views on this matter. It remains to be seen whether the Federal Court of Appeal can weigh in and clarify the situation.

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<sup>59</sup> *Supra note 47* at para. 311.

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# ROBIC

- + LAW
- + BUSINESS
- + SCIENCE
- + ART