Federal Court  Cour fédérale

Date: 20160531

Dockets: T-2175-04
T-2056-11

Citation: 2016 FC 593

Toronto, Ontario, May 31, 2016

PRESENT: The Honourable Mr. Justice Hughes

Docket: T-2175-04

BETWEEN:

JANSSEN INC. AND DAIICHI SANKYO COMPANY, LIMITED

Plaintiffs
(Defendants by Counterclaim)

and

TEVA CANADA LIMITED

Defendant
(Plaintiff by Counterclaim)

Docket: T-2056-11

AND BETWEEN:

JANSSEN-ORTHO LLC, JANSSEN PHARMACEUTICALS, INC., and OMJ PHARMACEUTICALS, INC.

Plaintiffs

and

TEVA CANADA LIMITED and DAIICHI SANKYO COMPANY, LIMITED

Defendants

PUBLIC JUDGMENT AND REASONS

[1] This decision relates to the determination of damages and quantification thereof arising out of a Judgment of this Court in Action No. T-2175-04 dated October 17, 2006, in which I determined that Claim 4 of Canadian Patent No. 1,304,080 was valid and had been infringed by the Defendant, Novopharm Limited, now Teva Canada Limited. I granted an injunction and damages but not profits. That decision, Reasons cited at 2006 FC 1234, was 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 was refused by the Supreme Court of Canada on December 6, 2007 (Docket No. 32200).

[2] For the purposes of this decision, the operative part of my previous Judgment, following a declaration as to validity and infringement of Claim 4 and an award of damages (as subsequently affirmed aforesaid), is as follows:

> 3. *The Defendant may, at its election, do one of the following in respect of levofloxacin containing products in its possession, custody or control as of the date of issue of this Judgment:*
>
> *a. Sell them in the normal course of business in accordance with paragraph 2 above, provided that all unsold product at the end of the thirty (30) day period shall be treated in the manner provided in one of b) or c) below;*
>
> *b. Destroy them and provide an appropriate affidavit of a responsible officer of the Defendant to that effect; or*
>
> *c. Deliver them up to the Plaintiffs at a place and manner as the Plaintiffs may direct provided that if such delivery is to take place outside of*

the Greater Toronto area it shall be at Plaintiffs' expense;

4. *The Plaintiffs are entitled to receive from the Defendant all damages sustained by them by reason of the activities of the Defendant which infringe claim 4 of the Patent. A separate trial, preceded by discovery if requested, shall be held as to the quantum of damages and interest as awarded herein. Any monies paid as set out in paragraph 2 above shall be taken into consideration by way of set off or otherwise, in the final calculation of damages.*

5. *The Plaintiffs are entitled to pre-judgment interest on the award of damages, not compounded, at a rate to be calculated separately for each year since infringing activity began at the average annual bank rate established by the Bank of Canada as the minimum rate at which it makes short term advances to the banks listed in Schedule 1 of the Bank Act, RSC 1985, c. B-1;*

6. *The Plaintiffs are entitled to post judgment interest, not compounded, at the rate of five percent (5%) per annum. This interest shall commence upon the final assessment of the monetary damage amount, prior to that, pre-judgment interest shall prevail;*

[3] The following is an Index to the topics covered in these Reasons, by paragraph number:

I. THE PARTIES

[4] The Plaintiff in Action No. T-2175-04 is Janssen Inc. (previously Janssen-Ortho Inc.) and is referred to herein as Janssen Canada. It was found, in my previous Reasons at paragraph 3, to be a Canadian Company which is licensee of the Plaintiff, Daiichi Sankyo Company, Limited, hence is a person claiming under the patent at issue.

[5] Daiichi Sankyo Company, Limited, referred to herein as Daiichi, was found in my previous Reasons at paragraph 2 to be a Japanese company and owner of the patent at issue. Daiichi, as an owner of that patent, is also a named Defendant in Action No. T-2056-11. By letter to the Court dated November 9, 2012, Daiichi's solicitors stated that it does not intend to participate in this proceeding, that it has settled its damage claim against Teva Canada Limited, and that Daiichi will abide by the outcome decided by the Court herein.

[6] The other Defendant in Action No. T-2056-11, and only Defendant in T-2175-04, is Teva Canada Limited. At the time of my earlier decision in T-2175-04, it was known as Novopharm Limited. I found in my previous Reasons at paragraph 4 that it was a Canadian-based corporation which had, since about December 2004, been marketing and selling levofloxacin products in Canada. I will generally refer to this party as Teva although sometimes it may be referred to as Novopharm.

[7] The Plaintiffs in Action No. T-2056-11, are three Janssen-related companies. Janssen-Ortho LLC is a Delaware limited liability company and is sometimes referred to in the evidence as JOLLC. Janssen Pharmaceuticals, Inc. is Pennsylvania corporation and is sometimes referred to in the evidence as JPI or Janssen US. OMJ Pharmaceuticals, Inc. is a Delaware corporation and is sometimes referred to in the evidence as OMJ. Collectively, JOLLC and OMJ are sometimes referred to as Janssen Puerto Rico.

II. PATENT AT ISSUE

[8] The patent at issue is Canadian Patent No. 1,304,080 which will be referred to as the 080 Patent. The application for that patent was filed in the Canadian Patent Office on June 19, 1986, thus the patent is governed by the provisions of the "old" (pre-October 1, 1989) *Patent Act*, RSC 1985, c. P-4. The patent was issued and granted to Daiichi on June 23, 1992, and expired seventeen (17) years from that date; that is, on June 23, 2009.

[9] Claim 4 of the 080 Patent was held by my previous Judgment to be valid and infringed by Teva by its sale, offering for sale, and other dealings in levofloxacin containing products in Canada. On October 17, 2006, I enjoined Teva from further sale and other dealings in levofloxacin containing products in Canada subject to a thirty (30) day sell-off period to permit it to dispose of such products subject to payment to Janssen. Teva took advantage of this sell-off period and has already paid Janssen in respect of such products. The expert witnesses have taken this payment into account in their calculations.

[10] After the patent expired on June 23, 2009, Teva as well as any other person, was able to sell and otherwise deal in levofloxacin containing products in Canada free from a claim for infringement of the 080 Patent.

III. JANSSEN'S PRODUCTS

[11] Janssen Inc. has sold and otherwise dealt with levofloxacin containing products in Canada since about 1998. They have been provided at various times in tablet form having strengths of 250 mg, 500 mg and 750 mg under the name LEVAQUIN.

[12] Janssen Inc. also sold and otherwise dealt with levofloxacin containing intravenous solution products in Canada but is not claiming damages in respect thereof in this action.

IV. TEVA / NOVOPHARM PRODUCTS

[13] The Defendant, Teva/Novopharm, introduced its generic levofloxacin containing tablets into the Canadian market in December 2004, and continued to sell and distribute them until the injunction was granted by this Court on October 17, 2006, subject to the thirty day sell-off period aforesaid. These tablets were sold in 250 mg and 500 mg strengths under the name Novo-levofloxacin.

V. THE EVIDENCE / WITNESSES

[14] The evidence adduced at trial is common to both actions, T-2175-04 and T-2056-11.

a) Agreed Evidence

[15] Counsel have done a commendable job in agreeing to many facts. These are set out in Exhibits A1, A2, A3, A40, and A43. They have also agreed as to several documents, the proof of which may be dispensed with, although the truth of the contents of some of them may be disputed. These documents are contained in seven volumes, each document is provided with a numbered tab; these volumes are collectively marked as Exhibit A4 supplemented by electronically recorded documents in a USB key, Exhibit A14. A booklet containing Notices to Admit and Responses thereto served by each party upon the other was entered as Exhibit A66.

b) Plaintiffs Janssen's Evidence

[16] Janssen called three expert witnesses all of whom submitted Reports which were deemed to have been read into the Record; they were:

1. Dr. Jerry Rosenblatt, Town of Mount Royal, Quebec. His Report and Reply were marked as Exhibits P5 and P6. The parties agreed that he could be called as an expert witness and agreed as to his qualifications as follows:

> *He is an expert in the marketing of pharmaceutical products in Canada and the data analysis and forecasting of pharmaceutical sales and market share in Canada including the impact of generic entry.*

I found him to be straightforward and professional in his evidence. Some of his opinions were based on what he was told by Dr. Chan as to the state of the marketplace in Canada.

2. Farley Cohen, Toronto, Ontario. His reports and schedules to those reports were marked as Exhibits P7, P8, P9, P10 and P11. The parties agreed that he could be called as an expert witness and agreed as to his qualifications as follows:

> *... expert chartered account and chartered business valuator with a specialist designation in investigative and forensic accounting and expertise in the quantification of economic damages, lost profits, and income determination.*

Again, I found him to be straightforward and professional in his evidence. Some of his opinions were based on those of Dr. Rosenblatt and Dr. Chan.

3. Dr. Charles Chan, North York, Ontario. His Report and Reply report were marked as Exhibits P19 and P20. The parties agreed that he could be called as an expert witness but disagreed as to his qualifications. Janssen's Counsel proposed his expertise as follows:

> *...as an expert on the following basis: a medical doctor with a specialist certification in respiratory medicine and expertise regarding respiratory tract diseases, antiinfectives, and prescribing practice including expertise on the Canadian antibiotic guidelines.*

Teva's Counsel did not agree as to his expertise respecting prescribing practice and expertise on Canadian antibiotic guidelines. Having heard Dr. Chan, I accept Janssen's statement as to his qualifications. I have some difficulties with respect to his evidence. While Dr. Chan has a depth of knowledge and years of experience with respect to many of the drugs at issue, he could not answer even simple questions from his own Counsel or cross-examining Counsel without going into long, complex, and often

irrelevant answers. He is undoubtedly a person not used to being challenged as to his opinions as he frequently accused cross-examining Counsel as trying to deceive him or misstate the facts or his answers. I treat Dr. Chan's evidence with caution.

[17] Janssen called seven fact witnesses; they were:

1. Rod Curtis, Markham, Ontario. He is Chief Financial Officer of Janssen's medical operations in Canada. He gave evidence as to the corporate structure of Janssen in Canada and elsewhere in the Western Hemisphere.

2. Jeff Smith, Flemington, New Jersey. He is Vice President, Business Development of Janssen Pharmaceuticals Inc. He has been with Janssen and its predecessors for about three decades and gave evidence as to the evolution of its corporate structure. He provided a corporate chart, Exhibit P17. While I accept his evidence, for what it was, it was not backed up by any documents. I am not surprised that he could not identify documents such as invoices. However, he could not identify more "high level" documents such as apparent license agreements and letters of agreement.

3. John Stewart, Holland Landing, Ontario. He is Business Unit Director of Janssen Inc., and has been involved at the senior level in Janssen Inc. and its predecessors in marketing its levofloxacin products in Canada. He gave his evidence in a straightforward manner in dealing with the marketing strategy and decisions of Janssen in respect of its levofloxacin products in Canada.

4. Seth Fischer, Bridgewater, New Jersey. He was with the Johnson & Johnson organization including various Ortho-McNeil entities for many years in the 1990's and 2000's. He has left the Johnson & Johnson organization and is presently employed by a

different organization in California. He gave evidence respecting the launch of levofloxacin products in the United States and Canada, and the relationship between various Johnson & Johnson entities and Daiichi. He identified several agreements between these entities and Daiichi and e-mail exchanges in respect thereof. He gave his evidence in a straightforward manner.

5. Lindsey Villacis, Flemington, New Jersey. She is a Senior Financial Analyst with the Johnson & Johnson group. She gave evidence as to the documents relating to manufacture and sale of the levofloxacin containing products within the Johnson & Johnson group of companies and, in particular, sales to the Canadian organization. She addressed many sales related documents found in Exhibit P37 but was unable to identify certain documents put to her in cross-examination. She was a straightforward, if careful, witness.

6. Carlos Fernandini, Bayamon, Puerto Rico. He is a Senior Finance Manager of Johnson-Ortho Puerto Rico. He gave evidence as to the shipment of levofloxacin (sometimes called the active pharmaceutical ingredient or API) from Daiichi to the Puerto Rico manufacturing facility and, from there, to Janssen Inc. in Canada. He identified several documents related to these transactions. His evidence was straightforward. He was unable to identify certain documents put to him in cross-examination.

7. Bob Roarty, Flemington, New Jersey. He is Director, Global Finance with the Janssen supply chain division of Johnson & Johnson, New Jersey. He gave evidence as to the physical flow of goods and related paperwork, from Daiichi through Puerto Rico, and then to Canada. This evidence is illustrated in charts entered as Exhibits P39 and

P17. His evidence was straightforward; he identified certain documents in his evidence in chief but could not identify others put to him in cross-examination.

[18] At the conclusion of the evidence of the Plaintiffs' witnesses, Plaintiffs' Counsel tendered an affidavit of Cheewooi Lim, a Japanese resident, who is with the Business Development and Licensing Department at Daiichi. Defendant's Counsel objected to the filing of this affidavit since Lim was not presented for cross-examination and apparently, is precluded from giving sworn evidence in Japan in a non-Japanese proceeding. I entered the affidavit into evidence as Exhibit P41 but indicated that I would give it little, if any, weight.

[19] The Plaintiffs introduced a portion of their Examination for Discovery of the Defendant as Exhibit P42 which was deemed to have been read into the Record.

c) Defendant Teva's Evidence

[20] The Defendant Teva did not call any fact witnesses but did call four expert witnesses. The parties agreed that these four witnesses could be called as experts, and agreed as to the scope of their expertise (Exhibit A45). Their reports were marked as Exhibits and were deemed to be read into the Record. These experts were:

1. Alan Mak, Toronto, Ontario. The parties have agreed as to his expertise:

   ...an expert in litigation and forensic accounting.

   Mr. Mak was provided with a number of assumptions and data and asked to calculate Janssen's losses (gains) consequent upon Teva's entry into the levofloxacin market with a generic product. His reports were marked as Exhibits D46, D47, and D48.

Mr. Mak gave his evidence in a straightforward manner. The opinions and conclusions that he reached however are dependent upon the assumptions that he was asked to make.

2. Dr. Paul Grootendorst, Oakville, Ontario. The parties have agreed as to his expertise:

...an expert in health and pharmaceutical economics.

Dr. Grootendorst was provided with a number of assumptions and data and asked to provide his opinion as to the market share Janssen's levofloxacin products, LEVAQUIN, would have had in the "but for" world had Teva not entered with a generic. His reports were entered as Exhibits D52, D53, with corrections as D54.

His opinions are dependent upon the assumptions which he was given and others that he made. His evidence was given in a frank and straightforward manner.

3. Dr. Lea Katsanis, Westmount, Quebec. The parties have agreed as to her expertise:

...an expert in pharmaceutical marketing.

Her report was marked as Exhibit D55. She gave evidence as to the likely market share that Janssen's Levaquin would have received in the "but for" world had Teva not entered the marketplace concluding that it would have been a declining share. I accept that she was endeavouring to give reasonable opinions although, in cross-examination, she tended to be overly loquacious or confused. When I asked her to compare Dr.Grootendorst's conclusion with hers, she said that they were about the same but that Dr. Grootendorst may have been working with more data than she had.

4. Dr. Andrew Simor, Toronto, Ontario. . The parties have agreed as to his expertise:

> *...an expert in medical microbiology and the treatment of infectious diseases.*

He gave evidence as to the use and recommendations for use (guidelines) of anti-infection drugs including macrolides and quinolones. His reports are marked as Exhibits D58 (2 volumes) and D59. He gave his evidence in a straightforward and candid manner.

[21] The Defendant entered into evidence four volumes of excerpts from its discovery of the Plaintiff in Action No. T-2175-04 as Exhibit D61, and a supplemental volume in the same action as Exhibit D62. Documents referred to in those excerpts were marked as Exhibit D63.

[22] Excerpts from the Defendant's Examination for Discovery of the Plaintiffs in Action No. T-2056-11 were marked as Exhibit D64, and documents referred to as Exhibit D65.

[23] All of this discovery material was deemed to have been read into the Record and, in accordance with the understanding in both these actions, all of these discovery excerpts and documents are applicable equally to both actions.

VI. GLOSSARY

[24] The following is a glossary of some of the terms used in evidence:

1. **Fluoroquinolones** were sometimes referred to in the evidence as **quinolones**. They include medications with generic names ending in –floxacin such as ciprofloxacin (CIPRO), levofloxacin (LEVAQUIN), moxifloxacin (AVELOX), and gatifloxacin (TEQUIN).

2. **Respiratory fluoroquinolones** are a subset of the fluoroquinolones. These are fluoroquinolones that may be used to treat a range of bacteria that cause Respiratory Tract Infections (RTI's) such as S. pneumoniae. Of the fluoroquinolones in the evidence, levofloxacin (LEVAQUIN), moxifloxacin (AVELOX), and gatifloxacin (TEQUIN) are respiratory fluoroquinolones. While ciprofloxacin (CIPRO) is not a respiratory fluoroquinolone, it was used to treat some RTI's in the 2000's.
3. **Macrolides** are a group of antibiotics also used in the treatment of RTI's. They have generic names ending in –omycin and include erythromycin, clarithromycin (BIAXIN BID or BIAXIN XL), and azithromycin (ZITHROMAX).
4. **Beta-lactams** or **β-lactams** are another class of antibiotics. An old example of a beta-lactam is penicillin. Of the drugs in this class, a common element is a molecular structure known as a beta-lactam ring. During the proceedings, mention was made of several of these antibiotics including amoxicillin, cefuroxime, and ceftriaxone.
5. **Combination therapy with beta-lactam and a macrolide** is a combination of one drug from each class that can be used together for the treatment of RTI's.
6. **API** or **active pharmaceutical ingredient** is the active medicinal ingredient in a drug. It is combined with other ingredients, often called excipients, to make the final product (e.g., a tablet). Levofloxacin is an API made by Daiichi and shipped to Puerto Rico where it is mixed with other ingredients (excipients) and made into tablets.
7. **A respiratory tract infection (RTI)** is an infection anywhere along the respiratory tract from the nose to the lungs. They are usually caused by a virus or bacteria and include colds, sinusitis, influenza, bronchitis, and pneumonia.

8. **Community-acquired pneumonia** or **CAP** is one of the more common RTI's. It is a pneumonia developed by someone who has not had contact with a hospital or other medical institution. **Hospital-acquired pneumonia** or **HAP** is a pneumonia developed by someone who has had contact with a hospital or other institution.

VII. ISSUES

[25] There are four issues that the Court must address in these proceedings; the first three are proposed by Janssen, and the fourth by Teva who agrees with the three proposed by Janssen. They are:

1. Does Janssen US have standing to claim damages as a result of Teva's infringement of the 080 Patent?
2. What is the quantum of damages suffered by each of Janssen Canada and Janssen US?
3. How is the pre-judgment interest, if any, awarded to Janssen US to be calculated?
4. Should Janssen Canada have taken steps to mitigate its damages and, if so, when and to what extent?

VIII. ISSUE NO. 1 – STANDING OF JANSSEN US

[26] The 080 Patent is owned by Daiichi and Daiichi has settled its claim against Teva. Janssen Inc., the Plaintiff in Action No. T-2175-04, has a claim for damages against Teva which

claim is contested only as to the quantum of damages, and not its right to damages which right was settled in the earlier decision in this case.

[27] There are three Plaintiffs in Action No. T-2056-11; of these, two, Janssen-Ortho LLC and OMJ Pharmaceuticals Inc. (collectively known as Janssen Puerto Rico), make no claim for damages. That leaves only Janssen Pharmaceuticals, Inc. (JPI or Janssen US) as the entity making a claim for damages in that action.

[28] The claim by Janssen US for damages rests on the provisions of section 55(1) of the *Patent Act* (the provisions are the same in the pre- and post- October 1989 versions of that *Act*) which state that an infringer is liable for all damages sustained not only by a patentee, but also by all persons "claiming under" the patentee.

55 (1) A person who infringes a patent is liable to the patentee and to all persons claiming under the patentee for all damage sustained by the patentee or by any such person, after the grant of the patent, by reason of the infringement.	*55 (1) Quiconque contrefait un brevet est responsable envers le breveté et toute personne se réclamant de celui-ci du dommage que cette contrefaçon leur a fait subir après l'octroi du brevet.*

[29] Who constitutes a person "claiming under" a patentee has generated a good deal of jurisprudence in Canadian Courts. By way of contrast, the United Kingdom *Patents Act 1977*, c. 37, sections 33, 61, 67 and 68, give a right to take action for infringement and to claim remedies not only to the proprietor (owner) of a patent but also to an exclusive licensee provided that the licensee has, within six months, registered the particulars of the licence with the Patent Office. This brings a good deal of certainty to the situation.

[30] The leading case in Canada is the decision of the Supreme Court in *Armstrong Cork Ltd. Canada v Domco Industries Ltd.*, [1982] 1 SCR 907. That case proceeded on an Agreed Statement of Facts. The patent owner (Congoleum) granted to Domco a restricted non-exclusive licence under a patent directed to etched pattern floor coverings. The licence provided that the patentee itself would not enter the Canadian market for three years and would not give a licence to anyone else for five years. The issue was whether Domco was a person "claiming under" the patentee. Martland J., for the Court, reviewed prior decisions including that of the Privy Council in *Spun Rock Wools Ltd. v Fiberglas Canada Ltd.*, [1947] AC 313, and the Federal Court of Appeal in *American Cyanamid Co. v Novopharm Ltd.*, [1972] FC 739. In *Fiberglas,* the Privy Council, at pages 320 to 321, stated that "licensees" were entitled to sue for damages under section 55 of the *Patent Act*. On the facts of that case, however, the "licensee" was an exclusive licence and Counsel sought to distinguish that decision on that basis. Martland J. rejected that submission and stated that there was no valid reason to exclude a non-exclusive licensee from the provisions of the *Patent Act* respecting persons "claiming under" the patentee. He wrote at pages 917 to 920:

> *While it is true that the licensee actually under consideration in the Fiberglas case was said to be "the exclusive sub-licensee" (or "exclusive licensee") under the patent, no information is given in any of the judgments as to the precise nature of the licence, and nothing in the reasons for judgment on this point turned on the distinction between an exclusive licensee and a non-exclusive licensee or a bare licensee. Both Mr. Justice Davis in this Court delivering his and Mr. Justice Taschereau's judgment and Lord Simonds in the Judicial Committee used the general word "licensee"*
>
> *in delivering their judgments. It cannot be supposed that they did so intending that only an exclusive licensee was being considered, particulary when Lord Simonds defined the issue of law as being: "Here the question is whether a licensee is a person claiming under the patentee" (p. 320).*

Armstrong sought to distinguish an exclusive licence from a non-exclusive licence on the basis that the former was a grant of a part of the monopoly and that such a licensee was practically an assignee of the patent for the term of the licence with all the beneficial rights of the patentee. It is difficult to reconcile this reasoning with what was said in Heap v. Hartley (supra) (applied by this Court in the Electric Chain Co. case) in the passage which I have already quoted. I repeat from that passage the following portion which is apt in relation to Armstrong's submission:

> *Now he puts his case in a two-fold manner. He says: "In the first place, as exclusive licensee, I am in the position of an assign of the letters patent for that district and for that term, and as an assign of letters patent, I have a right to restrain any person who is infringing within the district." That argument appears to be based on an entire error with regard to the nature of a license. An exclusive license is only a license in one sense; that is to say, the true nature of an exclusive license is this. It is a leave to do a thing, and a contract not to give leave to anybody else to do the same thing. But it confers like any other license, no interest or property in the thing.*

In my opinion, the reasons which led this Court and the Privy Council to the conclusion reached in the Fiberglas case are as applicable to a nonexclusive licensee as to an exclusive licensee. If an exclusive licensee is a person claiming under the patentee within s. 57(1), and the Fiberglas case so holds, there is no valid basis, under the wording of the subsection, to exclude its application to a non-exclusive licensee, and there is no valid basis for interpreting the Fiberglas case as holding otherwise.

It was also contended on behalf of Armstrong that a non-exclusive licensee has no rights which can be infringed and therefore has no claim against the infringer of a patent. This was the view of Jackett C.J. in the American Cyanamid case. He was of the opinion that the non-exclusive licensee had only a right to use the patent, which right was not affected by its infringement.

This was the legal position, even in respect of an exclusive licensee, prior to the enactment of s. 55 of the 1935 Act. Section 55 was enacted to meet this difficulty and, in my opinion, it has overcome the problem. Section 55(1), by its terms, imposes a liability upon the infringer of a patent to the patentee and also to all persons claiming under him for all damages sustained by the

> *patentee or any such person by reason of such infringement. It is the infringement of the patent which gives rise to a liability. If that infringement causes damage to the patentee or to any person claiming under him, the infringer must compensate for the damage sustained by reason of the infringement of the patent. A licensee relying on this subsection is not claiming against the infringer for infringement of his rights under the licence, he is claiming for the damage he has sustained in consequence of the infringement of the patent.*
>
> *On this point, I adopt the reasons of Sweet D.J. in the American Cyanamid case which have already been quoted.*
>
> *Armstrong contended that the meaning of the word "damages" in s. 57(1) meant loss resulting from interference with the legal rights of the claimant. "Damages", it was said, refers to pecuniary recompense given by process of law to a person for an actionable wrong that another has done to him.*
>
> *The meaning of the word "damages" must be ascertained in respect of its use in this specific statutory provision. In section 57(1) it is provided in terms that an infringer of a patent is liable for all damages sustained by reason of his infringe-*
>
> *ment by a patentee or by any person claiming under him. This is a statutory obligation to pay damages and it applies in favour of any person who comes within the provisions of the subsection. In my opinion, Domco does come within the terms of the subsection.*

[31] The Federal Court of Appeal considered whether a party was a person "claiming under" a patentee in *Signalisation de Montréal Inc. v Services de Béton Universels Ltée* [1993] 1 FC 341(CA). In that case, the owner of a patent directed to machines that moved highway barriers granted an exclusive license to an entity known as Barrier. In turn, Barrier appointed the Plaintiff Signalisation as its exclusive representative in Quebec. Hugessen J.A. took a broad view as to who was a person "claiming under" the patentee. He wrote at paragraphs 24 and 25:

> *24 In my view, a person "claiming under" the patentee is a person who derives his rights to use the patented invention, at whatever degree, from the patentee. The right to use an invention is one the monopoly to which is conferred by a patent.9 When a*

breach of that right is asserted by a person who can trace his title in a direct line back to the patentee that person is "claiming under" the patentee. It matters not by what technical means the acquisition of the right to use may have taken place. It may be a straightforward assignment or a licence. It may, as I have indicated, be a sale of an article embodying the invention. It may also be a lease thereof. What matters is that the claimant asserts a right in the monopoly and that the source of that right may be traced back to the patentee. That is the case with the appellant here.

25 In my view, the appellant has the status to assert a claim for damages under section 55 of the Patent Act and has done so inter alia in the paragraphs in the statement of claim reproduced and summarized above. That statement of claim should not have been struck out.

[32] Décary J.A. disagreed, writing at paragraphs 44 to 46:

44 Nor is it impossible that the appellant may have some ground for bringing action itself against the respondent on the basis of some form of liability in tort.

45 Whether or not there is, or was, any possibility of a contractual remedy against Energy or Barrier or of a remedy in tort against the respondent, it is not for this Court to extend the statutory remedy provided by Parliament. As Judson J. pointed out in Commissioner of Patents v. Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning, [1964] S.C.R. 49, at page 57:

> *There is no inherent common law right to a patent. An inventor gets his patent according to the terms of the Patent Act, no more and no less.*

The same is true of a person who claims under the patentee. That person is the person whom the Patent Act recognizes as such, and no one else. To accept the appellant's arguments would, in my opinion, be to interpret subsection 55(1) of the Act as if the words "claiming under the patentee" did not appear, and as if it were sufficient for damages to have been incurred as a result of the infringement of a patent in order for the injured party to have a remedy under that subsection.

> *46 I therefore conclude that a mere contract of purchase of a patented product does not make the purchaser a person claiming under the patentee within the meaning of subsection 55(1) of the Act.*

[33] Létourneau J.A. agreed with Hugessen J.A. and responded to Décary J.A. in writing at paragraph 51:

> *51 Nor do I believe as my colleague Décary J.A. suggests that the words "persons claiming under the patentee" in subsection 55(1) are more limited than the word "person" in subsections 60(1) and (2) of the Act. In subsection 60(1), it has to be an interested person and therefore it is not unqualified. In subsection 60(2), it has to be a person who uses or proposes to use a process or a person who makes, uses or sells an article that might constitute an infringement of a patent. Likewise in subsection 55(1), it has to be a person who claims under the patentee, that is to say a person who as a user, an assignee, a licensee or a lessee had a title or a right which may be traced back to the patentee.*

[34] The final words used by Létourneau J.A. are instructive; a person "claiming under" who, as a user, an assignee, a licensee or lessee, had a title or a right that may be traced back to the patentee, thus can be a person claiming under the patentee.

[35] There have been a number of more recent decisions of the Courts where consideration was given to whether a person was one "claiming under" a patentee. Some of these decisions dealt with circumstances not unlike those of the present case where it was agreed that, despite the lack of a written agreement, the claimant was part of a family or group of entities all dealing in some way with the patented goods.

[36] In *AstraZeneca Canada Inc. v Apotex Inc.*, 2014 FC 638 (aff'd 2015 FCA 158, leave to appeal to SCC granted March 10, 2016), Justice Rennie (as he then was) made a careful review of the evidence and concluded that one of the Plaintiffs, AstraZeneca Canada Inc., had standing as a person "claiming under". He wrote at paragraphs 10 and 23 to 24:

> *[10] In my view, AstraZeneca Canada has standing. More specifically, AstraZeneca Canada qualifies as a person claiming under the patentee because there is an implied license between AstraZeneca and AstraZeneca Canada regarding the sale of Nexium. However, prior to elaborating on this finding, it is important to note the factual background underlying Apotex's surprisingly technical standing defence against its alleged infringement.*
>
> ...
>
> *[23] In this case, there is something more. Indeed, a number of facts support the finding that AstraZeneca Canada's right of use can be traced back to AstraZeneca Aktiebolag:*
>
> > *1. AstraZeneca Canada and AstraZeneca Aktiebolag are both indirect subsidiaries of a common parent, AstraZeneca PLC, located in Sweden;*
> >
> > *2. AstraZeneca Aktiebolag, the owner of the '653 patent, is the principal source of supply to AstraZeneca Canada and globally;*
> >
> > *3. AstraZeneca Canada sought and obtained regulatory approval to sell Nexium in Canada. The information in support of the regulatory filing derived from AstraZeneca Aktiebolag – the holder of the master regulatory file for Nexium;*
> >
> > *4. AstraZeneca Canada and AstraZeneca Aktiebolag entered into a Formulation, Packaging and Distribution Agreement (Distribution Agreement) in December 2000. In the Distribution Agreement, AstraZeneca Canada is defined as the "Distributor," and is granted non-exclusive rights to the "Products" which are defined to include Nexium. This agreement addresses intellectual property rights in articles 24.1 and 24.2:*
> >
> > *24 INTELLECTUAL PROPERTY RIGHTS*

24.1 All intellectual property rights relating to the Products shall remain the property of ASTRAZENECA at all times. The Distributor shall not acquire any intellectual property rights relating to the Products and shall only have permission to use such rights granted to the Distributor under this Agreement.

24.2 The Distributor will inform ASTRAZENECA of any infringement or suspected infringement of any of ASTRAZENECA's intellectual property rights in the Market which comes to the notice of the Distributor. ASTRAZENECA will take all reasonable steps, at its own expense, to prosecute infringers. The Distributor will give ASTRAZENECA all reasonable assistance in such prosecution [emphasis added].

5. From 2001-2008 AstraZeneca Canada packaged Nexium which it received from AstraZeneca Aktiebolag in bulk tablets, prior to sale in Canada. In 2008, AstraZeneca Canada's packaging facility in Mississauga was closed. The letter agreement between AstraZeneca Canada and AstraZeneca Aktiebolag dated December 12, 2007 stated that after closure, Nexium would be supplied by AstraZeneca Aktiebolag to AstraZeneca Canada in finished packaged form, and that AstraZeneca Canada would continue to act as the distributor. Accordingly, after 2008, AstraZeneca Canada received pre-packaged Nexium from AstraZeneca Aktiebolag for sale in Canada. Thus, AstraZeneca Canada has always received its supply of Nexium (pre-packaged or in bulk) from AstraZeneca Aktiebolag, except for a three month period in 2001 and a six month period in 2012, during which AstraZeneca UK was the source of supply.

6. According to the evidence of Ms. Elaine Campbell, CEO of AstraZeneca Canada, AstraZeneca Canada has obtained the consent of AstraZeneca Aktiebolag to file Form IV patent lists under the PMNOC Regulations;

7. Ms. Campbell testified that all of AstraZeneca Canada's legal costs in respect of this litigation were being paid by AstraZeneca Aktiebolag.

> *[24] When assessed against this factual landscape, AstraZeneca Canada's right to use the patent may be traced back to AstraZeneca Aktiebolag, the patentee. All rights of use of Nexium by AstraZeneca Canada are derivative, by an implied agreement, from AstraZeneca Aktiebolag. While there is no express licence and no plea of licence, the conduct of the parties is consistent with a finding of an implied licence granted by AstraZeneca Aktiebolag. The Distribution Agreement grants AstraZeneca Canada permission to use AstraZeneca Aktiebolag's intellectual property rights "insofar as is necessary to exercise the rights granted" under the Distribution Agreement. These rights include the right to sell Nexium and the obligation to assist AstraZeneca Aktiebolag in the civil prosecution of possible infringement by others. Commencement of an infringement action by AstraZeneca Canada falls within a reasonable interpretation of sections 24.1 and 24.2, and implicit to that is an acknowledgment of a right to recover damages on behalf of the patentee for infringement. Consequently, AstraZeneca Canada is a person claiming under the patentee as required by section 55(2) of the Patent Act and has standing in this trial.*

[37] *In Eli Lilly and Company* **v** *Apotex Inc.*, 2009 FC 991 (aff'd 2010 FCA 240), Justice Gauthier (was she then was) also reviewed the facts thoroughly and concluded that one of the Plaintiffs, Lilly Canada, had standing. She wrote at paragraphs 76 to 83:

> *[76] Lilly Canada does not disagree with the above-noted statements, it simply says that in this case it has not only established, through the testimony of Mr. Pytynia (Transcript Volume 7, pp. 56-63; 83-84) that Lilly Canada is a wholly owned subsidiary, but also that it had an express licence to both the Lilly and Shionogi Patents at issue in this case. It has also been admitted that Lilly Canada has been selling Ceclor® (cefaclor) in Canada since 1980. Lilly Canada made specific references to various exhibits filed during the hearing to support its position, particularly an agreement executed and effective as of January 1, 1991 between Lilly U.S. and Lilly Canada (TX-109) where:*
>
> > *Lilly represents and warrants that for Canada, it has the exclusive right to grant licenses to enable the licensee to make, have made, use and sell certain products, including the right to use within Canada, certain patents, trademarks*
> >
> > *[...]*

> *relating to such products and to their preparation, manufacture, processing and packaging.*

[77] In the said agreement, Lilly U.S. appoints Lilly Canada as its authorized distributor of all Lilly U.S. products in Canada (which includes Ceclor®) and at s. 1.2:

> *Lilly further grants to Lilly Canada a non-exclusive sublicense (without right of further sublicense except as further granted in writing by Lilly) under the Canadian patent applications and patents listed in Schedule "A"*
>
> *[...]*
>
> *to make, have made, use or sell, and/or import Lilly Products whose preparation is covered by the patent applications and patents.*

[78] At pp. 8 and 9 of Schedule A, the four Lilly patents at issue here are listed. Normally, it should thus not be contentious that Lilly Canada has proper standing pursuant to subs. 55(1) of the Patent Act, at least in respect of those patents.

[79] Apotex, however, says that on January 1, 1995, the 1991 agreement was amended (TX-110) to delete the various schedules which, according to Mr. Pytynia, was done to avoid having to keep them up to date which was found to be difficult. According to Apotex, the result of this amendment is simply that licences to the Lilly or Shionogi patents were no longer granted to Lilly Canada.

[80] This, according to Apotex, makes particular sense[23] in respect of the Shionogi patents, given that none of the material purchased by Lilly Canada was made by the processes protected thereunder and that Lilly Canada never actually made, purchased or sold any of the actual compounds claimed in the patents in suit. Apotex also discards the impact of the General Supply and Distribution Agreement, filed as TX-112, on the basis that Lilly Canada's role as distributor appears to be based on an agreement that says nothing about patent rights, nor does it characterize Lilly Canada as an agent and expressly disclaims any other rights flowing between the parties.

[81] The Court agrees with the plaintiff that such an interpretation of the 1991 agreement as amended through time leads to an absurd result and is simply incorrect. The January 1, 1995 agreement expressly states:

> *WHEREAS the parties desire to maintain the rights, licenses and sublicenses granted by the AGREEMENT while also recognizing that the parties will receive full compensation under the Master Supply and Distribution and Manufacturing or other Agreements.*

[82] It is also worth noting that the 1991 agreement was further amended on April 9, 1998 (TX-113) giving Lilly Canada the right to further sub-licence a third party under some of the patents covered by the agreement, in conformity with s. 1.2 of the 1991 agreement. More particularly, the amendment refers to the licence granted under the 1991 agreement for cefaclor and:

> *grants to Lilly Canada the right to sub-license the following licenses granted to it under the [1991] License Agreement (collectively, the "Licenses") for cefaclor: (i) licenses granted under patent rights of Lilly U.S. (including, without limitation, the patents listed in Schedule A hereto).*

Said schedule made specific reference to three of the Lilly Patents in suit (the only ones missing are the '007 and '026, the latter having expired by that time).

[83] Having considered all of the evidence, the Court is satisfied that Lilly Canada has properly established its standing based on an express licence from the patentee.

[38] In *Apotex Inc. v Sanofi-Aventis*, 2011 FC 1486 (rev'd on other grounds, 2013 FCA 186), Justice Boivin (as he then was) reviewed the factual circumstances of the case and concluded that a "Partnership" had standing. He wrote at paragraphs 46 to 48 and 55 to 57:

> *[46] Against this background, the Court now turns to the evidence put before it in connection with the rights conferred to the Partnership.*
>
> *D. The Evidence before the Court*
>
> *[47] During the trial, Dr. Thierry Saugier, Vice-President Alliance and Partnership at Sanofi-Aventis, was called by Sanofi to testify as to the standing of the Partnership. Dr. Saugier testified that, since April 2006, he has managed group of alliances for*

Sanofi-Aventis, including the alliance referred to the Territory B Partnership and the Territory A Partnership.

[48] In particular, Dr. Saugier testified that, in order to structure the alliance, Sanofi granted an exclusive licence for clopidogrel to the Partnership, as can be seen in the Partnership Agreements which are still in effect today. The various agreements produced into evidence indeed support Dr. Saugier's oral testimony as to the rights granted thereunder.

...

[55] The Court believes that such a list could not, on a practical point of view, be amended each time a development occurred in connection with products under research or in a process of a patent application. The terms and scope of the agreement at issue are such that [...] must be interpreted to encompass newly developed compounds. To conclude otherwise would fly in the face of the very purpose of the Partnership Agreements, which was to allow the Partnership to carry out all activities related to the development, manufacturing, sourcing and commercialization of clopidogrel in the specified territory known as Territory B, would otherwise be defeated.

[56] Finally, the Court recalls that counsel for Apotex questioned Dr. Saugier in connection with the absence of manufacturing facilities, employees and registered place of business in Canada in order to demonstrate the lack of standing. In light of the breadth of the Partnership Agreements, the Court finds this line of questioning to be of no assistance for the purposes of the standing issue.

E. Conclusion on Standing

[57] In sum, considering the broad meaning of "persons claiming under" a patentee as referred to under ss 55(1) of the Patent Act, and based on the Court's review of the Partnership Agreements and the testimony given in that regard, the Court finds that the Partnership has a "credible and legally sufficient basis" for claiming under a patentee in the circumstances. Indeed, the evidence clearly shows that the Partnership was granted an exclusive licence for clopidogrel products through the various Agreements as of 1997. It follows that the Partnership has standing to bring the action at issue for any infringement that it alleges to have occurred prior to December 6, 2007.

[39] In *Apotex Inc. v Wellcome Foundation Ltd.*, [2001] 1 FC 495, the Federal Court of Appeal held that, since both the patentee and the person "claiming under" were before the Court and both were asserting that the person "claiming under" had standing, the Court would not deny that standing. Rothstein J.A. wrote at paragraph 99:

> *[99] It is perhaps not uncalled for to observe that this is not a case in which the alleged licensee is alone in advancing its claim for patent infringement. Here, the patentee is also before the Court as a co-plaintiff supporting the claim of GWI. It is difficult to conceive of what more is necessary to prove the existence of a licence than to have the licensor and licensee both attesting to the validity of the licence. Where both the patentee and the person claiming under the patentee are before the Court, are affiliated as being owned by the same parent and have an identity of interest in the litigation--with the patentee supporting the person claiming under the patentee--it is, to say the least, surprising that technical questions of status to sue would be advanced as a defence to infringement.*

[40] In circumstances involving parties who are very similar to those before the Court here, Justice Reed of this Court considered standing in *Kirin-Amgen Inc. v Hoffmann-LaRoche Ltd.* (1999), 87 C.P.R. (3d) 1 (aff'd 11 CPR(4th)78). She wrote at paragraphs 89 to 94:

> *89 Kirin-Amgen is the owner of the '047 patent. That patent issued on May 27, 1997, and as noted, was divided from a more comprehensive patent application that had been filed on December 12, 1984. On September 30, 1985, Kirin-Amgen licensed Ortho Pharmaceutical Corporation (now known as Ortho-McNeil Pharmaceutical Inc.) and its affiliates to use and sell in a number of countries, including Canada, products made in the United States of America that are within the scope of the broader patent application. A written agreement to that effect exists. The recombinant EPO used in the EPREX product that is sold in Canada is made in Puerto Rico, a commonwealth of the United States.*
>
> *90 In 1986 Ortho Pharmaceutical Corporation gave Janssen-Ortho's predecessor a mandate to market and sell EPREX in Canada. No written licence documenting that agreement can be found. No written notice to Kirin-Amgen of that sub-licence has*

been found. Nevertheless, it appears that Kirin-Amgen has had notice that Janssen-Ortho's predecessor and now Janssen-Ortho had been sub-licensed to use and sell the EPREX product in Canada. The EPREX product was launched on the Canadian market in 1990. Since that time, Janssen-Ortho has been paying royalties, first to what was then the Ortho Pharmaceutical Corporation, and more recently to Ortho Biotech Inc. The royalties are then paid to Kirin-Amgen.

91 The rights acquired from Kirin-Amgen in 1985 were subsequently assigned by Ortho Pharmaceutical Corporation (renamed Ortho-McNeil Pharmaceutical Inc.) to Ortho Biotech Inc. under an Asset Transfer Agreement effective January 1, 1998. Kirin-Amgen consented to this assignment.

92 Since no written document could be found of the 1986 agreement between Ortho Pharmaceutical Corporation and Janssen-Ortho's predecessor, a written licence agreement was signed by Ortho Biotech, Ortho McNeil, and Janssen-Ortho on November 20, 1998 confirming that Janssen has been sub-licensed since 1986 by Ortho-McNeil's predecessor Ortho Pharmaceuticals to use and sell products containing erythropoietin in Canada. In the agreement, Ortho Biotech also grants to Janssen-Ortho a non-exclusive right to use and sell licensed products containing erythropoietin as provided in the product licence agreement signed between Kirin-Amgen and Ortho Pharmaceuticals on September 30, 1985. Written notice of this agreement was given to Kirin-Amgen (Exhibit D-6).[para93] It is also necessary to note that the Ortho companies are all affiliated. Johnson & Johnson a New Brunswick, New Jersey corporation owns 100% of the voting stock of Janssen-Ortho. It also owns either directly or indirectly 100% of the voting stock of Ortho-McNeil Pharmaceutical Inc. and Ortho Biotech Inc.

94 Counsel for the plaintiffs argues that applying the test articulated in Apotex Inc. v. Wellcome Foundation Ltd. (1998), 79 C.P.R. (3d) 193 (F.C.T.D.) at 300 - 301, (which test is: can the right asserted by the claimant be traced back to the patentee), leads to the conclusion that Janssen-Ortho is a person "claiming under" the patentee for the purpose of section 55 of the Patent Act. I agree.

[41] In *Jay-Lor International Inc. v Penta Farms Systems Ltd.*, 2007 FC 358, Justice Snider of this Court reviewed the authorities and in particular, the Reasons of Justice Wetston of this

Court, in *Apotex Inc. v Wellcome Foundation Ltd.* (1998), 79 C.P.R (3d) 193, and concluded that the ability of a person to claim under a patentee depends on whether the party can trace an interest under the patent; it does not necessarily require the existence of an express licensee. She wrote at paragraphs 32 to 38:

> *[32] More recently, in Apotex Inc. v. Wellcome Foundation Ltd., 79 C.P.R. (3d) 193, 145 F.T.R. 161, [1998] F.C.J. No. 382 (F.C.T.D.) (QL), aff'd on this point 2000, 10 C.P.R. (4th) 65 (F.C.A.), 262 N.R. 137, (referred to as Wellcome), the court considered the relationship between the two related companies who had brought an action for infringement and provided some helpful analysis on the issue of the right to assert rights under s. 55(1) of the Patent Act. In that case, Glaxo Wellcome Inc. (GWI) claimed that it was entitled to bring an infringement action because it was exclusively licensed by the Wellcome Foundation Ltd. to import, manufacture, use and sell the invention described in the patent. Wellcome was listed as the owner of the patent. Although, no written licence was produced to establish GWI as a licensee, GWI maintained that the licence was implied.*
>
> *[33] The arguments of the plaintiffs in Wellcome were very similar to those made by the Defendants in this case. The plaintiffs asserted that GWI failed to meet its onus to establish that it had an entitlement to sue under s. 55(1) of the Patent Act. They argued that a licence, like any other contract, must be proven according to its terms and effects.*
>
> *[34] In Wellcome, at paras. 360-361, Justice Wetston provided the following comments on the interpretation of s. 55(1):*
>
> > *Canadian jurisprudence has provided a broad interpretation of "persons claiming under" the patentee. A range of interests is held to have been contemplated, including the exclusive licensee, the non-exclusive licensee, the purchaser of a patented articles and sales agents. This interpretation is embodied in Signalisation de Montréal Inc. v. Services de Béton Universels Ltée et al. (1992), 46 C.P.R. (3d) 199 (F.C.A.) per Hugessen J.A. at p. 211:*
> >
> > > *It matters not by what technical means the aquisition of the right to use might have taken place. It may be a straightforward assignment*

> *of a licence. It may, as I have indicated, be a sale of an article embodying the invention. It may also be a lease thereof. What matters is that the claimant asserts a right in the monopoly and that the source of that right may be traced back to the patentee.*

[35] In the Wellcome case, Justice Wetston did not find that a parent/subsidiary relationship exist between GWI and Wellcome. However, the two companies were under the ownership, common care and control of Glaxo Wellcome plc. The evidence was that licences were seldom written. Based upon his review of the facts of the case, Justice Wetston concluded, at para. 367, that "GWI is indeed able to trace an interest under the patent to the patentee in virtue of the corporate practices with respect to implied licensing within the group of companies under the care and control of Glaxo Wellcome plc".

[36] In sum, what I can take from the Wellcome case and other jurisprudence is that the ability of a party to claim under a patentee depends on whether the party can trace an interest under the patent to the patentee and does not necessarily require the existence of an express licence. Where no express licence exists, each case will be determined on its facts.

[37] In the case before me, I am satisfied, on a balance of probabilities, that JAY-LOR Fabricating has met the burden of demonstrating that it can trace an interest under the patent to JAY-LOR International. The key facts supporting this conclusion can be summarized as follows:

- *Both JAY-LOR Fabricating and JAY-LOR International are under the same control of Mr. Tamminga;*
- *No other licence has been granted – either explicitly or by implication – to any third party; and*
- *The two companies have structured their affairs in a manner consistent with a licensee-licensor relationship.*

[38] In conclusion, I am satisfied on this point that JAY-LOR Fabricating has standing to bring this action.

[42] Lastly, I turn to the decision of Justice Snider in *Les Laboratories Servier v Apotex Inc.*, 2008 FC 825 (affirmed without discussion on this point, 2009 FCA 222). She determined that the mere existence of a corporate affiliation is not conclusive of a right as a person "claiming under" a patentee; there must be something more. She concluded that an entity which did not operate "in Canada" was not a person "claiming under" the patentee. She wrote at paragraphs 70, 81 and 82 and 88 to 91:

> *[70] The test for who qualifies as a person claiming under a patentee is not simply whether the patentee has consented to the person being joined as a plaintiff in an action; nor is it enough to demonstrate that two parties are related. In each case, the facts must demonstrate a credible and legally sufficient basis for claiming under a patentee (Jay-Lor International Inc. v. Penta Farm Systems Ltd. (2007), 59 C.P.R. (4th) 228 at paras. 31, 36 (F.C.) [Jay-Lor]).*
>
> ...
>
> *[81] Mr. Langourieux confirmed that none of the non-ADIR Foreign Plaintiffs manufacture, offer for sale or import any of the compounds claimed in the '196 Patent into Canada. He also agreed that each local affiliate in a particular country has the focus of promoting, marketing, and registering the product in its specific jurisdiction. For example, Servier UK promotes, markets, sells and distributes the medicines of Groupe Servier in the U.K. market only. I have seen no evidence that Servier Canada sells perindopril in the United Kingdom. For that purpose, Servier UK exists. Servier Australia promotes, markets, sells and distributes the Servier products in the Australian and New Zealand markets. Manufacturing of the active ingredient (the API) in COVERSYL is done by Oril Industries in France. Thus the evidence shows that the affiliated companies within Groupe Servier do not operate as a single entity; each has its own sphere of operation and its own responsibilities within Groupe Servier. Nevertheless, the non - ADIR Foreign Plaintiffs may still be able to satisfy s. 55(1) of the Patent Act, through a licence or other such arrangement.*
>
> *[82] As noted above, the mere existence of a corporate affiliation is not conclusive evidence of a right under s. 55(1) of the Patent Act. There must be something more. That something more has consistently been described in the jurisprudence as a "licence" or some other arrangement (for example, a lease, an*

assignment, or a sale) that would give the affiliate the right to use the patent.

...

[88] As shown by the evidence, none of the non-ADIR Foreign Plaintiffs operates in Canada. In final argument, counsel for Servier tried to counter Apotex's arguments on the use of the patent by the non-ADIR Foreign Plaintiffs through the following hypothetical:

> *It is wholly conceivable that if Servier Australia ran out of perindopril and Servier Canada had too much of it, that Servier Australia would purchase perindopril from Canada, or even in Canada.*
>
> *My friends' position would either prevent that situation from happening, because Servier Australia would not have a licence in Canada, or would make everybody stop, negotiate a sublicence under the '196 Patent, or bring in Adir to award Servier Australia a licence under the Canadian patent.*
>
> *That is nonsensical . . . when we view the manner in which the Servier group of companies views itself and operates.*

[89] There are two problems with this line of reasoning. First, this argument is not based on any evidence that this has ever happened in the history of Groupe Servier; it is totally speculative. Secondly, it is not at all "nonsensical" to require affiliates to enter into some type of document to reflect legal rights.

[90] Further, none of these Plaintiffs has ever needed a licence in respect of the '196 Patent because none of their foreign activities relating to the manufacture, use or sale of perindopril can constitute an infringement of the '196 Patent.

[91] Quite clearly, the non-ADIR Foreign Plaintiffs do not use the '196 Patent in Canada or elsewhere. They do not need a licence from ADIR in respect of that patent. It is a stretch to say that the non-ADIR Foreign Plaintiffs are parties to an implied licence for the '196 Patent when no such licence is required.

[43] From all this jurisprudence, I determine that for a Court to conclude that a party is a person "claiming under" the patentee for the purposes of section 55(1) of the *Patent Act*:

- the person must be one who, as a user, an assignee, a licensee or lessee has a title or a right that can be traced back to the patentee (*Signalisation*);
- it does not matter whether a licensee is exclusive or non-exclusive (*Domco*);
- the licence must be proved but it need not exist in writing (*Jay-Lor*);
- the claim must be one in respect of a use in Canada and not elsewhere in the corporate chain (*Servier*).

[44] I will now review the evidence in this case.

[45] The parties agree that Daiichi, the patentee, has entered into a written license agreement with an entity called Johnson & Johnson, a New Jersey corporation [J&J], effective as of May 28, 1991 with respect to levofloxacin. That agreement is in evidence at Tab 298 of Exhibit 4. It is agreed that this agreement applies to the 080 Patent. That licence, Article 2.1, grants J&J a licence to manufacture finished products containing levofloxacin and to sell them in Canada, among other countries, in exchange for payment of certain royalties as set out in Article 6.00. Article 7 provided that Daiichi will supply all of J&J's requirements for levofloxacin [the API]. Article 11.00 provides that J&J shall notify Daiichi of any infringement, and Daiichi shall take action in respect thereof assisted by J&J. Article 21.00 provides that any modification to the agreement shall be confirmed in writing. Article 2.3 is important in this case and I reproduce it in full since it relates to sublicenses to J&J subsidiaries:

> *2.3 J&J has the right to sublicense to J&J's Subsidiaries in each country of the Territory any or all of the license herein*

> *granted upon the terms and conditions of this Agreement, provided, however, that the right of sublicense to manufacture the Finished Preparation from the Compound shall be granted to one J&J's Subsidiaries in each country of the Territory. No sublicense agreement entered into pursuant to this paragraph shall be deemed to relieve J&J of its responsibility hereunder, including without limitation the responsibility of insuring that proper payment is made to DAIICHI of all amounts that may become due and owing under this Agreement. Furthermore, J&J shall have the right to appoint distributors and to sublicense such distributors in each of the countries in Territory B to sell the Finished Preparation subject to the terms and conditions of this Agreement. In the event that J&J intends to grant a sublicense pursuant to this paragraph, J & J shall obtain DAIICHI's prior written consent on the contents of such sublicense agreement, which consent shall not be withheld unreasonably.*

[46] A number of written amendments and supplements to the licence agreement have been put in evidence. None of them directly relate to Janssen Pharmaceuticals, Inc. (or its predecessors) nor do any of them deal in any specific way with Canada.

[47] There is no written agreement in evidence directly between Daiichi and Janssen Pharmaceuticals, Inc., or any of its predecessors.

[48] Through the evidence of Seth Fischer there was introduced Exhibit P35 which included an e-mail from a Daiichi executive to Fischer who was at the time a senior executive at a Johnson & Johnson subsidiary. That e-mail, according to Fischer, was in response to a letter sent by Fischer to Daiichi, a draft of which was, according to Fischer, "something like" Exhibit P36. That draft said, in part:

> *Changes in the U.S. Tax Laws affecting the tax status of our manufacturing operations for Levaquin in Puerto Rico became effective as of today, December 1. While highly technical in nature, those changes will have no substantive effect on the way we*

manufacture Levaquin. However, we have concluded that we should document a form of sub-license from Johnson & Johnson to our wholly owned Puerto Rican based subsidiary, Janssen Ortho LLC, so that we have a written record for its rights to manufacture Levaquin. Such sublicenses are contemplated by our License Agreement with you in Section 2.3 of the 1991 Agreement.

I enclose for your review a draft of the proposed manufacturing sub-license from Johnson & Johnson to Janssen Ortho LLC.

My people tell me that Section 2.3 is somewhat ambiguous as to whether a sub-license to our subsidiary requires consent from Daiichi, or whether the consent requirement in Section 2.3 is limited to agreements for the appointment of third party distributors.

I will very appreciate your confirming that you agree that the consent requirement in Section 2.3 does not apply to a sub-license to our subsidiary, or in any event confirm that you have no objection to the enclosed sub-license.

[49] The responding Daiichi e-mail, Exhibit 35, said in part:

Dear Seth,

I was forwarded your e-mail addressed to Dr. Une.

Our understanding of the Agreement Section 2.3 is that the consent requirement shall apply to both the sub-license to Johnson & Johnson's subsidiaries and third party distributers.

However, in view of the reality and our previous communication records, it is expressly understood that you have granted a manufacturing sub-license to your subsidiaries (in this case, Janssen Ortho LLC) of Levaquin in the Territory, and we have already agreed with you on such sub-license.

Therefore, notwithstanding Section 2.3, there is no need to give our written consent on a sub-license agreement for Janssen Ortho LLC.

Nevertheless, if Daiichi were to comment on the draft of sub-license agreement, I would like to share the same understanding with you that this sub-license agreement dose not seem to fit into the License Agreement (e.g. Article 1.6 or Article 2).

> *I simply assume the reason being that this agreement was drafted as an "comprehensive contract" between Johnson & Johnson and its subsideries, in response to the changed Tax Laws, not limited to Levaquin.*
>
> *In short, as long as Johnson & Johnson's obligations stipulated in the License Agreement are fulfilled by Johnson & Johnson and its subsideries, we do not think this sub-license agreement should create any problems on our side.*

[50] The evidence of Jeff Smith in that he, and others in the Ortho-McNeill branch of the J&J organization, had frequent meetings and communications with Daiichi in Japan and the United States, and that Daiichi was well aware as to how the J&J organization was making and selling levofloxacin finished products through one or more of its related companies.

[51] The affidavit of Lim, Exhibit P41, to which I attach little weight, is largely hearsay and of little assistance in any event.

[52] Addressed in evidence by the witnesses Smith and Roarty were charts, the first of which is Exhibit P17, showing the corporate history of Janssen US, and Exhibit P38, providing an overview of the Levaquin supply chain. The evidence, as far as it goes, as shown in those charts was not seriously challenged in cross-examination.

[53] Exhibit P17 shows that Janssen Pharmaceuticals, Inc. merged with Ortho-McNeil Inc. on December 31, 2007, with the merged corporation continuing under the name Ortho-McNeil-Janssen Pharmaceuticals, Inc. That entity changed its name on June 22, 2011 to Janssen Pharmaceuticals, Inc., the current Plaintiff that we call Janssen US.

[54] Exhibit P38 shows that Johnson & Johnson [J&J] is the parent company of Janssen Puerto Rico, Janssen U.S. and Janssen Canada. It shows that Daiichi supplies levofloxacin to Janssen Puerto Rico who manufactures finished levofloxacin tablets in Puerto Rico (Gurabo), and ships them directly to Janssen Canada. However, the paperwork flow showing the sales transactions is one wherein Janssen Puerto Rico sells these tablets to Janssen U.S. who then sells them to Janssen Canada. The price at which Janssen U.S. sells to Janssen Canada is sometimes referred to as the transfer price. Janssen US's claim for damages is based on alleged loss of sales to Janssen Canada at the transfer price less costs such as payments to Janssen Puerto Rico for the product and other expenses.

[55] In addition to the documents I have already referred to, there were introduced into evidence several business records reflecting transactions as to the levofloxacin products within the J&J companies as well as to Janssen Canada customers. Many of these were excerpted from a system called SAP which is a vast computerized programme into which data such as sales and transfer of products can be entered, stored and excerpted. This data does not reflect information such as where title to the product may pass.

[56] Copies of some invoices and the like were entered into evidence such as Exhibit P37 through the witness Lindsey Villacis, an executive with Janssen Supply Group in New Jersey. Neither she, nor any other fact or expert witness, could advise the Court as to when and where title passed in respect of the levofloxacin product. I provide an excerpt of Ms. Villacis' cross-examination at page 853 of the transcript:

> *Q. When you speak of title passing in Gurabo, that is the title passing to Janssen Canada in Gurabo?*

A. I can't speak to which specific legal entity that it passes at the point of shipping, but I can speak to the fact that financial ownership changes at the end of the month. At the time, Janssen-Ortho Inc. owns the product.

Q. It is just the finances you can speak to, not so much telling this court where title passes?

A. True. Yes.

Q. You can't tell me at what point in the process title moved from one party to another, from LEVAQUIN going from Puerto Rico to Canada?

A. I cannot tell you that. I can tell you that it starts in Gurabo, and at the end of the process, it ends with Janssen-Ortho Inc.

[57] Fernandini, an executive with Janssen Puerto Rico, at pages 886 to 888 of his cross-examination, said:

Q. You don't know who had title to the product at any point?

A. Title of the product, when this is Janssen-Ortho LLC, we have the burden of the risk of having that API in Gurabo. If material is rejected or damaged, Janssen-Ortho was responsible for the material.

Q. They also had title to the finished product there in Gurabo?

A. Once it is in Gurabo, it is Gurabo inventory.

Q. When they put it on the plane to ship it to Canada, the title-

A. Depending on the terms and conditions, I don't remember. We need to see the terms and conditions.

Q. You can't tell me who has title after?

A. No. It is in transit. It depends on the terms.

...

Q. You don't know if it had an impact on the title?

A. But the title was Janssen-Ortho. All the time, it was Janssen-Ortho LLC.

Q. When you told me that Janssen-Ortho LLC had title to the product in Puerto Rico, it had title at least until it was put on the plane to go to Canada?

A. Yes.

[58] Roarty, an executive with Johnson & Johnson, in cross-examination said at pages 910 to 911:

Q. At the time LEVAQUIN – you understand LEVAQUIN was manufactured in Puerto Rico?

A. Yes.

Q. At the time LEVAQUIN was shipped out the door and put on a plane, it was not owned by Janssen Pharmaceuticals Inc. or any previous incarnation of Janssen Pharmaceutical Inc.; right?

A. I don't believe so. It would have been owned by either OMJ Pharmaceuticals or Janssen-Ortho LLC, depending on when.

Q. They would have owned it as it got onto the plane, and at some point later possibly, the SAP entry is entered into the system?

A. I never was involved in those transaction[s]. I don't know the exact sequence or when title passed or things like that.

Q. It was owned by Janssen-Ortho LLC or OMJ Pharmaceuticals Inc. while it is in transit, and then it lands in Canada?

A. I am not sure who owned it while it is in transit.

Q. You can only tell me who owned it when it got on the plane?

A. I believe it would have been owned by the manufacturer.

Q. Who is Janssen-Ortho LLC?

A. Correct.

Q. That is true in the period of 2005 to 2006, etc.?

A. After 2006, I believe, it was Janssen-Ortho LLC. Prior to that, it was OMJ Pharmaceuticals.

Q. You wouldn't be able to tell me who owned the LEVAQUIN when the plane landed in Canada?

A. I am not sure if it was owned by Canada at that point or the U.S. or Puerto Rico.

Q. That is because you just don't know?

A. That is correct.

[59] Teva argues that Janssen US cannot be a person "claiming under" the patentee, Daiichi, since there is no clear evidence that Janssen US "used" the patented invention in Canada. Teva argues that Janssen US bears the burden of demonstrating that it had, even if for a moment, title to the levofloxacin containing tablets in Canada whereby, save for a licence from Daiichi, it would be infringing on the 080 Patent. Teva argues that the evidence falls far short of proving, even on a civil burden, that Janssen US had title to the tablets in Canada, hence "used" the invention in Canada.

[60] Janssen argues that it is unnecessary to show that Janssen US "used" the invention in Canada whether by having title to the tablets in Canada or otherwise. It is sufficient, Janssen argues, to demonstrate that Janssen US was part of the chain whereby the tablets flowed through the licence from Daiichi to J&J through unwritten licences, to Janssen Puerto Rico, then to Janssen US and finally, to Janssen Canada; it was part of a chain licensed, not in writing, but by implication and acquiescence, by Daiichi.

[61] In my determination, Janssen's argument is consistent with the state of the law as it exists in Canada, at least at the level of this Court, today. Janssen US has proven to my satisfaction that it has the licence or permission, by acquiescence, of Daiichi, to be involved in the chain of the sale of tablets made in Puerto Rico by Janssen Puerto Rico, through Janssen US to Janssen Canada. It is immaterial whether Janssen US had title, even momentarily, to the tablets in Canada.

[62] The matter was faced squarely by Polowin J. of the Ontario Superior Court in *Roche Palo Alto LLC v Apotex Inc.* (2005), 44 C.P.R. (4th) 431. She wrote at paragraph 37:

> *37 Subsection 55(1) of the Patent Act sets out no geographical restriction. Further, the Signalisation case, supra, supports that the court must view broadly those who can claim under a patent. The claim to damages on the part of Allergan Sales and Allergan Ireland arises from the alleged infringement by Apotex of the 614 Patent which is a Canadian patent. The elements of the cause of action of patent infringement are set out in the Statement of Claim. Allergan Ireland has been the exclusive manufacturer of ketorolac ophthalmic products under the 614 Patent sold to Allergan Canada for sale in Canada. Allergan Sales is the licensor of technical know-how to Allergan Ireland with respect to these products and has entered into a royalty agreement in this regard. As such, both Allergan Sales and Allergan Ireland allege that they have been damaged by the infringement of the 614 Patent.*

[63] While not binding upon me, I agree with the interpretation given by that Court, of section 55(1) of the *Patent Act* and the *Signalisation* case.

[64] The case of *AlliedSignal Inc. v DuPont Canada Inc.* (1998), 78 C.P.R. (3d) 129 (FCTD) (aff'd 86 C.P.R. (3d) 324 (FCA)), demonstrates the Canadian *Patent Act* permits recovery of damages in respect of activity outside Canada. A United States patentee selling to customers in

the United States could recover damages for loss of sales where a Canadian infringer sold Canadian made product to United States customers. Heald D.J., in determining a reference to damages, wrote at paragraph 33:

> *33 In conclusion, the right to claim lost profits is not circumscribed by the territorial limitations of the Patent Act to profits made on sales within Canada. The patentee has a right to be compensated for all damages flowing from the infringement of the patent within Canada, which may include profits lost on sales outside Canada. Furthermore, lost profits are merely a useful measure to help determine an appropriate and fair level of compensation. In the case at bar, the plaintiff is entitled to lost profits on those sales, whether in Canada or the United States, that it proves it would have made but for the presence of the defendant's DARTEK (R) film in the market.*

[65] The decision of Justice Reed in *Kirin Amgen,* previously referred to, while not specifically addressing the point, came to the same result in allowing a US corporation that was part of the J&J chain of companies engaged in the manufacture and sale of goods, to participate in a claim for damages without specifically demonstrating that it had title to the product, even for a moment, in Canada.

[66] I also rely on the decision of the Federal Court of Appeal in *Apotex Inc. v Wellcome Foundation Ltd.,* previously referred to, where Rothstein J.A. wrote that since the patentee and the person "claiming under" were before the Court both urging that the person had status, the Court would not deny that status. The present case is different in that the patentee, Daiichi, has not actually participated in this proceeding. Nonetheless, Daiichi clearly knows of this proceeding and has taken no steps to object to the status of Janssen US.

[67] I distinguish the decision of Justice Snider in *Les Laboratories Servier*, *supra*, in that she found particularly at paragraph 81 that each of the foreign entities had to own a sphere of operation and its own responsibilities within Group Servier, thus those entities not operating in a Canadian sphere could not be considered as persons "claiming under" the patentee. In the case before me, the J&J group of companies are operating as a team whereby licensed tablets ultimately found their way to Canada.

[68] Thus I conclude that, in the circumstances of this case, Janssen US is a person "claiming under" the patentee, Daiichi, for the purposes of having standing to claim damages for infringement by Teva of the 080 Patent in these proceedings.

IX. ISSUE NO. 2 – QUANTUM OF DAMAGES

a) Quantifying Damages Generally

[69] The quantification of general damages by a Court is said to be the exercise of a sound imagination and the practice of a broad axe in seeking to restore a plaintiff by monetary means to the condition that it would have been had the infringement not occurred. The words of Lord Shaw in *Watson, Laidlaw & Co. Ltd. v Pott Cassels, and Williamson* (1914), 31 R.P.C. 104 over a hundred years ago are still appropriate today. He wrote at pages 117 to 118:

> *In my opinion, the case does raise sharply an important question as to the assessment of damages in patent cases, and with that question I proceed to deal. It is probably a mistake in language to treat the methods usually adopted in ascertaining the measure of damages in patent cases as principles. They are the practical working rules which have seemed helpful to Judges in arriving at a true estimate of the compensation which ought to be awarded*

> *against an infringer to a patentee. In the case of damages in general, there is one principle which does underlie the assessment. It is what may be called that of restoration. The idea is to restore the person who has sustained injury and loss to the condition in which he would have been had he not so sustained it. In the cases of financial loss, injury to trade, and the like, caused either by breach of contract or by tort, the loss is capable of correct appreciation in stated figures. In a second class, of cases, restoration being in point of fact difficult, as in the case of loss of reputation, or impossible, as in the case of loss of life, faculty, or limb, the task of restoration under the name of compensation calls into play inference, conjecture, and the like. This is necessarily accompanied by those deficiencies which attach to the conversion into money of certain elements which are very real, which go to make up the happiness and usefulness of life, but which were never so converted or measured. The restoration by way of compensation is therefore accomplished to a large extent by the exercise of a sound imagination and the practice of the broad axe. It is in such cases, my Lords, whether the result has been attained by the verdict of a jury or the finding of a single Judge, that the greatest weight attaches to the decision of the Court of first instance. The reasons for this are not far to seek-such as the value of testimony at firsthand, down to even the nuances of its expression, and they include, of course, the attitude and demeanour of the witnesses themselves. In all these cases, however, the attempt which justice makes is to get back to the status quo ante in fact, or to reach imaginatively, by the process of compensation, a result in which the same principle is followed. In Patent cases the principle of restoration is in all instances to some extent, and in many instances to the entire extent dependent upon the same principle of restoration.*

[70] Reference to the principle of a broad axe as expressed by Lord Shaw in *Watson, Laidlaw* was made by Kerwin J. of the Supreme Court of Canada in *Colonial Fastener Co. Ltd. v Lightning Fastener Co. Ltd.*, [1937] SCR 36 at page 44.

[71] A similar thought was expressed by Lord Buckley in *Meters Ltd. v Metropolitan Gas Meters Ltd* (1911), 28 RPC 157 (Eng CA) at page 161:

> *Therefore, in a case such as the present, where licences are not granted to anyone who asks for them for a fixed sum, it is a matter which is to be dealt with in the rough-doing the best one can, not attempting or professing to be minutely accurate-having regard to all the circumstances of the case, and saying what upon the whole is the fair thing to be done.*

b) Facts, Assumptions and Fun with Numbers

[72] Many of the underlying facts including numbers have been agreed upon between the parties. The application of those facts in arriving at a reasonable calculation of damages by the parties creates a difference as much as tenfold. Janssen asserts that it is owed up to eight figures in dollars in damages; Teva argues that it saved Janssen seven figures in dollars. Much depends on the assumptions made and applied by the experts put forward by the parties.

[73] Given certain assumptions, the application to agreed facts and numbers can lead to remarkable differences. An illustration is given in Dr. Rosenblatt's Reply Report, Trial Exhibit P6 at paragraphs 7 and 8 where graphs are presented which illustrate, in Figure 1, how it can be seen that sales of levofloxacin were rising over a period whereas, in Figure 2, it seems that sales are declining. The difference is slight but the results are significantly different. The Figures each show a "trend line" generated by a computer for sales over a certain number of years. Figure 1 is for the period 1/2000 to 11/2004 whereas Figure 2 is for the period of 1/2001 to 11/2004; in other words, Figure 2 starts a year later than Figure 1.

Figure 1

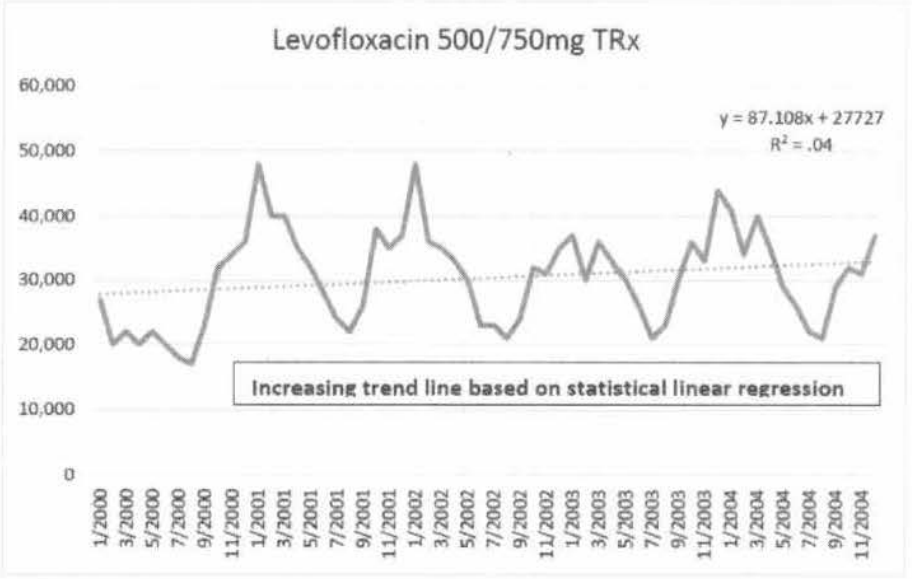
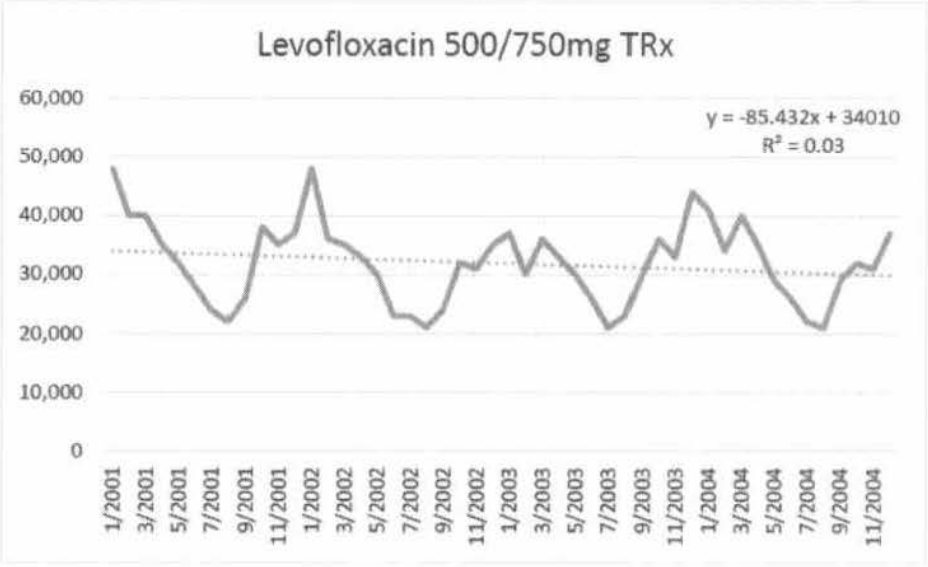


Figure 2



c) Positions and Concessions

[74] Prior to and during trial, the parties took certain positions and made certain concessions worthy of note, some of which are mentioned elsewhere in these Reasons. The following are of note:

1. Janssen Puerto Rico, the Plaintiffs Janssen-Ortho LLC and OMJ collectively in Action No. T-2056-11, have withdrawn any claim for damages. They remain as Plaintiffs in that action only because, as the matter approached trial, it was too late to remove them. As a practical matter, Janssen US, that is Janssen Pharmaceuticals, Inc., is the only actively participating Plaintiff in that action;
2. Janssen US is not claiming damages for any period prior to December 19, 2005 but is claiming for a period up to December 31, 2010 notwithstanding that the 080 Patent expired June 23, 2009;
3. Janssen Canada, a Plaintiff in Action No. T-2175-04, is seeking damages for the period December 1, 2004 to December 31, 2010;
4. Teva sold 250 mg and 500 mg strength levofloxacin tablets in Canada. It never sold 750 mg strength;
5. Sales of Teva's 250 mg strength levofloxacin tablets are to be considered, for damage purposes, on a one-for-one substitution basis with Janssen's LEVAQUIN 250 mg strength tablets;
6. Daiichi's claim for damages has been satisfied and it played no active part in these proceedings;
7. Following the injunction that I granted on October 17, 2006, Teva took advantage of the thirty (30) day sell off period that I permitted, and made a payment to Janssen in that respect. The parties have all deducted that payment in the submissions in respect of damages.

d) The Marketplace as it Existed in Fact

[75] There was a debate between the experts as to how to define the relevant marketplace. I will begin by speaking in broad terms. We are speaking of drugs used as antibiotics in the treatment of infection, particularly respiratory tract infections (RTI's) and to some degree, urinary tract infections (UTI's).

[76] In the 1950's, a class of drugs known as macrolides were developed for the treatment of several bacterial infections. The quinolone class of macrolides developed in the 1950's was a particularly significant class which proved effective against bacteria defined as gram-negative; however, quinolones were not found to be effective against other types of bacteria known as gram-positive.

[77] In the 1980's, certain types of quinolones known as fluoroquinolones were developed; among the most popular was ciprofloxacin or CIPRO. This drug however proved to be effective only in respect of a particular group of patients infected with particular gram-negative bacteria. Nonetheless, CIPRO continues to be used by doctors in treating patients to this day including the use of a variant known as CIPRO XL.

[78] Also introduced in the 1990's for the treatment of RTI's, were drugs known as ZITHROMAX (azithromycin) and BIAXIN (clarithromycin), a later version of which was introduced as BAIXIN XL. These drugs, particularly BIAXIN XL, continue in use to this day.

[79] In the late 1990's, a particular group of fluoroquinolones were introduced known as respiratory fluoroquinolones. The first of these was levofloxacin (LEVAQUIN) which is the subject of these proceedings. Others coming later were moxifloxacin (AVELOX) and gatifloxacin (TEQUIN). Other fluoroquinolones were introduced into the marketplace but were short-lived and play no role in the considerations in these proceedings.

[80] Janssen Canada launched its LEVAQUIN in Canada in late 1997 or early 1998. It was available in tablets of 250 mg and 500 mg strength, as well as intravenous (IV) formulations which IV formulations form no part of these proceedings. The 500 mg tablets were used to treat RTI's and the 250 mg tablets were used to treat UTI's.

[81] AVELOX (moxifloxacin), a product competitive in the marketplace with LEVAQUIN, was introduced in late 2000 and continues in use to this day. In the period from 2000 to 2010, there were no generic versions of this drug in the Canadian marketplace.

[82] TEQUIN (gatifloxacin), another product competitive in the marketplace with LEVOQUIN, was introduced in late 2001. Concerns as to the safety of this product began to emerge in 2004, and it was ultimately withdrawn in June 2006. There was no generic version of this product.

[83] On or about November 29, 2004, Teva launched its generic version of LEVAQUIN under the name Novo-levofloxacin in 250 mg and 500 mg strength tablets. It withdrew from the market by reason of the injunction granted by this Court on October 17, 2006 subject to the thirty

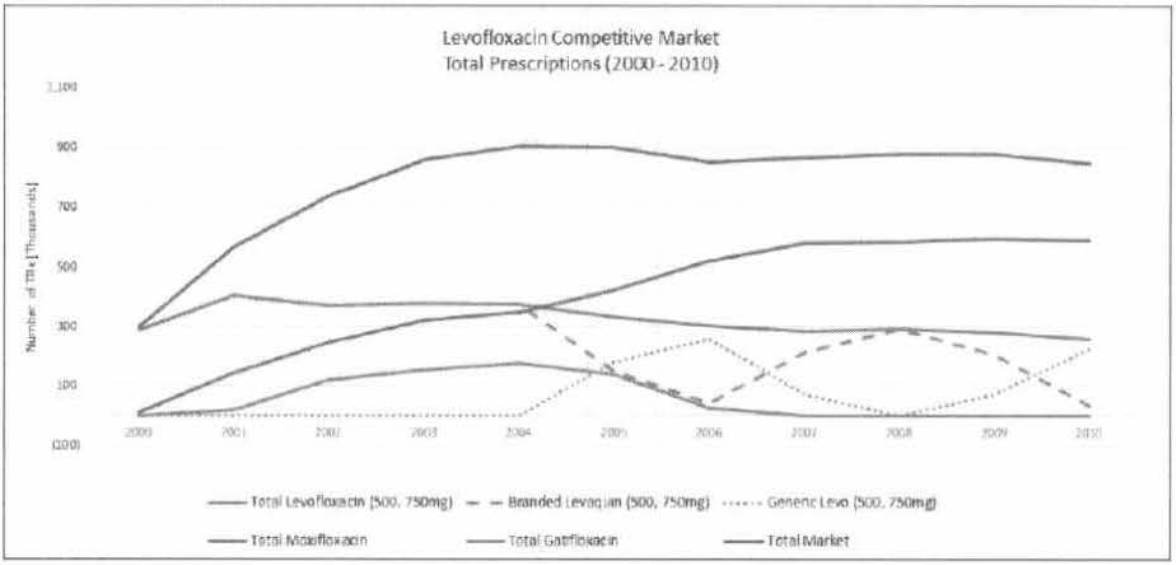
(30) day sell-off previously discussed. This was the only generic levofloxacin product on the marketplace until after the expiry of the 080 Patent.

[84] In about early 2003, Janssen Canada introduced LEVAQUIN tablets in 750 mg strength which it continued to sell at least until the end of 2010. Teva did not market a tablet of that strength during the relevant period nor did any other competitor of Janssen.

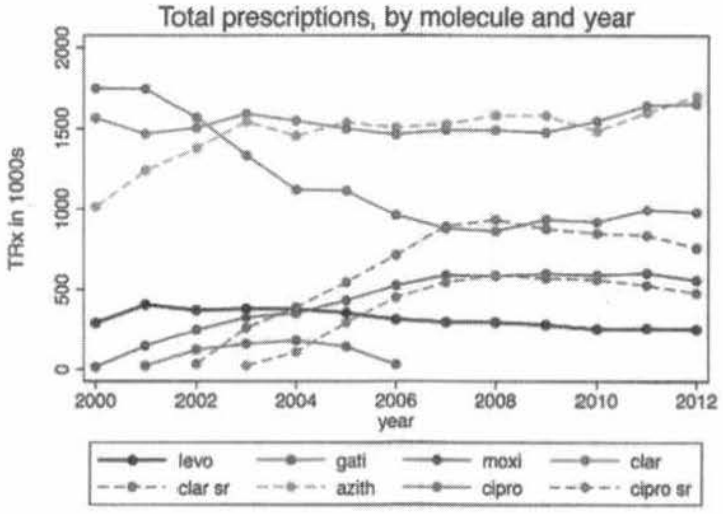
[85] The customers of levofloxacin and other antibiotics have been gathered into two or perhaps three groups in the evidence. One group is direct sales to hospitals; another group is called retail that is sales directly or indirectly to drug stores and the like. A third group includes government and educational groups whose classification is subject to some dispute in these proceedings.

[86] I provide by way of illustration graphs prepared by experts from each of the parties showing the number of prescriptions written for some these drugs. The graph prepared by Rosenblatt, a Janssen expert, illustrates the total respiratory fluoroquinolone market and breaks out sales of levofloxacin (brand and generic), moxifloxacin (AVELOX) and gatifloxacin (TEQUIN) over the period from 2000 to 2010.

Figure 1b – Retail Prescription Trends in the Levofloxacin Competitive Market in Canada



[87] The graph prepared by Dr. Grootendorst, a Teva expert, includes, in addition, other drugs including ciprofloxacin (CIPRO) and clarithromycin (BIAXIN) and extends the time period to 2012.



source IMS Compuscript
Note: levo = levofloxacin, gati = gatifloxacin, moxi = moxifloxacin, clar = regular release formulation of clarithromycin, clar sr = sustained release formulation of clarithromycin, azith = azithromycin, cipro = regular release formulation of ciprofloxacin, cipro sr = sustained release formulation of ciprofloxacin.

[88] While there were some disputes concerning these graphs, they are sufficient to illustrate that the number of prescriptions for levofloxacin (Janssen plus Teva) declined since about 2004, that gatifloxacin declined since 2004 and disappeared in 2006, and that moxifloxacin gained from 2000 to 2006, and then levelled off. The market for other drugs such ciprofloxacin and clarithromycin remained strong.

e) Scenarios

[89] Janssen, through its expert witness, Dr. Rosenblatt, presented two scenarios as to what might have happened in the marketplace "but for" the entry of Teva's generic levofloxacin product. He called them Scenario A and Scenario B which he described at paragraphs 51(a) of Report, Exhibit P5, as follows:

> *51. In the paragraphs that follow I provide But For prescription volume estimates based on two different market scenarios. The major assumption common to both scenarios is that the total number of prescriptions in the Damages Period in the Levofloxacin Competitive Market does not change from what actually occurred during this time period. The two scenarios are defined below:*
>
> *51(a) The two "But For" Scenarios are:*
>
> > *51a(i)* ***Scenario A*** *– For this scenario I have assumed that LEVAQUIN®, by virtue of having sales efforts at levels similar to those in the period immediately preceding the Damages Period, would have captured 51.8% of the actual combined levofloxacin (500mg and 750mg strength) and AVELOX® market. As of December 2004, at the start of the Damages Period, the LEVAQUIN® share of the combined levofloxacin (500mg & 750mg) and AVELOX® market was 51.8%. I believe this is the most likely scenario.*

> *51a(ii)* ***Scenario B*** *– For this scenario I have been asked to assume that LEVAQUIN®, would have maintained pre-Damages Period selling efforts and all other market factors would have remained stable. In other words, I have been asked to ignore actual prescription data for TEQUIN® and AVELOX®. A statistical forecast model (exponential smoothing, detailed in Schedule E) estimates that the average level of prescription volume between 2000 and 2004 would have occurred between 2005 and 2010; this is a very conservative scenario and assumes no growth at all for the levofloxacin molecule, even with continued promotion. I do not believe this is a likely scenario.*
>
> [Emphasis in the original]

[90] Teva, through its witness Mak, presented six different scenarios as set out in paragraph 7 of his Sur-Reply Report, Exhibit D47:

> *7. I have revised my calculations as explained herein. The results of the economic loss scenarios that I have considered are summarized as follows:*
>
> ***Scenario 1:*** *Lost volumes based upon Teva's ex factory sales, with alternative assumptions regarding advertising and promotion ("A&P") expenses and loss periods for price erosion. Estimated losses (net benefit), with prejudgment interest, range from* ***$[redacted] to $[redacted]****, after deducting the $[redacted] that Teva has already paid to Janssen Canada.*
>
> ***Scenario 2:*** *Same as Scenario 1, but lost volumes for 500mg tablets are based on TRx (dispensed prescription) data. Estimated losses (net benefit), with prejudgment interest, range from* ***$[redacted] to $[redacted]****, after deducting the $[redacted] that Teva has already paid to Janssen Canada.*
>
> *Scenario 2.1: Same as Scenario 2, but lost volumes for 500mg tablets are based on ex factory volumes recognized according to the months in which TRx is sold (dispensed prescription). Estimated losses (net benefit), with prejudgment interest, range from* ***$[redacted] to $[redacted]****, after deducting the $[redacted] that Teva has already paid to Janssen Canada.*
>
> ***Scenario 3:*** *Based upon Scenario A of the CHS Report, but adjusted for corrected TRx volumes and with alternative*

> *assumptions regarding A&P expenses and loss periods for price erosion. No permanent loss of market share is assumed for the LEVO 2 plaintiffs. Estimated losses (net benefit), with prejudgment interest, range from* ***$[redacted] to $[redacted],*** *after deducting the $[redacted] that Teva has already paid to Janssen Canada.*
>
> ***Scenario 4:*** *Same as Scenario 3, but permanent loss of market share is assumed for the LEVO 2 plaintiffs. Estimated losses (net benefit), with prejudgment interest, range from* ***$[redacted] to $[redacted],*** *after deducting the $[redacted] that Teva has already paid to Janssen Canada.*
>
> ***Scenario 5:*** *Based upon Scenario B of the CHS Report, with the same adjustments made in Scenario 3. Estimated losses (net benefit), with prejudgment interest, range from* ***$[redacted] to $[redacted],*** *after deducting the $[redacted] that Teva has already paid to Janssen Canada.*
>
> ***Scenario 6:*** *Same as Scenario 5, but permanent loss of market share is assumed for the LEVO 2 plaintiffs. Estimated losses (net benefit), with prejudgment interest, range from* ***$[redacted] to $[redacted],*** *after deducting the $[redacted] that Teva has already paid to Janssen Canada.*
>
> [Emphasis in the original]

f) The "But for" Marketplace

[91] The Court must engage in an attempt to reconstruct what would have been the sales of Janssen's LEVAQUIN tablets in the Canadian marketplace "but for" the entry, for a period, by Teva with a generic Levaquin product.

[92] Janssen's expert, Cohen, considered the two scenarios presented by Dr. Rosenblatt; Scenario A and B, and endeavoured to recreate the marketplace in the "but for" world, and arrive at a calculation of damages suffered by each of Janssen Canada and Janssen US. He also prepared a Scenario C which served to illustrate some of his rebuttal to Teva's expert, Mak. Scenario C may be disregarded as any attempt by Janssen to put forth its damage claim; only

Scenarios A and B need to be considered for that purpose. The following is a chart setting out these various scenarios and the claim made for damages:

[redacted]

[93] Teva's expert, Mak, presented six scenarios based on the assumptions he was given by a number of Teva witnesses including Dr. Simor, Dr. Grootendorst and Dr. Katsanis. He prepared charts setting out a number of scenarios based on several different assumptions. I set out his Scenario 1 as an illustration:

[redacted]

[94] The differences between the scenarios presented by the experts are greater than might have been expected. For instance, Janssen postulates damages of $[redacted] dollars in one of its scenarios whereas Teva postulates that Janssen actually saved some $[redacted] in one of its scenarios.

[95] At the end of his examination and cross-examination, I put the following questions to Teva's expert, Mak, and received the following answers at pages 1010 and 1011 of the trial transcript:

> *JUSTICE HUGHES: I will ask some questions of the witness. Mr. Mak, I am looking at the various scenarios, but I take it that they culminate in Exhibit D-48 in terms of various adjustments you made, having a look at the opinions of others, and so forth.*
>
> *THE WITNESS: That is correct.*
>
> *JUSTICE HUGHES: Looking at tab C of Exhibit D-48, am I correct in concluding that, in terms of a grand total, you say that as a result of Teva being on the marketplace the plaintiffs, Janssen and others, are ahead by $4 million?*

THE WITNESS: Yes. As a result of Teva being on the marketplace and not spending -

JUSTICE HUGHES: They would be better off if the generic came in even earlier. They would have more money in pocket. Is that what you are saying?

THE WITNESS: Possibly if they were able to avoid this additional spending.

JUSTICE HUGHES: When I take a look at Mr. Cohen's analysis, for instance, P-9. I don't know if you have it in front of you, but you may want to get P-9 in front of him. It is his reply report, and he takes into account various things.

If you turn to page 4, he has a chart. We will forget about pre-judgment interest. He has scenarios. The one he prefers is the one that results in a profit loss, that is Janssen is out of pocket almost $20 million. Is that right.

THE WITNESS: That is right.

JUSTICE HUGHES: I am having trouble getting my head around the fact that you say Janssen actually benefited by Teva being in the marketplace by over $4 million and Mr. Cohen saying there was a loss of almost $20 million. What is the biggest difference or differences between the two of you?

THE WITNESS: The lost volumes. The biggest difference or source difference in terms of dollars has to do with how we each defined lost volumes. Whether you accept that [h]as being Teva's volumes as in my scenarios or the levofloxacin competitive market as in Mr. Cohen and Dr. Rosenblatt's scenarios.

[96] In argument, Counsel addressed a number of factors that they said contributed to the differences in the scenarios presented by the experts as a quantification of damages.

i) What Would Have Been the Normal Course of Events

[97] In the ideal marketing world, a drug company would introduce a new product and promote it heavily, largely through visits by sales representatives to doctors, hospitals and others, in order to acquaint potential buyers and prescribers as to the benefits of the drug. This phase would be followed by a maintenance phase where promotion such as this would continue but at a more moderate pace. The last phase would be the harvest phase where the life of the patent protection would be nearing an end; promotion would lessen to reduce costs and maximize profits.

[98] John Stewart explained this marketing strategy in his direct examination:

> *Q. I would like to move into a new area. I want to talk to you about a life cycle of a patented drug at Janssen. How does Janssen structure the promotional efforts for a patented product?*
>
> *A. How do we – over the life cycle?*
>
> *Q. Yes.*
>
> *A. There are four phases typical to product development and promotion. It begins with the pre-launch phase where the workup is done to develop the overall strategy and tactics and complete understanding of the marketplace. Once we receive approval from Health Canada, we shift into the growth phase. This is where we apply a lot of investment to accelerate the growth of the brand.*
>
> *At a certain point in time – very individual to the brands – we hit what we call a peak share. Our share has been maximized and starts to level off. We shift into what we call a maintenance phase where the question we are answering is: What resources do we need to put against the brand to hold that level of market share or that level of sales?*
>
> *That carries through to the end of our patent life where we go into the harvest stage which is four to six months before the patent expires. We take all resources off it to maximize our profitability.*

Q. Let me back up a little bit and have you explain in a little more detail. Tell me what happens during the pre-launch phase. When does it begin, and what work is done?

A. One year or two years in advance of the anticipated approval by Health Canada, we invest in a marketing director, sometimes a product director or sometimes a product manager as well. Their role is to completely dig into the marketplace and understand what is it had size of the market, who are the competitors, what are the issues in the marketplace, where will our brand fit in, develop the strategies and tactics, make recommendations on sales force size, what programs are needed, etc. – everything that is going to get us to the point that, at approval, we are ready to launch this product.

Q. On approval, what happens next?

A. At approval, we will launch the product at a sales meeting. The representatives have their goals objectives set and they go. It is a heavy invest on both the dollars and manpower to accelerate the growth. Oftentimes, those investments exceed the revenue coming in and that is by design to make sure we move up as fast as we can to that peak share.

Q. On approval, what is that phase of growth called?

A. That is the growth phase.

Q. How long does a growth phase typically last?

A. It can depend. It can be three years. It can be five years. It depends on the brand, the market circumstances, etc. There is no standard prediction as to what that might look like.

Q. How does Janssen decide when the growth phase is going to come to an end?

A. Essentially, it is when you look at the growth curve in terms of the sales revenue or the market share or both. When that starts to level out or slow down where the investment isn't driving incremental growth, the decision is made or the question is asked – we have spent a lot of money and lost a lot of money throughout that growth period. The question is asked: What resources can we apply against it, a reduced amount of resources to hold that level of revenue through to the end of the life cycle?

Q. What do you do with the human resources who were involved in promotion during the growth phase? Are they still necessarily in the maintenance phase?

A. There are resources necessarily in the maintenance phase. You need sales representatives and promotion dollars but to a lot smaller scale.

Q. What type of sales and marketing efforts are undertaken during the maintenance phase?

A. Essentially, in the maintenance phase, the physician are completely aware of your brand. They have utilized it. There isn't a lot of information they need to put in front to make them – to feel comfortable prescribing it. They have built these habits, and they are continuing to prescribe.

Essentially there are core selling materials just to reinforce the advantages of our brand. There are samples because clinicians like to have samples to trial the product with patients sometimes, patient support materials, that kind of thing.

Q. You mentioned earlier that the fourth phase was called the harvest phase. Can you tell us about the harvest phase?

A. It is quite straightforward. It is when the decision is made that we are going to pull all resources off the brand. As the word denotes, we are going to harvest the profit there. At the end of the day, we look at the brand over its entire life cycle, and hopefully, we have generated a positive ROI across the entire life cycle.

Q. When does the life cycle typically end?

A. It ends at your patent expiration.

Q. How is a decision made to move from maintenance to harvest?

A. General timing is maybe four to six months in advance.

Q. In advance of what?

A. Sorry. In advance of the patent expiration. If there are opportunity to move people to new opportunities, new growth opportunities, it may be six month or four months. Generally, as we approach the end of the patent life, we are making those decisions.

Q. Still in a general sense, what effect, if any, does genericization have on the planned life cycle of a Janssen drug?

A. It means you immediately go into the harvest phase since you are going to cut off all your investment in the brand.

Q. Why do you do that?

A. The erosion model of your business once a generic to launch is well established. Within 12 month, you may have 10 to 20 percent of your revenue left. Any incremental investment you are putting in during that phase is doing nothing but actually driving demand for the generic version.

Q. Do you change the amount of human resources on a project?

A. Absolutely. We cancel all the spending. We will redeploy people to other roles in the organization. Hopefully, we can do that versus the other which would be having to terminate people.

ii) Competition – Other Molecules

[99] Janssen's levofloxacin product LEVAQUIN was the first respiratory fluoroquinolone to be introduced into the Canadian market and for a period of time, had that particular market to itself subject to different existing non-respiratory fluoroquinolones such as CIPRO. A year or two later, other products, also respiratory fluoroquinolones but different molecules, came into the market, moxifloxacin (AVELOX) and gatifloxacin (TEQUIN). Janssen had to fight for market share of this particular market which it did on the terms of its "proven safety record".

[100] John Stewart explained this at pages 674 and 675 of the trial transcript:

Q. When moxifloxacin and gatifloxacin entered the market, did that change the way that Janssen promoted LEVAQUIN?

A. Yes, in terms of now we have two people vying for the fluoroquinolone decision, but it did not change our focus which was to display the macrolides in the treatments paradigm for those higher risk patients.

Q. How did Janssen position LEVAQUIN versus the other fluoroquinolones?

A. In the early going, it is not our position to immediately start attacking the other fluoroquinolones. It is their job to say why they are superior to LEVAQUIN. When the conversation came up, the products were more alike than they were different.

They were all highly effective, but the two things that stood out for us was our safety record for LEVAQUIN – moxifloxacin had QT prolongation which is a heart-arrhythmia type side effect that is not a good thing, and gatifloxacin had issues with hyper- and hypoglycemia so glucose fluctuations which are not good either. We differentiated based on the proven safety record of LEVAQUIN.

iii) Disruptions in the Market

[101] In the time period of 2004 to 2006, there were two disruptions experienced in the fluoroquinolone market. One was the disappearance of gatifloxacin (TEQUIN) due to safety concerns. The other was the introduction by Teva of its generic levofloxacin and subsequent removal of that product by reason of this Court's injunction. The issue before the Court now is, if Teva's generic had not been in market, what would Janssen's sales, and therefore profits, have been.

[102] When Teva's generic levofloxacin entered the market, Janssen's promotion of its LEVAQUIN tablets essentially stopped, as explained by John Stewart, transcript pages 694 to 698; why promote a product when the competition will get the greatest share of the market?

[103] When TEQUIN was withdrawn, it is clear that AVELOX, which was being promoted by its drug company (Bayer), gained a share of the TEQUIN market. Would LEVAQUIN also have gained a share of that market and in which proportion? Would doctors or hospitals abandon the respiratory fluoroquinolone class of drugs entirely and go to other drugs such as CIPRO or BIAXIN?

g) Findings as to What the "But for" World Would have Been

[104] There were a variety of different assumptions that help create the different Scenarios A and B of Rosenblatt and 1 through 6 of Mak, which I will consider in more detail.

[105] There were differences between Drs. Chan and Simor as to what doctors who wrote prescriptions for antibiotics such as LEVAQUIN would have been likely to have done in respect of prescribing that drug, or another in the "but for" world had Teva's generic product not entered the marketplace. Among the matters in controversy were:

- the effect of sales representatives (detail persons) in visiting doctors and promoting the product. Having considered all the evidence, I am satisfied that, in the initial stages of a launch of product, these visits have an effect. Once a product is established, such visits have a lesser effect;
- the habitual or persistence level whereby doctors tend to prescribe what they are familiar with and seems to work best for their patients. I am satisfied that there is a significant effect in this regard;

- the effect of guidelines published for hospitals or doctors as to what should or may be prescribed. I am satisfied that guidelines have an effect but do not create dictatorial terms as to what should be prescribed;
- switching once Tequin disappeared from the market. I am satisfied that most doctors would have switched to levofloxacin or moxifloxacin but some may have switched to other products such as CIPRO or one of the macrolides;
- the relevant comparator market is the respiratory fluoroquinolone class;
- spending on promotion, research and development by Janssen if Teva's generic product had not been present. I am satisfied that promotional spending would have continued but, given that the patent term was nearing an end, the spending would probably have diminished. As to research spending, I prefer Janssen's estimate as Teva puts too much emphasis on an abnormally large spending by Janssen in one year; and
- introduction of Janssen's 750 mg LEVAQUIN tablet probably took sales from its 500 mg tablet but also from AVELOX (moxifloxacin).

[106] Taking all the evidence presented by each of the parties, I am satisfied that Scenario A presented by Janssen's expert witness Rosenblatt best represents what would have happened in the "but for" world. However, I find that there are some changes to be made to some of the assumptions that underlie that scenario; they are changes to the damage period, to hospital sales percentage, and whether educational institute/government sales should be included as hospital sales. I will consider what those changes should be as well as set out what I find to be appropriate assumptions underlying Scenario A.

h) Damage Period

[107] The Plaintiffs Janssen calculated their losses over a period commencing when Teva entered the marketplace in December 2004, until December 2010. The patent expired on June 23, 2009.

[108] Teva, through its expert, Mak, calculated its numbers based on the period Teva was on the market but, in the case of hospital price suppression, included various options varying from the date Janssen regained exclusivity up to a few months after the expiry of the patent in order to deal with fulfillment of contracts.

[109] As Justice Snider held in *Merck & Co., Inc. v Apotex Inc.*, 2013 FC 751 at paragraph in 183, a claimant is entitled to damages sustained after the grant of the patent has expired in respect of losses that were incurred as a result of the infringer's activity during the period when the patent was in force. She wrote:

> *[183] There is nothing in the Patent Act that limits damages to those sustained during the life of the patent. Section 55(1) states that the infringer is liable "for all damages sustained by the patentee [or licensee] after the grant of the patent, by reason of the infringement". Merck is entitled to its damages for infringing sales even though those sales actually would take place during the post-expiry period.*

[110] In this case, it would be reasonable to presume that some time would extend beyond the date that the patent expired. Prescriptions would have to be filled, contracts complied with, and other existing obligations incurred during a period of price suppression when the patent was in force would have to be fulfilled.

[111] However, I find no reasonable basis in the Record to support an extended date of damages up to December 2010, nor can I find any reasonable basis to find that damages cease upon expiry of the patent or one month thereafter.

[112] Under the circumstances, I must apply the "broad axe" principle and find that losses due to prescription (retail) sales would terminate about two months after the patent expires, that is August 31, 2009, and that hospital losses would terminate about a year after the patent expired, that is as of June 30, 2010.

[113] Teva's expert, Mak, made calculations that included a one-month lag at the beginning of the damages period in considering TRx data, that is, data relating to sales by pharmacies to patients, on the basis that pharmacies keep inventory on hand which would have been sold by Janssen to the pharmacy or wholesaler approximately one month before the pharmacy sold the product to the patient. Because Janssen's losses occur when they sell the tablet and not when the pharmacy sells the tablet, this lag was intended to compensate when using TRx data.

[114] Janssen's expert, Cohen, agrees that there is a lag when you follow the product, but says that prescription sales are a good surrogate for *ex-factory* sales because they match closely (see Chart 1 on page 11 of his Reply report, Exhibit P9). Even though the same physical tablet is not being sold immediately from the factory to the patient, the numbers match well enough that they can be used for economic modeling. Cohen says there is therefore no need to build this lag into the model even when TRx data is used.

[115] I am persuaded by Cohen's analysis for to say otherwise would be to create a one month window in the middle of Janssen's exclusivity period where they effectively have no sales. Further, because the TRx data matches *ex-factory* sales closely, it is a reasonable surrogate for the "broad axe" approach.

i) Hospital Sales - Price Suppression

[116] The law is clear that if, due to activities of an infringer, the patentee or person claiming under the patentee had to reduce prices because of the entry into the market of an infringer offering the product at a lower price, a claim for damages can be made for price suppression. As Heald D. J. wrote in *AlliedSignal Inc. v Du Pont Canada Inc.* (1998), 78 C.P.R. (3d) 129 (FCTD, aff'd 86 CPR (3d)324 (FCA)) at paragraph 23:

> *23 In addition to lost profits due to lost sales, the patentee may also claim lost profits due to price suppression if it can establish that it necessarily reduced its prices because of the competition of the infringer: Colonial Fastener Co. v. Lighting Fastener Co.,12 American Braided Wire Co. v. Thomson.*

[117] The evidence is that Janssen Canada reduced its prices to hospitals by [redacted]% when Teva entered the marketplace with its generic levofloxacin, and could not raise them after Teva was forced to withdraw. As Janssen's witness John Stewart said at pages 698 to 699, 703 to 704 and 758 of the trial transcript:

> *Q. Did the presence of Novopharm in the market have an effect on Janssen hospital pricing?*
>
> *A. Yes, to the extent that, once you have lost all your opportunity to partner with the hospitals and specialists, you don't have anything left except a generic strategy. The only thing you*

have left to try to leverage to try to hold on to your business is lower your price and compete on price.

In [redacted] of 20[redacted], we lowered our hospital prices another [redacted] percent universally across the board so all hospitals had an opportunity to save money because we also had no resources to go out and differentiate between the hospitals on a pricing standpoint. This was a blanket drop in the price as a result.

Q. Before Novo-levofloxacin came to the market, did Janssen intend to lower its hospital prices?

A. There was no plan to implement that 30 percent reduction across the board strategy.

...

Q. In the period after Novopharm left the market, did that have an effect on Janssen's hospital prices for LEVAQUIN?

A. There was no change to our hospital pricing.

Q. How come?

A. You have established relationships and listings based on the hospital prices that have been offered for the last two years plus. We are not going to rock that boat and change it on these customers. It is not the way we operate.

...

Q. Your told Mr. Wilcox when he was asking you about the price drops in the hospitals -- pardon me, Mr. Markwell -- that after you had lowered the hospital prices in 2006 when you regained the market, you didn't want to raise them because you didn't want to rock the boat, yes?

A. Yes.

Q. By that, you meant you could alienate customers and they would buy the product from someone else?

A. We were coming into the market with other hospital antiinfectives that was the future of our antiinfective franchise at the time. Why would you want to upset the customer by nickel and diming then on one when you want to come in later then asking them to list enough?

[118] The actual changes to the hospital prices are part of the agreed evidence.

j) Hospital Sales – Diamond, Non-Diamond and Educational Institution/Government

[119] Janssen's claim for damages for price suppression is in respect of "hospital sales". In answer to the question put to Janssen on discovery paraphrased as:

> *Advise as to whether there is a claim for damages for price suppression and/or erosion for sales other than Hospital Sales as a result of the market entry of Novo-levofloxacin*

the answer provided by Counsel in writing was (Trial Exhibit D61):

> *There is not. The only claim for damages for price suppression and/or erosion is for hospital sales.*

[120] The question is what are "hospital sales"?

[121] The evidence shows that Janssen Canada divided its customers into groups including "Diamond" hospitals (which were the larger or more influential hospitals), "Non-Diamond" hospitals and "Education Institution/Government". The latter was explained by Janssen's representative on discovery, Park (Exhibit D61, questions 3331 to 3333) as follows:

> *Q. Okay. And what about "Educational Institute..."*
>
> *Maybe I will pause.*
>
> *"Drug Wholesaler", that would not include any sales going to hospitals? Or it could?*
>
> *A. It could, if there were a smaller hospital that ---*
>
> *Hospitals can order directly through Janssen or they can go through a wholesaler.*

So they can go through either.

Q. Okay.

The next line is "Educational Institution/Government"...

A. Yes. That could have been any Provincial Government or the National Government that make significant purchases for epidemics or for the concern over whatever it is: Anthrax, or whatever.

It looks like there is...

I think I saw something that lined up with that number, "53,722", before.

It was a large Government purchase.

Q. Okay. And then "Hospital".

A. "Hospital" would be those that order directly to Janssen for Levaquin.

[122] The evidence is that Cohen included Educational Institution/Government sales as Non-Diamond hospital sales when determining the hospital price suppression, thus excluding them when calculating the retail price. Mak did not. The difference in the two approaches would benefit Janssen Canada by about $[redacted].

[123] I am concerned that, on discovery, Janssen provided an answer that could be considered to be misleading. No correction or clarification was ever made in respect of that answer. While the answer could be interpreted as somewhat ambiguous, Janssen should have clarified the ambiguity. Even at trial, no effort was made to clarify the answer.

[124] I find that sales to Educational Institute/Government should be excluded from hospital sales with an apparent reduction to Janssen's damage claim of about $300,000.

k) Hospital Sales - Percentage

[125] The evidence shows that hospitals are demanding as to price and generally require, and receive, a discounted price on drugs. By way of example at page 93 of the trial transcript, Dr. Rosenblatt suggested that a tablet sold at five dollars ($5.00) at retail (meaning to wholesalers) would be sold at four dollars ($4.00) per tablet directly to hospitals. However, not all sales that ultimately end up in hospitals are direct sales to hospitals, some hospitals some of the time may purchase from retailers/wholesalers (Rosenblatt, Reply Exhibit P6 paragraph 35, Grootendorst, transcript page 1097, Stewart, transcript page 679). The higher the number of sales made indirectly to hospitals, e.g. through retailers/wholesales, the higher the profit margins to Janssen since the tablets involved would be those sold by Janssen at the higher price to retailers/wholesalers.

[126] Both Dr. Rosenblatt and Dr. Grootendorst, the experts for each of the parties who addressed this issue, agreed that there was no precise way in which to determine the percentage of indirect sales to hospitals. Dr. Rosenblatt used a figure of [redacted]%. Dr. Grootendorst used a figure of [redacted]%. The higher figure would favour Janssen.

[127] Dr. Rosenblatt explained and justified his selection of [redacted]% in his Report (Exhibit P5, paragraph 66) and his Reply (Exhibit P6, paragraph 35) as well as in his examination and cross-examination at trial (transcript pages 90 to 95 and 183). The facts were substantiated by the testimony of John Stewart (transcript page 679) and discovery read-ins (Exhibits D61 and D62).

[128] Dr. Grootendorst relied on a [redacted]% figure in his Report (Exhibit D52, paragraph 170). In cross-examination at trial (trial transcript pages 1096 to 1098), he agreed that he was given this figure by Counsel for Teva and that his own calculations, at least for the year 2004, would yield a figure of about [redacted]%.

[129] In closing argument, Janssen's Counsel agreed that the figure of [redacted]% was high estimate but argued that the [redacted]% estimate put forth by Teva was far too low.

[130] In respect of this issue, I must apply the "broad axe" approach. The median between [redacted]% and [redacted]% is [redacted]% but, on the evidence, a higher figure is more probable as I favour Dr. Rosenblatt's approach more than the approach of Dr. Grootendorst which finds its genesis on a figure given by Counsel.

[131] I find that an appropriate figure to use for these sales to hospitals is [redacted]%.

l) Royalty Paid to Janssen Puerto Rico

[132] Mak debited [redacted]% and [redacted]% royalty expenses paid to one of the Janssen Puerto Rico companies in respect of sales made in the 2006 to 2010 period. These royalties should only be applied when considering the year 2010 as there is no evidence that they were paid in any of the previous years.

X. ISSUE NO. 3 – PRE-JUDGMENT INTEREST

[133] In my previous Judgment in Court File No. T-2175-04 at paragraph 5, I awarded the Plaintiffs, Janssen Canada and Daiichi pre-judgement interest, not compounded, at the average established bank rate. That Judgment was not varied on appeal and is binding upon Janssen Canada.

[134] Janssen US argues that, if it can establish that it lost profits as a result of the infringement, and that those profits would have generated income on a regular basis over the period of deprivation, then it has also sustained the damage of that lost income on those profits; exact proof of how those lost profits would have been used is not required. It relies on the decision of Justice Zinn of this Court in *Eli Lilly and Company v Apotex Inc.*, 2014 FC 1254, particularly at paragraphs 115 to 119 where he wrote:

> *[115] In conclusion Apotex has taken a far too narrow view of the judgment in Bank of America. It is true that the Supreme Court of Canada stated that "equity has been recognized as one right by which interest may be awarded other than as specifically stated" in the relevant court's statute, and that "the common law right in contract law to be awarded expectation damages is another such right;" however, the Supreme Court did not state that these were the only other "rights" available to support an award of compound interest.*
>
> *[116] Interest may be payable by a right under another statutory provision. Justice Gauthier implicitly recognized this when she wrote that Lilly could be awarded compound prejudgment interest "as an element of compensation." The source for "compensation" is subsection 55(1) of the Patent Act which provides that the infringer is liable to the patentee "for all damage sustained" by reason of the infringement. If the patentee can establish that it lost profits as a result of the infringement and that those profits would have generated income on a regular basis over the period of deprivation of those profits, then the patentee has also sustained the damage of the lost income from those profits.*

[117] Apotex submits that Lilly has failed to prove any such loss. It has failed to prove that it would have invested the lost profits and reinvested any income from it or that it would have paid down existing debt.

[118] In my view, the patentee is not required to prove exactly what use it would have made of the profit it has lost as a result of the infringer's actions. This is after all, a hypothetical scenario because it did not have the funds in hand. I subscribe to the view expressed by S. M. Waddams in The Law of Damages (3rd ed 1997), at 437, cited at para 37 of Bank of America:

> *[T]here seems in principle no reason why compound interest should not be awarded. Had prompt recompense been made at the date of the wrong the plaintiff would have had a capital sum to invest; the plaintiff would have received interest on it at regular intervals and would have invested those sums also. By the same token the defendant will have had the benefit of compound interest.*

I would go further and say that in today's world there is a presumption that a plaintiff would have generated compound interest on the funds otherwise owed to it and also that the defendant did so during the period in which it withheld the funds.

[119] Apotex argues that an award of compound interest will over compensate Lilly because it permits pre-tax dollars to be compounded rather than after-tax dollars. It says that "an award of simple interest obviates the need to take such tax considerations – which considerations may be quite complex – into account and permits a more facile calculation." The ease of calculation is not a relevant consideration in determining damages. Other than to state that the calculation may result in some windfall to the patentee, Apotex has offered no evidence to support any informed reduction in the award of compound interest over the 12 years period under consideration. Any discounting of compound interest by the court on this record would be nothing more than mere speculation. In any event, while the failure to consider that interest would have been earned on after-tax dollars may generate a higher award to Lilly, this is off-set in whole or part by the fact compound interest does not precisely account for the three factors the Supreme Court identified for the depreciation of the value of money: (i) opportunity cost, (ii) risk, and (iii) inflation.

[135] That decision is currently under appeal. I do note that the decision was that plaintiff in that case was awarded compound interest and not the profits that it alleged would have been generated.

[136] Janssen US relies on the evidence of Smith in direct examination at pages 448 to 449 of the transcript. I repeat that portion of his evidence:

> *Q. I have a few questions to ask you. It is about financial issues at Ortho-McNeil. Did you have any financial accountability at Ortho-McNeil for Ortho-McNeil-Janssen Pharmaceuticals?*
>
> *A. Sure. I was accountable for the commercial profit and loss statement for the business. So yes.*
>
> *Q. If those companies had extra profits would you have left that extra profit to sit in a bank to earn interest at a bank rate?*
>
> *A. No. For sure not. It is still true today. It was true then. We never have enough resource to take advantage of all the opportunities that we have. We are always prioritizing things we invest in. We don't have enough money in all the things that are potentially there for us to invest in.*
>
> *As a company that has shareholders and publicly held, we are accountable to grow that business every year and hopefully increase profits every year. We are always challenged on making decisions on doing an extra clinical trial on a brand that might help it be more successful or be more available to patients, to doing more pure sales and marketing effort, to again licensing in another important molecule that could be of benefit to patients over the long haul. We are always making those trade-offs. If we had extra money, it wouldn't be in the bank. It would be reinvested in the business for sure.*
>
> *Q. Would that have been true for the time period starting in December 2005 and moving forward?*
>
> *A. Absolutely.*
>
> *Q. Would that be true for any additional profits you might have received in respect of LEVAQUIN?*

> *A. I don't think it is respected to the particular product the profits come from. Profits would have been reinvested no matter what product they came from. If there was extra profits from LEVAQUIN, we would have reinvested in the business for sure.*

[137] Teva argues that, at least in this case, the terms of my previous Judgment applicable to Janssen Canada should apply equally to Janssen US; that Judgment was not altered on appeal nor did Janssen Canada even challenge that portion of the Judgment on appeal. In any event, Teva argues, the evidence of Smith is vague and inconclusive; the US income tax returns of Janssen US in evidence before me show a profit in some years and losses in other years; there is no evidence specific to the LEVAQUIN product.

[138] I agree with Teva. The terms of my previous Judgment respecting Janssen Canada and pre-judgment interest should apply equally to Janssen US. The decision of Zinn J. in *Eli Lilly* appears to consider lost profit arising from damages for lost sales is somehow reflected in an award of compound interest. Perhaps the Court of Appeal will clarify the situation. In any event, I am not satisfied that the evidence in this case, that of Smith and the tax returns, suggests that a claim for lost profits or compound interest in respect of damages is warranted.

XI. ISSUE NO. 4 - MITIGATION

[139] It is clear Canadian law that a party seeking to recover damages in a lawsuit bears the duty of taking all reasonable steps to mitigate those damages. Justice Estey of the Supreme Court of Canada wrote in *Asamera Oil Corporation Ltd. v Sea Oil & General Corporation*, [1979] 1 SCR 633 at page 661 in quoting Lord Haldane in *British Westinghouse Electric and*

Manufacturing Company, Limited v. Underground Electric Railways Company of London, Limited, [1912], AC 673 at page 689:

> *The fundamental basis is thus compensation for pecuniary loss naturally flowing from the breach; but this first principle is qualified by a second, which imposes on a plaintiff the duty of taking all reasonable steps to mitigate the loss consequent on the breach, and debars him from claiming any part of the damage which is due to his neglect to take such steps. In the words of James L.J. in Dunkirk Colliery Co. v. Lever, "The person who has broken the contract is not to be exposed to additional cost by reason of the plaintiffs not doing what they ought to have done as reasonable men, and the plaintiffs not being under any obligation to do anything otherwise that in the ordinary course of business."*

[140] Karakatsanis J. of the Supreme Court of Canada wrote in *Southcott v Toronto Catholic School Board*, 2012 SCC 51 at paragraph 24 that where it is alleged that a plaintiff failed to mitigate, the burden is on the defendant to prove that the plaintiff failed to make reasonable efforts to mitigate and that mitigation was possible.

[141] There are two evidentiary matters to consider. The first is to determine what was actually done. The second is to determine whether something more or different ought to have been done.

[142] First, as to what was actually done. My decision enjoining Teva from continuing to sell levofloxacin tablets, subject to the thirty day (30) day sell-off period, came out on October 17, 2006. The matter was appealed and affirmed by the Federal Court of Appeal on June 7, 2007. Leave to appeal to the Supreme Court of Canada was sought and refused on December 6, 2007. Thus, the matter of validity and infringement was not finally determined until December 6, 2007.

[143] The evidence on discovery given by Janssen, as read into evidence at trial by Teva, is that, as far as the hospital group of customers was concerned, Janssen as a practical matter could not raise its prices as it was bound by an existing contract. I repeat pages 544 to 545 of Park's discovery:

> *MR. KLEE: And then I would like to know the basis for the statement that the "price reductions must remain in place even after the Injunction has taken place, to avoid alienating customers..."*
>
> *THE WITNESS: It is a 3-Year Contract. Once we get the new (sic) Patent back, it wouldn't make any difference to a hospital. It is a 3-Year Deal. And then you would, at that point in time, renegotiate, after the Terms of the Contract were over, relative to what is going on in the new marketplace...*

[144] This position was affirmed at trial during the examination-in-chief of John Stewart. I repeat part of what he said at pages 703 to 704 of the trial transcript:

> *Q. In the period after Novopharm left the market, did that have an effect on Janssen's hospital prices for LEVAQUIN?*
>
> *A. There was no change to our hospital pricing.*
>
> *Q. How come?*
>
> *A. You have established relationships and listings based on the hospital prices that have been offered for the last two years plus. We are not going to rock that boat and change it on these customers. It is not the way we operate.*

[145] As far as the so-called retail customers such as doctors, the evidence is that Janssen started to revise its marketing plans for LEVAQUIN in April 2006 but did not reassign its marketing team to LEVAQUIN until later in 2007. John Stewart explained the reason why at pages 702 to 703 of the trial transcript.

> *Q. Do you know why Janssen didn't reassign people to LEVAQUIN until the third cycle in 2007?*
>
> *A. As stated previously, these things don't turn on a dime. You don't have the people in the organization and may have to hire them for the specialty role in particular. Then you have to retain absolutely everybody because there is turn over and change in our sales forces.*
>
> *You have to prepare all the selling materials. You have to get caught up on the issues in the marketplace. It is not a turnkey operation. There is a lot of work that goes into developing strategies and tactics. You tend don't do this in the middle of a cycle. It is in the beginning of cycle 1 or cycle 2. In this case, it is prepared for cycle 3. That is a reasonable amount of time.*

[146] This is what was actually done. There is no evidence from Teva as to what ought to have been done. There are only assertions by Teva's lawyers in argument as to what ought to have been done and when. The Court has no evidence from any marketing person from Teva or any other evidence to suggest that the steps actually taken by Janssen were too late or inadequate.

[147] Given the evidence that I have, I cannot conclude that the steps taken by Janssen were insufficient to mitigate the damages incurred.

XII. COSTS

[148] The parties have asked for an opportunity to make submissions as to costs once they are apprised of my decision. Therefore, I ask that I receive submissions as to costs from the Plaintiffs within twenty (20) days from the release of this Judgment and from the Defendant within twenty (20) days thereafter.

XIII. CONCLUSIONS

[149] I have sent these Reasons in draft to Counsel for each of the parties and asked that they, working with their experts, Cohen and Mak, prepare an agreed upon set of figures that result from these changes to some of the assumptions underlying Scenario A. They have done so and have submitted an agreed set of numbers which include pre-Judgment interest calculated in accordance with the terms of these Reasons and my previous Judgment up to the last day of May, 2016. It is understood that, in agreeing to these numbers, the parties are reserving their rights to challenge any or all of my findings herein. The damages together with pre-Judgment interest are calculated individually for each of Janssen Canada and Janssen US.

[150] I have determined that Janssen Pharmaceuticals, Inc. (Janssen US) has standing as a person "claiming under" Daiichi, the patentee of the 080 Patent, to make a claim for damages herein.

[151] Janssen US is entitled to pre-Judgment interest on the same terms as expressed in paragraph 5 of my previous Judgment dated October 17, 2006, respecting Janssen Canada.

[152] It has not been shown that Janssen Canada failed to mitigate its damages.

[153] Janssen Canada is entitled to be paid damages by Teva in the sum of $5,498,270.00 inclusive of pre-Judgement interest as aforesaid and Janssen US is entitled to be paid damages in the sum of $13,342,949.00, inclusive of pre-Judgment interest.

JUDGMENT

FOR THE REASONS PROVIDED HEREIN:

THIS COURT'S JUDGMENT is that:

1. Teva Canada Limited shall pay Janssen Inc. damages, inclusive of pre-Judgment interest, in the sum of $ 5,498,270.00.
2. Teva Canada Limited shall pay Janssen Pharmaceuticals, Inc. damages, inclusive of pre-Judgment interest, in the sum of $ 13,342,949.00.
3. Costs will be the subject of a subsequent Judgment once the submissions of the parties have been received in accordance with the timetable set out in the Reasons, and considered.

"Roger T. Hughes"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-2175-04
STYLE OF CAUSE:	JANSSEN INC. AND DAIICHI SANKYO COMPANY, LIMITED V TEVA CANADA LIMITED
AND DOCKET:	T-2056-11
STYLE OF CAUSE:	JANSSEN-ORTHO LLC, JANSSEN PHARMACEUTICALS, INC., AND OMJ PHARMACEUTICALS, INC. V TEVA CANADA LIMITED AND DAIICHI SANKYO COMPANY, LIMITED
PLACE OF HEARING:	TORONTO, ONTARIO
DATES OF HEARING:	APRIL 4, 5, 6, 7, 8, 11, 12, 14, 15 AND 21, 2016
PUBLIC JUDGMENT AND REASONS:	HUGHES J.
DATED:	MAY 31, 2016

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