Federal Court  Cour fédérale

Date: 20090512

Docket: T-1168-01

Citation: 2009 FC 494

BETWEEN:

APOTEX INC.

Plaintiff

and

SYNTEX PHARMACEUTICALS INTERNATIONAL LTD.
and HOFFMANN LAROCHE LIMITED

Defendants

REASONS FOR JUDGMENT

HUGHES J.

[1] This is an action brought by Apotex Inc. for damages and other relief under the provisions of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (*PMNOC Regulations*). This action raises a number of complex issues, some of which have been deferred pending the outcome of other proceedings now before the Federal Court of Appeal. All of the issues, including those not deferred, arise from the arcane nature of the *PMNOC Regulations*, imperfections in their draughtsmanship often the subject of comment by the Courts, and the presumably large amounts of money at stake, all of which motivates the

parties and their lawyers to leave no stone unturned. For the reasons that follow, I find that the action is dismissed with costs to the Defendant Hoffmann LaRoche Limited.

PARTIES PATENT AND DRUG

[2] The Plaintiff Apotex Inc. is an Ontario corporation which has been engaged in extensive litigation as a generic drug company. It can be referred to as a "second person" in the *PMNOC Regulations*. Syntex Pharmaceuticals International Limited is the owner (patentee) of the patent at issue, Canadian Letters Patent No. 1,204,671 ('671 patent). However, this action was discontinued against that party by Notice filed January 31, 2007. The style of cause was never changed. The Defendant Hoffman-LaRoche Limited is the corporate successor of another company Syntex Inc. (both collectively referred to as Roche) which has listed the '671 patent with the Minister of Health under the provisions of the *PMNOC Regulations*. Roche is referred to as a "first party" under those *Regulations*.

[3] The '671 patent was issued and granted to the Defendant Syntex Pharmaceuticals on May 20, 1986 (Trial Exhibit 2-2). That patent is subject to the version of the *Patent Act*, R.S.C. 1985, c. P-4, applicable to patents maturing from applications filed before October 1, 1989, the so-called "old" *Patent Act*. That patent would normally enjoy a term of 17 years from the date of grant that is until May 20, 2003. The technical aspects of that patent and its claims are not particularly relevant in this action. It is directed to a controlled release formulation of a tablet containing naproxen or naproxen sodium as the active ingredient. That drug is, according to the '671 patent, useful as an anti-inflammatory agent. The Defendant Roche sells such a product

under the brand name NAPROSYN SR and listed the ’671 patent in respect of that product under the provisions of the *PMNOC Regulations* on about April 7, 1993 (Trial Exhibit 2-3).

APOTEX ENGAGES THE *PMNOC REGULATIONS*

[4] The *PMNOC Regulations* were put into effect as of March 12, 1993. They replaced an earlier system of compulsory licenses granted by the Commissioner of Patents in respect of patents directed to medicines. Roche was quick off the mark in listing the ’671 patent, among others, under those *Regulations*. Apotex was equally quick to engage the *Regulations* by serving a Notice of Allegation respecting, among other patents, the ’671 patent, on or about June 15, 1993 (Trial Exhibit 2-4). Apotex made two allegations as to the ’671 patent. The first was a technical one as to whether the claims were in fact directed to a medicine itself or drug itself and thus whether the patent came within the scope of the *Regulations*. The second was an allegation directed to non-infringement and simply said:

> *Furthermore, Apotex Inc. hereby undertakes that any tablets produced and sold by Apotex will not fall within the scope of the claims of patent 1204671, so that no claim would be infringed.*

[5] It is important to take note that, at this time, Apotex did not allege invalidity of the ’671 patent.

[6] Roche and Syntex Pharmaceuticals, upon receipt of the Notice of Allegation, commenced an application for prohibition in this Court as provided for by the *PMNOC Regulations* on August 3, 1993 (Trial Exhibit 2-5). The result of that application was a prohibition Order.

THE PROHIBITION ORDER AND REASONS

[7] As a result of the application by Roche and Syntex Pharmaceuticals to this Court, Reed J. granted a prohibition Order against the Minister of National Health and Welfare as provided for in section 6(2) of the *PMNOC Regulations* on March 20, 1996 (Trial Exhibit 2-6). The operative part of the Order stated:

> *THIS COURT ORDERS THAT:*
> *The Minister is prohibited from issuing a Notice of Compliance to Apotex, with respect to its new drug submission pertaining to 750 and 1000[sic] Sustained Release tablets of the medicine Naproxen and to which the notice of allegation dated June 15, 1993, relates, until after the expiration of Canadian Letters Patent 1,204,671.*

[8] In her Reasons (also Trial Exhibit 2-6 reported as 67 C.P.R. (3d) 484) Reed J. dealt with the two specific allegations made by Apotex. As to the first, whether that patent fell within the scope of the *PMNOC Regulations*, she held that recent jurisprudence determined that such a patent was within the scope of the *Regulations*. She wrote at pages 486-487:

> *These applications deal yet again with the procedures and burden of proof that apply in applications brought pursuant to subsection 6.(1) of the Patented Medicines (Notice of Compliance) Regulations. Many aspects of the issues originally raised in the present applications have been settled, at least, insofar as the Trial Division is concerned. This is the result of decisions such as: Deprenyl Research Ltd. v. Apotex Inc. (1994), 55 C.P.R. (3d) 171 (F.C.T.D.) affirmed (1995), 60 C.P.R. (3d) 501 (F.C.A.) (process claims are not claims which contain a claim for the medicine itself); Eli Lilly and Co. v. Apotex Inc. (1995), 63 C.P.R. (3d) 245 (F.C.T.D.) (process claims for intermediate substances are not claims for the medicine itself); Hoffmann-La Roche Ltd. v. Canada (Minister of Health and Welfare)(1995), 62 C.P.R. (3d) 58 affirmed A-389-95, December 5, 1995[reported 67 C.P.R. (3d) 25] (composition or formulation claims are claims for the medicine itself).*

[9] As to the allegation of non-infringement, Reed J. found that the facts had not been sufficiently alleged and that the allegation was not justified. She wrote at page 503:

> *In the case of patent 1,204,671 (file T-1898-93), however, there is no assertion of fact that could lead to a conclusion that the allegation of non-infringement is justified. Even if I accept counsel's interpretation of the allegation and find that it implicitly contains the assertion of fact suggested, the claim is framed in approximate terms. The implied assertion that the respondent's product does not fall within the specific range of weight percentages listed would not support the allegation of non-infringement. Also, an undertaking by the respondent not to infringe the applicants' patent is not an assertion of fact. It cannot support a finding that the allegation of non-infringement is justified.*

[10] Apotex requested permission to file further evidence as to non-infringement, which was denied. Reed J. wrote at page 504 of her Reasons:

> *Counsel for the respondents argues that if I should find against his clients, I should allow the respondents to adduce further and better affidavit material to support their allegation. Rule 303 provides that the Court may, at any stage of the proceedings, order any document to be amended in order to determine the real controversy. Alternatively counsel asks that any order which is given be expressed to be without prejudice to the respondents to file with the Minister another notice of allegation.*
> *I am not persuaded that rules 6 and 320(b) are appropriate. What I am being asked to do is not to waive compliance with the rules but to substitute an alternate procedure (requesting information from the respondent) for the one required (obtaining the record from the Minister). Compliance with the rules has been waived in a significant way already, by not insisting on compliance, for example, with rules 1602 and 1603.*

[11] Apotex also requested that any Order of prohibition be expressed in terms that would allow a new notice of allegation to be made. Reed J. declined. She wrote at pages 504 and 505:

> *With respect to the second proposition, that the order of prohibition against the Minister should be expressed to be without prejudice to the respondent's right to file new notices of allegation, I do not think that option is open to me. Subsection 6.(2) of the Regulations requires the issuing of an order of prohibition if the allegations are found not to be justified:*
>
> > *The court shall make an order pursuant to subsection (1) [an order prohibiting the Minister from issuing a notice of compliance until after the expiration of one or more of the patents that are the subject of an allegation(s)] ... if it finds that none of the allegations is justified. (emphasis added)*
>
> *Subsection 55.2(5) of the Patent Act provides that section 55.2 of the Patent Act as well as the Regulations made thereunder, prevail over any other Act of Parliament or set of regulations. Therefore, the mandatory nature of subsection 6.(2) of the Regulations would not seem to leave the option which is suggested open to me. In addition, the notice of allegation is part of the new drug submission which is before the Minister. It is not under the control of this Court. Whether that document can be amended, or withdrawn, is a matter to be dealt with by the Minister in accordance with the rules normally applied to material filed as part of a new drug submission and in accordance with the rules normally applied to the withdrawal or substitution of the submission as a whole.*

[12] The decision of Reed J. was appealed and cross-appealed to the Federal Court of Appeal. That Court, on October 21, 1996, dismissed the matter upholding Reed J. on the disposition she made respecting the ’671 patent including her refusal to permit further evidence (Trial Exhibit 2-7 reported at 70 C.P.R. (3d) 1). I am advised by Counsel that no leave to appeal to the Supreme Court of Canada was sought or if it was nothing came of it.

OTHER PROCEEDINGS RESPECTING THE ’671 PATENT

[13] Two days after Reed J. issued the prohibition Order, Apotex served a new Notice of Allegation on Roche. Roche filed a new Notice of Application with this Court on May 2, 1996. That matter and related matters, Court files numbered T-1712-95; T-421-96 and T-998-96, came before MacKay J. of this Court. On January 8, 1997, he gave an Order permanently staying the proceedings. MacKay J. wrote at paragraphs 49 to 54 of his Reasons cited as (1997), 71 C.P.R. (3d) 129:

> ***49*** *The later notice of allegation, dated March 22, 1996, two days after the Order of Reed J., includes more detail concerning the claims under the patent in issue, an undertaking that any tablets formulated by Apotex will not fall within the scope of the claims, and that Apotex' formulation will be that earlier provided to the applicants' solicitors under a letter of January 29, 1996 in Court file T-1898-93, before Madame Justice Reed's decision, which should form part of the notice of allegation. In T-1898-93, Madame Justice Reed had declined to grant leave to Apotex to introduce evidence of its formulation, which when tendered to the applicants' solicitors in January 1996 had been declined, and her decision was upheld by the Court of Appeal in its decision of October 21, 1996.*
>
> ***50*** *In the result, as I compare the notices of allegation, that of June 15, 1993, which was determined not to be justified by Reed J., and that of March 22, 1996 which gives rise to the second application for an Order of prohibition to the Minister, in my opinion, they are essentially the same at this stage. Moreover, in view of comments of Stone J.A. for the Court of Appeal in considering the denial by Reed J. of leave to Apotex to adduce further evidence, I consider there is no likelihood of a grant of leave for the same purpose in this proceeding, T-998-96, should it be sought.*
>
> ***51*** *Thus the application of Hoffmann-La Roche and Syntex, here raises different considerations than in the two other files, for here the second notice of allegation is in essence the same as that already determined by Reed J., and upheld by the Court of Appeal, not to be justified. To permit a second round of proceedings, to*

> *determine an issue already determined by a judge of this Court and upheld by the Court of Appeal, would be an abuse of process. Yet that process is here initiated by the applicants, in accord with the Regulations, to preserve their interests in light of what can be deemed to be a frivolous action by Apotex, the filing of a second notice of allegation similar to one found not to be justified.*
>
> ***52*** *In these circumstances, the issues raised having already been determined so that the principle of res judicata applies, in my opinion, it is in the interests of justice that proceedings in Court file T-998-96, be stayed, permanently, unless by further order the Court were to permit the matter to proceed, if for example, the application by Apotex for leave to appeal to the Supreme Court of Canada, in relation to the order of the Court of Appeal, should ultimately prove successful. So long as the stay is in effect, the existing Order of Madame Justice Reed continues, prohibiting issue of an NOC to Apotex in respect of its NDS pertaining to 750 and 1000 sustained release tablets of Naproxen until expiry of the '671 patent.*
>
> ***53*** *There is one final argument of the applicants that warrants brief reference. It is urged that by the principle of res judicata, in its broad application, Apotex is estopped from raising in a second proceeding issues or grounds that it might have raised in the first proceedings which resulted in orders prohibiting issue of NOCs in the cases concerning the three drugs in issue. I am not prepared to apply that principle in circumstances where Apotex' notices of allegation are not a pleading before this Court, but rather are statements submitted to the Minister and to the holder of an NOC. The notices are not without legal significance, as has been noted elsewhere, but they come before this Court as a matter of evidence which the Court is to weigh in accord with the Regulations when the application for judicial review, seeking an order of prohibition, is heard.*
>
> ***54*** *I should note that while the Court may not direct the form or content of a Notice of Allegation, it may control any abuse of the process under the Regulations by its assessment of those notices, and by awards of costs if it be considered the process is abused or in cases where the action of a party which gives rise to the proceedings is deemed to be frivolous.*

[14] I am advised by Counsel that an appeal was taken from that decision but never pursued.

[15] Oddly, however, the Minister of Health, 30 months after the second Notice of Application was filed and no determination on the merits having been made, issued an NOC to Apotex on November 2, 1998. Immediately Roche filed an application with this Court to quash that NOC. The matter was heard by Evans J. (as he then was) who, after some deliberation and with reluctance quashed the NOC. He wrote at paragraphs 30 to 33, 36 and 37 of his Reasons reported as (1999), 1 C.P.R. (4th) 1:

> ***30*** *It is important to remember that, as a result of Eli Lilly, supra, orders of prohibition issued in this area are not in rem. That is, they do not operate to prevent the Minister from ever issuing a Notice of Compliance with respect to a particular product. Their scope is limited to the kind of allegation that the Court found to be unsupported by the evidence adduced by the respondent when it issued the order of prohibition. Hence, when a different kind of allegation is made with respect to the same patent, the patent holder must seek another order of prohibition in order to restrain the Minister from having to issue a Notice of Compliance. This was the conclusion that MacKay J. had also reached in AB Hassle, supra, when dealing with the second notice of allegation by Apotex.*
>
> ***31*** *Thus, the prohibition issued by Reed J. could only apply to the allegation of non- infringement before her, and any other allegation that was found to be essentially similar. Accordingly, in the absence of either an order of prohibition issued by MacKay J. with respect to the allegation of invalidity, or an order extending the thirty month statutory stay, Apotex became entitled to a Notice of Compliance by virtue of its allegation that Hoffmann-La Roche's patent with respect to naproxen sustained release 750 mg tablets is invalid.*
>
> ***32*** *If I were to decide in favour of Hoffmann-La Roche and thus, on the facts of this case, prefer the advantages offered by the principle of res judicata, namely certainty and a measure of finality to litigation, I would thereby give an effect to a judgment of this Court that it could not have been intended to have, and exhibit a preference for form over substance. Conversely, to accede to the*

> *argument advanced on behalf of Apotex would inevitably sacrifice the important principle that, subject to their reversal on appeal, orders of this Court are final and should be given effect according to their clear terms.*
>
> ***33*** *I do not regard this as an attractive choice. However, I have decided that on the facts of this case the lesser evil is to find in favour of the applicant, and thereby uphold the values underlying the res judicata doctrine. My reasoning is as follows.*
>
> …
>
> ***36*** *Naturally, it is hard not to be troubled by the fact that a consequence of my decision is that Apotex is prevented from litigating under the Patented Medicines (Notice of Compliance) Regulations its allegation of invalidity and from having the Court determine whether it is sufficiently supported as to prevent the Court from prohibiting the Minister from issuing a Notice of Compliance. I am mindful also, of course, that the effect of my order may well be to delay the introduction of competition until well after the expiry of Hoffmann-La Roche's patent on naproxen sustained release 750 mg tablets. However, the protection of patent rights also rests on public interest considerations, and I am in no position to determine here how the competing public interests should be balanced out in this case.*
>
> ***37*** *What I do know is that standing firmly on the res judicata doctrine will forestall the expenditure of additional time and resources, both public and private, that a finding in favour of Apotex would have involved. However, I have no illusions that my reasons and order disposing of this application for judicial review will be taken as the final word on the matter.*

[16] In the meantime Apotex started an action, not under the *PMNOC Regulations* but under the *Patent Act, inter alia*, for a declaration that the ’671 patent is invalid, void and of no force and effect. The Statement of Claim (Trial Exhibit 2-8) was filed with this Court on January 21, 1997. This action came to trial before Reed J., the same judge who granted the prohibition Order. Reed J. by a Judgment dated April 19, 1999, released together with Reasons on April 23,

1999, (Trial Exhibit 2-9) declared, *inter alia*, that the '671 patent "*…is invalid, void and of no force and effect*". Further she held that the particular Apotex formulation put in evidence would not have infringed that patent, if valid. Reed J. in her Reasons, reported at (1999), 1. C.P.R. (4th) 22, wrote in respect of the earlier NOC proceedings that they were separate and distinct from the action and did not impact on the findings to be made in the action. She wrote at paragraphs 25, 26 and 29:

> ***25*** *With respect to the broader question, the effect of the plaintiff having had an opportunity, at an earlier time, to have had the question of infringement based on the formulation now in issue determined, the jurisprudence discussing the differences between an application for an order of prohibition under the Notice of Compliance Regulations and an action for patent infringement is relevant. The Federal Court of Appeal and the Supreme Court of Canada have made it very clear that a determination as to whether or not a Notice of Allegation is justified is a separate and different proceeding from a finding of infringement or invalidity in a patent action. In Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare) (1994), 55 C.P.R. (3d) 302 at 320, the Federal Court of Appeal stated:*
>
> > *Those proceedings, after all, are instituted by the patentee and seek a prohibition against the Minister; since they take the form of a summary application for judicial review, it is impossible to conceive of them giving rise to a counterclaim by the respondent seeking such a declaration. Patent invalidity, like patent infringement, cannot be litigated in this kind of proceeding. I can only think that the draftsperson had in mind the possibility of there being parallel proceedings instituted by the second person which might give rise to such a declaration and be binding on the parties. [Underlining added.]*
>
> ***26*** *In Pharmacia Inc. v. Canada (Minister of National Health and Welfare) (1994), 58 C.P.R. (3d) 209 at 217, Mr. Justice Strayer writing for the Federal Court of Appeal stated:*

> *It will be noted that the regulations nowhere create or abolish any rights of action between the parties; instead they confer a right on the patentee to bring an application for prohibition against the Minister of National Health and Welfare. That is, the regulations pertain to public law, not private rights of action. ... If the Governor in Council had intended by these regulations to provide for a final determination of the issues of validity or infringement, a determination which would be binding on all private parties and preclude future litigation of the same issues, it surely would have said so. This court is not prepared to accept that patentees and generic companies alike have been forced to make the sole assertion of their private rights through the summary procedure of a judicial review application. As the regulations direct that such issues as may be adjudicated at this time must be addressed through such a process, this is a fairly clear indication that these issues must be of a limited or preliminary nature. If a full trial of validity or infringement issues is required this can be obtained in the usual way by commencing an action. [Underlining added.]*
>
> …
>
> ***29*** *As I understand the jurisprudence, one of the reasons the Federal Court of Appeal has held that the two proceedings are separate and distinct is because an application for an order of prohibition pursuant to the Regulations is a summary proceeding. Also, the issue in the two proceedings is different, since in the one case it is the justification of an allegation made to the Minister that is the subject of the proceeding, while the other determines private rights as between the parties. I do not consider the comments in the above jurisprudence to be merely obiter dicta, and I note that the law does not always endorse a policy of no duplication of proceedings. There are many circumstances in which hearings or trials de novo are allowed, or where an administrative decision-making process and private litigation deal with the same underlying factual situation without a determination in the former precluding an independent determination in the latter.*

[17] This decision was not pursued on appeal.

APOTEX REVISITS THE PROHIBITION ORDER

[18] Four days after Reed J. gave her Judgment invalidating the '671 patent, Apotex brought a motion in the earlier application proceedings seeking to have the prohibition Order set aside and the application dismissed (Trial Exhibit 2-10).

[19] On April 30, 1999, Reed J., who heard the motion, made an Order setting aside her prohibition Order and dismissing the application. The Order stated:

ORDER

> ***UPON*** *an application on behalf of the respondent, Apotex Inc., for:*
> *1. An order setting aside the order of Madame Justice Reed dated March 20, 1996;*
> *2. An order dismissing the within application;*
> *3. Such further and other order as to this Honourable Court may seem just;*
>
> ***AND*** *for the reasons for order issued this day;*
>
> ***THIS COURT ORDERS***
>
> *the orders sought in paragraph 1 and 2 above are granted.*

[20] In the proceedings before Evans J., Counsel for the Minister of Justice, acting on behalf of the Minister of Health, wrote a letter to the Court dated April 20, 1999 (Trial Exhibit 3), in which it was submitted that the proper course of action was for Apotex to seek to set aside the Prohibition Order.

[21] That letter said, in part:

> *Accordingly, the Minister respectfully submits that the appropriate remedy for Apotex Inc. at this time is not to seek to apply the judgment of April 19 in the stay motion. Rather, it is to seek to set aside the Prohibition Order of March 30, 1996 and to vary the Order of January 8, 1997, under Rule 399. If successful, that motion would have the effect of rendering moot the judgment of this currently the subject of the stay motion. Considering the effect of the judgment of April 19, 1999, the Minister would consent to a motion to set aside the Prohibition Order.*

[22] Reed J. wrote reasons for her Order (Trial Exhibit 2-11) reported at (1999), 167 F.T.R. 111. She stated that the earlier prohibition Order by its own terms had ceased to be operative once a Judgment had issued declaring the patent invalid. However "*for greater certainty*", she stated that she would grant the Order as requested. At paragraphs 14 to 16 of her Reasons Reed J. wrote:

> ***14*** *I turn then to my analysis. I am not persuaded that the order that is being sought is necessary to allow the Minister to issue a Notice of Compliance. The order that was given in T-2870-96 declared the '671 patent to be "invalid, void and of no force and effect". In my view, this entitles the Minister to treat the patent as a nullity for section 4 purposes. The Minister is entitled to proceed as though the patent had never been listed. In addition, the March 20, 1996, order of prohibition that issued in this case stated that it would continue "until after the expiration of Canadian Letters Patent 1,204,671". The patent has now been declared invalid, that is for all practical purposes an expiration of the patent. Thus, I think the order by its own terms ceases to have any operative effect with the issuance of the order in T-2870-96 declaring the patent invalid.*
>
> ***15*** *I can understand, however, why the Minister's legal advisers are being cautious. The spectacle of a Minister being accused of not obeying a Court order is not one they would wish him to encounter. Accordingly, I am prepared, for greater certainty, to grant the order that is requested.*

> ***16*** *I have been persuaded that the Court has jurisdiction to set aside the March 20, 1996, order in a situation such as the present, not on the ground that it was void when given, but as a result of changed circumstances. That is, I accept that the Court has a continuing jurisdiction, as exists in the case of injunctions, to modify the order of prohibition. I am not persuaded that the present motion is a collateral attack on Mr. Justice Evans' decisions. The foundation of the March 20, 1996, order no longer exists, thus, the orders requested must be granted.*

[23] No appeal was taken from this decision. Apotex was granted an NOC on May 4, 1999 (Trial Exhibit 2-12).

[24] It is this Order of Reed J. that is the basis for Apotex's claim made under section 8 of the *PMNOC Regulations*. Many issues arise in this regard.

RELIEF-CLAIMED-DROPPED-DEFERRED

[25] The Plaintiff Apotex has claimed the following relief in its Amended Statement of Claim (Trial Exhibit 1-1):

> *1.The Plaintiff, Apotex Inc. ("Apotex"), claims:*
>
> *(a) damages suffered by Apotex in respect of the drug naproxen slow release tablets by reason of the commencement of a proceeding by the Defendants pursuant to the Patented Medicines (Notice of Compliance) Regulations (the "Patented Regulations"), in respect of:*
>
> > *(i) lost sales of Apotex' naproxen slow release tablets;*
> > *(ii) legal and other expenses incurred in defending the proceeding under the Patent Regulations as well as a second proceeding commenced under the Patent Regulations;*

> *As more particularly hereinafter detailed:*
>
> *(b) an accounting of the profits realized by the Defendants in respect of the sales of naproxen slow release tablets made by them that would have been made by Apotex as described in subparagraph (a)(i), if Apotex so elects in the alternative to subparagraph (a)(i);*
>
> *(c) disgorgement of the Defendants' revenues of naproxen slow release tablets attributable to the higher price charged by the Defendants for their naproxen slow release tablets, unjustly realized by the Defendants in respect of the sales made by them that would have been made by Apotex as described in subparagraph (a)(i) by reason of the commencement of a proceeding by the Defendants under the Patent Regulations, as more particularly hereinafter detailed;*
>
> *(d) pre-judgment and post-judgment interest,*
>
> *(e) costs of this action on a scale to be determined by this Honourable Court; and*
>
> *(f) such further and other relief as this Honourable Court deems just.*

[26] As the outset of the trial Counsel for Apotex advised the Court that the claim for unjust enrichment (paragraph 1(c)) was dropped as was the claim for legal and other expenses (paragraph 1(a)(ii)). No further or other relief as claimed in paragraph 1(f) was sought.

[27] By an Order of this Court dated July 19, 2004 (Trial Exhibit 1-4) the quantification of any damages or profits awarded and any quantification of sales revenues was deferred to be determined, if necessary, at a later trial or reference.

ISSUES – DERERRED AND REMAINING

[28] By agreement between the parties (Trial Exhibit 5) the following issues that would otherwise require determination at this trial will follow the result in another action, T-1144-05, subject to any different disposition on appeal. Those issues are set out in paragraph 1 of that agreement as follows:

> *1. Subject to paragraphs 3 and 4 below, the disposition of the following issues and in addition the issue referred to in paragraph 2 ("Issues") will follow the result in T-1144-05 as set below:*
>
> *(i) Section 8 of the Patented Medicines (Notice of Compliance) Regulations SOR/93-133 as amended (SOR/98-166) effective until 2006 is:*
>
> *a. within the competence of the Federal Court to hear and determine an action brought thereunder;*
> *b. enabled by the Patent Act, R.S.C., c. P-4 as amended S.C. 1993, c. 2, s. 4 and*
>
> *c. intra vires the constitutional authority of the federal Parliament of Canada.*
>
> *(ii) Apotex Inc. is not entitled to elect an account of the profits of Hoffmann-LaRoche Limited (as claimed in paragraph 1(b) of the Amended Statement of Claim).*

[29] I need not set out the rest of that agreement in those reasons, but the parties reserve their rights on appeal and so forth.

[30] The parties were in substantial agreement as to the issues remaining for determination at this trial. I will take the issues as set out by Apotex at paragraph 10 of its Memorandum and by

Roche at paragraph 31 of its first Memorandum and recast them slightly. The first three issues are essentially common to all parties, the last two are those raised by Roche:

1. Which version of the *PMNOC Regulations*, the 1993 or 1998 version, is applicable to the claims made by Apotex in this action?
2. If the 1998 version of the *PMNOC Regulations* is applicable, do the events respecting the prohibition Order proceedings trigger section 8 of those *Regulations*?
3. If the 1993 version of the *PMNOC Regulations* is applicable, do the events respecting the prohibition Order trigger section 8 of those *Regulations*?
4. If either the 1993 or 1998 version of the *PMNOC Regulations* is applicable, is Apotex disentitled to any relief by its conduct in the prohibition Order proceedings?
5. If Apotex is entitled to relief under either the 1993 or 1998 *PMNOC Regulations* what is the most appropriate beginning date for the period of liability?

ISSUE #1: *Which version of the PMNOC Regulations, the 1993 or 1998 version, is applicable to the claims made by Apotex in this action?*

[31] The *PMNOC Regulations* were enacted effective March 12, 1993. The first amendment to those *Regulations*, SOR/98-166, came into force March 11, 1998. I will refer to these as the 1993 and 1998 versions respectively. The 1993 version contained certain provisions as to relief that may be claimed by a second person such as Apotex in certain circumstances as set out particularly in section 8. The 1998 version made a number of changes to the *Regulations*,

including to section 8. The 1998 amendments included transitional provisions in section 9 of the amendments. Of particular interest is section 9(6). I reproduce the whole of section 9:

TRANSITIONAL PROVISIONS	*DISPOSITIONS TRANSITOIRES*
9. (1) Subsection 4(4) does not apply to an allegation if, before the coming into force of these Regulations, it was served on the first person, if proof of that service was served on the Minister and if the first person has commenced a proceeding under subsection 6(1).	*9. (1) Le paragraphe 4(4) ne s'applique pas aux allégations si, avant l'entrée en vigueur du présent règlement, elles ont été signifiées à la première personne, si la preuve de leur signification a été signifiée au ministre et si la première personne a présenté une demande aux termes du paragraphe 6(1).*
(2) Subsections 6(5) and (9) and paragraphs 6(10)(a) *and (*b*) of the Regulations, as enacted by section 5, apply to an application pending on the coming into force of these Regulations.*	*(2) Les paragraphes 6(5) et (9) et les alinéas 6(10)*a*) et* b*) du même règlement, édictés par l'article 5, s'appliquent aux demandes qui sont pendantes à la date d'entrée en vigueur du présent règlement.*
(3) Subsections 6(6) to (8) and paragraph 6(10)(c) *of the Regulations, as enacted by section 5, apply to an application commenced on or after the coming into force of these Regulations.*	*(3) Les paragraphes 6(6) à (8) et l'alinéa 6(10)*c*) du même règlement, édictés par l'article 5, s'appliquent aux demandes présentées à la date d'entrée en vigueur du présent règlement ou après cette date.*
(4) Paragraph 7(1)(e*) of the Regulations, as enacted by subsection 6(2), applies to an application made on or after the coming into force of these Regulations. Paragraph 7(1)*(e*) of the Regulations as it read before the coming into force of these Regulations, continues to apply to an*	*(4) L'alinéa 7(1)*e*) du même règlement, édicté par le paragraphe 6(2), s'applique aux demandes présentées à la date d'entrée en vigueur du présent règlement ou après cette date. L'alinéa 7(1)*e*) du même règlement, dans sa version antérieure à la date*

application pending at the time of that coming into force.	*d'entrée en vigueur du présent règlement, continue de s'appliquer aux demandes qui sont pendantes à cette date.*
(5) Subsection 7(5) of the Regulations, as enacted by subsection 6(3), applies to an application pending on the coming into force of these Regulations.	*(5) Le paragraphe 7(5) du même règlement, édicté par le paragraphe 6(3), s'applique aux demandes qui sont pendantes à la date d'entrée en vigueur du présent règlement.*
(6) Section 8 of the Regulations, as enacted by section 8, applies to an application pending on the coming into force of these Regulations.	*(6) L'article 8 du même règlement, édicté par l'article 8, s'applique aux demandes qui sont pendantes à la date d'entrée en vigueur du présent règlement.*

[32] The relevant dates and events for consideration of this issue are:

- March 12, 1993 – Original *PMNOC Regulations* in force
- August 3, 1993 – Roche files its Notice of Application with this Court
- March 20, 1996 – Reed J. grants the prohibition Order
- October 21, 1996 – Federal Court of Appeal affirms the prohibition Order
- March 11, 1998 – Amendments to *PMNOC Regulations* came into force
- April 23, 1999 – Apotex files a motion respecting the prohibition Order
- April 30, 1999 – Reed J. sets aside the prohibition Order and dismisses the application.

[33] This issue must be decided by considering whether the proceeding in which the prohibition Order was granted then subsequently set aside and the application dismissed was "pending" or, in the French language version, "pendantes", as of March 11, 1998 within the meaning of section 9(6) of the 1998 amendments. If proceeding was "pending - pendantes" as of that date then the 1998 version of the *Regulations* applies. If not, then the 1993 version applies.

[34] The term "pending" or "pendantes" is not defined in the *PMNOC Regulations* or in the *Patent Act*, nor has there been any judicial consideration of section 9 or those terms in the context of the *PMNOC Regulations*. *The Canadian Law Dictionary*, Law and Business Publication (Canada) Inc., 1980 defined "pending" as:

> ***Pending, pendency****: An action or legal proceeding is said to be pending after it has been commenced and before the final judgment or disposition of the same has been given or made.*
> *The word 'pending' can also mean awaiting as in the expression 'pending an application'. Re North Huron Election, (1926) 1 D.L.R. 590, 58 O.L.R. 197.*

[35] *Black's Law Dictionary*, 8th ed., Thomson West defines "pending" as:

> ***Pending****, adj 1. Remaining undecided, awaiting decision <a pending case>. 2. Parliamentary law. (Of a motion) under consideration; moved by a member and stated by the air as a question of the meeting's consideration. See Consideration (2); On the floor. A motion may be immediately pending, meaning that it is directly under consideration, being the last motion stated by the chair and next in line for a vote; or it may be pending subject to other motions of higher rank that have taken precedence over it. See immediately pending motion, pending motion under Motion (2).*

[36] The *Dictionnaire du Droit Québécois et Canadien*, 3rd ed., Wilson & Lafleur defines "pendant, ante" as:

> ***Pendant, ante*** *adj.*
>
> - *1. Se dit d'une affaire portée devant une juridiction mais n'ayant pas encore fait l'objet d'une décision. Ex. Une cause pendante.*
>
> *Angl. Pending, undecided.*
>
> - *1. Se dit d'une condition suspensive ou résolutoire qui n'est pas encore accomplie. Comp. Condition pendante, pendente conditione*
>
> *Angl. Pending*

[37] The online dictionary, JuriTravail.com defines "pendante" as:

> *On dit qu'une affaire est pendante lorsqu'un tribunal a été saisi et que la cause n'a pas encore été jugée. Elle est "pendante" jusqu'à ce que (selon le cas) le jugement ou l'arrêt soit prononcé.*
>
> *On retrouve cette expression dans sa forme latine dans les écrits de la doctrine, plus rarement dans les jugements, pour exprimer qu'un fait dont l'arrivée subordonne la naissance ou l'exigibilité d'une prestation, ne s'est pas encore produit. On dit alors que l'obligation est " pendente conditione" ou encore "sous condition".*

[38] Thus the plain and ordinary meaning of "pending" or "pendante" with respect to legal proceedings is a proceeding that is not yet finished, one in which there is no final judgment.

[39] In most Courts, including this one, a judgment is final once it has been determined and issued by the judge or Court hearing the matter. Such a judgment is often subject to appeal and, if an appeal is taken, may not be considered final until all appeals have disposed of the matter.

In certain circumstances a judgment may be amended where there are clerical errors or matters overlooked. A judgment may also be revisited in cases of fraud or if some material fact, not otherwise previously discoverable, comes to light. Nonetheless, once issued, such a judgment is considered final.

[40] In certain unusual circumstances, such as the present, a final judgment may be varied or set aside. Recently Sharlow JA. for the Federal Court of Appeal in *Apotex Inc. v. AB Hassle et al.*, December 22, 2008, 2008 FCA 416, indicated that there were circumstances in which a judgment resulting in a prohibition Order could be set aside: for instance where there has been a determination of invalidity or non-infringement in another action. At paragraph 30 she wrote:

> *[30] As mentioned above, it has been established that a final determination by the Federal Court that a patent is invalid will prevail over a prohibition order relating to that patent, justifying the setting aside of the prohibition order (Hoffmann-La Roche, cited above). By the same reasoning, the prohibition orders in Case 1 or Case 2 may be set aside if it is determined in an action that the Apotex product will not infringe any of the patents in issue in those cases. I understand from the submissions of Astrazeneca in this appeal that the question of infringement is to be determined in an action in the Federal Court (File T-1409-04). Nothing in these reasons will prejudice the right of Apotex to seek to set aside the prohibition orders in Case 1 or Case 2, if it is successful in that case.*

[41] The English Courts have in a series of cases, *Poulton v. Adjustable Cover and Boiler Block Company* (1908), 25 R.P.C. 661 (CA); *Coflexip SA v. Stolt Offshore MS Ltd. (No. 2)*, [2004] F.S.R. 708 (CA); and *Unilin Beheer BV v. Beerry Floor NV*, [2007] EWCA Civ. 364 (CA), considered the situation where a party was found to infringe a patent and, subsequently, that patent was found to be invalid in other proceedings. The result has been that the award of

damages and costs remains but the injunction is terminated. The position of the English Court of Appeal was nicely put by Lord Justice Jacob in the recent *Unilin* decision at paragraphs 44 to 46:

> *44. Now a purist may say: it is a nonsense, and moreover an unjust nonsense, for a man to have to pay for doing what, with hindsight, we know to have been lawful. The purist might, I suppose, also say that a licensee who has paid royalties under a patent subsequently revoked ex tunc should get his money back. He might even say that a man who lost profits by refraining from some commercial activity by reason of a fear, now known to be groundless, of infringing the patent should have some remedy.*
>
> *45. But I think there are good and pragmatic reasons why the purist approach makes bad business sense. You cannot unravel everything without creating uncertainty. And where a final decision has been made on a fair contest between the parties, that should stand as the final answer between them.*
>
> *46. In a sense a patent is always potentially at risk – someone may come up with a bang on but obscure piece of prior art (my favourite pretend example is an anticipation written in Sanskrit wrongly placed in the children's section of Alice Springs public library), or simply with better evidence on known prior art. That is no reason for undoing what has been done or regarding a final decision as merely provisional. After a final decision businessmen should be able to get on with their businesses, knowing what the position is.*

[42] The point of these cases is that even a "final" judgment can be set aside or varied in some circumstances. That does not mean that the judgment was not "final".

[43] In the present circumstances the prohibition Order of Reed J. as set out in the Judgment issued by her on March 20, 1996 and affirmed by the Federal Court of Appeal on October 21, 1996 was "final" before the amendments to the *PMNOC Regulations* on March 11, 1998. There was, as of March 11, 1998, no "pending" application within the meaning of section 9(6) of the

1998 amending provisions of those *Regulations*. The fact that the Judgment was later varied and set aside does not mean that the matter was "pending" as of March 11, 1998.

[44] Therefore I find that the 1993 version of the *PMNOC Regulations* is applicable in the circumstances of this action.

Issue #2: *If the 1998 version of the PMNOC Regulations is applicable, do the events respecting the prohibition Order proceedings trigger section 8 of those Regulations?*

[45] Having found that the 1993 version of the *PMNOC Regulations* and not the 1998 version is applicable in the circumstances of this action this issue need not be addressed. However, in contemplation of an appeal which is almost inevitable in any proceeding of this kind, I will provide my views on this issue.

[46] The 1998 version of section 8 of the *PMNOC Regulations* reads as follows:

8. *(1) If an application made under subsection 6(1) is withdrawn or discontinued by the first person or is dismissed by the court hearing the application or if an order preventing the Minister from issuing a notice of compliance, made pursuant to that subsection, is reversed on appeal, the first person is liable to the second person for any loss suffered during the period*	***8.*** *(1) Si la demande présentée aux termes du paragraphe 6(1) est retirée ou fait l'objet d'un désistement par la première personne ou est rejetée par le tribunal qui en est saisi, ou si l'ordonnance interdisant au ministre de délivrer un avis de conformité, rendue aux termes de ce paragraphe, est annulée lors d'un appel, la première personne est responsable envers la seconde personne de toute perte subie au cours de*
(a) beginning on the date, as	

certified by the Minister, on which a notice of compliance would have been issued in the absence of these Regulations, unless the court concludes that

(i) the certified date was, by the operation of An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa), chapter 23 of the Statutes of Canada, 2004, earlier than it would otherwise have been and therefore a date later than the certified date is more appropriate, or

(ii) a date other than the certified date is more appropriate; and

(b) ending on the date of the withdrawal, the discontinuance, the dismissal or the reversal.

(2) A second person may, by action against a first person, apply to the court for an order requiring the first person to compensate the second person for the loss referred to in subsection (1).

(3) The court may make an order under this section without regard to whether the first person has commenced an action for the infringement of a patent that is the subject

la période :

a) débutant à la date, attestée par le ministre, à laquelle un avis de conformité aurait été délivré en l'absence du présent règlement, sauf si le tribunal conclut :

(i) soit que la date attestée est devancée en raison de l'application de la Loi modifiant la Loi sur les brevets et la Loi sur les aliments et drogues (engagement de Jean Chrétien envers l'Afrique), chapitre 23 des Lois du Canada (2004), et qu'en conséquence une date postérieure à celle-ci est plus appropriée,

(ii) soit qu'une date autre que la date attestée est plus appropriée;

b) se terminant à la date du retrait, du désistement ou du rejet de la demande ou de l'annulation de l'ordonnance.

(2) La seconde personne peut, par voie d'action contre la première personne, demander au tribunal de rendre une ordonnance enjoignant à cette dernière de lui verser une indemnité pour la perte visée au paragraphe (1).

matter of the application.

(4) The court may make such order for relief by way of damages or profit as the circumstances require in respect of any loss referred to in subsection (1).

(5) In assessing the amount of compensation the court shall take into account all matters that it considers relevant to the assessment of the amount, including any conduct of the first or second person which contributed to delay the disposition of the application under subsection 6(1).

(3) Le tribunal peut rendre une ordonnance aux termes du présent article sans tenir compte du fait que la première personne a institué ou non une action pour contrefaçon du brevet visé par la demande.

(4) Le tribunal peut rendre l'ordonnance qu'il juge indiquée pour accorder réparation par recouvrement de dommages-intérêts ou de profits à l'égard de la perte visée au paragraphe (1).

(5) Pour déterminer le montant de l'indemnité à accorder, le tribunal tient compte des facteurs qu'il juge pertinents à cette fin, y compris, le cas échéant, la conduite de la première personne ou de la seconde personne qui a contribué à retarder le règlement de la demande visée au paragraphe 6(1).

[47] The triggering event under the 1998 version of section 8 is that an application must be "*withdrawn…discontinued…or dismissed by the Court hearing the application [or]…on appeal*".

[48] In the present circumstances the Court that heard the original application, Reed J., dismissed the application by the Order dated April 30, 1999. She did two things in that Order. The first was to vary the original Order so as to remove the prohibition. The second was to

dismiss the application. Perhaps a dismissal was unnecessary, but it was done. Roche did not appeal that Order.

[49] Plain and simply, the 1998 *PMNOC Regulations*, section 8(1) if they were to be applicable, which they are not, would be triggered by the circumstance applicable in this action because of the dismissal.

Issue #3: ***If the 1993 version of the PMNOC Regulations is applicable, do the events respecting the prohibition Order trigger section 8 of those Regulations?***

[50] Section 8 of the 1993 version of the *PMNOC Regulations* reads as follows:

Remedies	*Conclusions*
8. (1) The first person is liable to the second person for all damage suffered by the second person where, because of the application of paragraph 7(1)(e), the Minister delays issuing a notice of compliance beyond expiration of all patents that are the subject of an order pursuant to subsection 6(1).	*8. (1) La première personne est responsable envers la second personne de tout préjudice subi par cette dernière lorsque, en application de l'alinéa 7(1)e), le ministre reporte la délivrance de l'avis de conformité au-delà de la date d'expiration de tous les brevets vises par une ordonnance rendue aux termes du paragraphe 6(1).*
(2) The court may make such order for relief by way of damages or profits as the circumstances require in respect of any damage referred to in subsection (1).	*(2) Le tribunal peut rendre toute ordonnance de redressement par voie de dommages-intérêts ou de profits que les circonstances exigent à l'égard de tout préjudice subit de fait de l'application du paragraphe*

(1).

[51] The term “expire or “expiré” is defined in section 2 of the *Regulations*:

> *“expire” means, in relation to a patent, expire, lapse or terminate by operation of law; (expiré)*
>
> *« expiré » Se dit du brevet qui est expiré, qui est périmé ou qui a pris par l’effet d’une loi (expire)*

[52] Given the definition of “expire” or “expiré” a patent will expire at the end of its term, here 17 years from the date of its grant, or if it lapses, for instance if maintenance fees are not paid, or if it terminates by operation of law, for instance a declaration of invalidity by a Court under section 60 of the *Patent Act*.

[53] With respect to “lapse” Justice Richard (as he then was in this Court) in *Zeneca Pharma Inc. v. Canada (Minister of National Health and Welfare)* (1996), 66 C.P.R. (3d) 169 considered a situation where a prohibition Order had been granted until the “expiration” of two patents. Unbeknown to Counsel one of those patents had lapsed for failure to pay maintenance fees before the Order was issued. The parties disclosed this fact to the Court and the generic (Apotex) moved to have the application dismissed with respect to the lapsed patent. Justice Richard refused to do so on the basis that it was unnecessary to amend the Order as the patent had expired. He wrote at page 174:

> *Further, there is no purpose to be achieved by varying the order at this time and in these circumstances. In my order dated May 26, 1995, I prohibited the Minister from issuing to Apotex a Notice of Compliance for the medicine lisinopril until the expiry of the '351 patent. The '351 patent lapsed in March 1995. The term "expire" is specifically defined under the Regulations to include the lapse of a*

> *patent. The '351 patent has therefore expired. Accordingly, the Minister is no longer prohibited in respect of the lapsed '351 patent and no amendment to my order is necessary. The order is clear and need not be varied.*

[54] Justice Reed expressed the same sentiments in her Reasons accompanying her Order varying the prohibition Order and dismissing the application as set out earlier in these Reasons. However for "greater certainty" she issued the Order that she did not only setting aside the prohibition Order but also dismissing the application.

[55] The scope of an Order that the Court could make under the 1993 version of the *PMNOC Regulations* is set out in sections 6(1) and (2). If the application is allowed the Court shall make an order "*prohibiting the Minister from issuing a Notice of Compliance [to the second party] until after the expiration of one or more patents…*". Sections 6(1) and (2) read as follows:

Rights of Action	*Droits d'action*
6. (1) A first person may, within 45 days after being served with a notice of an allegation pursuant to paragraph 5(3)(b), apply to a court for an order prohibiting the Minister from issuing a notice of compliance until after the expiration of one or more of the patents that are the subject of an allegation.	*6. (1) La première personne peut, dans les 45 jours suivant la signification d'un avis d'allégation aux termes de l'alinéa 5(3)b), demander au tribunal de rendre une ordonnance interdisant au ministre de délivrer un avis de conformité avant l'expiration de un ou plusieurs des brevets visés par une allégation.*
(2) The court shall make an order pursuant to subsection (1) in respect of a patent that is the subject of one or more allegations	*(2) Le tribunal rend une ordonnance en vertu du paragraphe(91) à l'égard du brevet visé par une ou plusieurs allégations si elle conclut qu'aucune des*

if it finds that none of those allegations is justified.	*allégations n'est fondée.*

[56] Again, expiration of the patent(s) given the definition in section 2 must be taken to include not only expiration of the term of the patent but also lapse and expiration by operation of law. I agree with Richard J. that if a patent lapses, for instance for failure to pay maintenance fees, and with the Reasons of Reed J. that if by operation of law in a Court decision a patent is declared to be invalid, it is unnecessary to vary an Order prohibiting the Minister from issuing an NOC "until the expiration" of that patent. In effect it is self-executing.

[57] Section 7 of the 1993 *PMNOC Regulations* deals with what the Minister must do. Section 7(1)(e) requires the Minister to wait 30 months before issuing an NOC to a generic if an application to the Court has been made by the first party. Sections 7(1)(f) and 7(2)(a) direct that the Minister does not have to wait if the patent has "expired". Section 7(2)(b) directs that the Minister does not need to wait if the Court has declared the patent to be invalid or not infringed. Section 7(1) and (2) state:

Notice of Compliance	***AVIS DE CONFORMITÉ***
7. *(1) The Minister shall not issue a notice of compliance to a second person before the latest of*	***7.*** *(1) Le ministre ne peut délivrer un avis de conformité à la seconde personne avant la plus tardive des dates suivantes :*
(a) the expiration of 30 days after the coming into force of these Regulations	*a) la date qui suit de 30 jours la date d'entrée en vigueur du présent règlement ;*
(b) the day on which the second person complies with section 5,	*b) la date à laquelle la*

(c) subject to subsection (3), the expiration of any patent on the register that is not the subject of an allegation,

(d) subject to subsection (3), the expiration of 45 days after the receipt of proof of service of a notice of allegation under paragraph 5(3)(a) in respect of any patent on the register,

(e) subject to subsections (2), (3) and (4), the expiration of 24 months after the receipt of proof of the making of any application under subsection 6(1), and

(f) the expiration of any patent that is the subject of an order pursuant to subsection 6(1).

(2) Paragraph (1)(e) does not apply if at any time, in respect of each patent that is the subject of an application pursuant to subsection 6(1),

(a) the patent has expired; or

(b) the court has declared that the patent is not valid or that no claim for the medicine itself and no claim for the use of the medicine would be infringed.

seconde personne se conforme à l'article 5;

c) sous réserve du paragraphe (3), la date d'expiration de tout brevet inscrit au registre qui ne fait pas l'objet d'une allégation;

d) sous réserve du paragraphe (3), la date qui suit de quarante-cinq jours la date de réception de la preuve de signification de l'avis d'allégation visé à l'alinéa 5(3)a) à l'égard de tout brevet ajouté au registre;

e) sous réserve des paragraphes (2), (3) et (4), la date qui suit de 24 mois la date de réception de la preuve de présentation de la demande visée au paragraphe 6(1);

f) la date d'expiration de tout brevet faisant l'objet d'une ordonnance rendue aux termes du paragraphe 6(1).

(2) L'alinéa (1)e) ne s'applique pas si, à l'égard de chaque brevet visé par une demande au tribunal aux termes du paragraphe 6(1) :

a) soit le brevet est expiré;

b) soit le tribunal a déclaré que le brevet n'est pas valide ou qu'aucune

> *revendication pour le médicament en soi, ni aucune revendication pour l'utilisation du médicament ne seraient contrefaites.*

[58] Thus the Minister need not delay in granting a Notice of Compliance to a generic if the relevant patent has expired by its term ending, or by lapse of that patent such as failure to pay maintenance fees, or if the Court in the *PMNOC* proceeding declares the patent invalid between the parties to that proceeding, or by any Court making, by operation of law such as under section 60 of the *Patent Act*, a declaration that the patent is invalid.

[59] Turning to section 8 of the 1993 *PMNOC Regulations* I am mindful that Courts in the past have been fortunate enough to be able to avoid interpreting that section. Hugessen J.A. (as he then was) said at page 316 of *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)* (1994), 55 C.P.R. (3d) 302 (FCA):

> *Section 8 is particularly obscure in its meaning. It appears to create a liability in the first person in the event that the Minister should comply with the 30 month prohibition in circumstances where subsection 7(2) specifically provides that that prohibition shall have ceased to apply. Fortunately, we are not required to interpret it on this appeal.*

[60] Apotex's Counsel argues that any interpretation of section 8 can only lead to absurd results. Therefore Apotex's Counsel suggests several extensive re-writes of that section on order to give it meaning consistent with what Apotex argues is the intent of that provision.

[61] Roche's Counsel also suggests re-writing section 8 but to a much more modest extent in order to bring the meaning of that section more into line with what Roche argues is the true intention of that provision.

[62] From time to time the Courts have had regard to a Regulatory Impact Analysis Statement (RIAS) that often accompanies Regulations such as these when they are published in the Canada Gazette. Very little can be gathered from the 1993 RIAS. At best marginal insight can be gained from the following statement:

> *Compliance costs to the private sector include the costs of obtaining and verifying the patent information to be provided to the Health Protection Branch. The filing and certification requirements established by these Regulations will place some burdens on patentees and subsequent drug applicants; however they are necessary to give effect to the law. In addition, some generic products turn out to have infringed an original applicant's product or use patents could be delayed under these Regulations where patents listed in a patentee NOC application turn out either not to be valid or not to be infringed by the sale of a later applicant's drug. However, the frequency and costs associated with any such delays arising from these Regulations will be minimized by the fact that such a patentee will be liable for all damage suffered from the delay.*

[63] The 1998 RIAS acknowledged that a "clearer indication" as to the circumstances in which damages could be awarded to a generic was needed, thus section 8 was amended in 1998 as previously discussed. The 1998 RIAS said in part:

> ***Specifying circumstances in which damages or costs can be awarded.*** *A clearer indication is given to the court as to the circumstances in which damages could be awarded to a generic manufacturer to compensate for loss suffered by reason of delayed market entry of its drug, and the factors that may be taken into account in calculating damages. The court may also award costs*

> *to either a generic manufacturer or a patentee, including solicitor and client costs, as appropriate, consistent with Federal Court Rules.*

[64] Counsel for each party cites various "rules" of construction derived from various cases and from Professor Sullivan's text (previously Driedger) *Construction of Statutes*, LexisNexis, now in its 5th edition. That textbook has been held by most Courts to be authoritative.

[65] The basic rule for interpretation is now undisputed. I cite the opening passage at page 1 of Professor Sullivan's text which refers to the Supreme Court of Canada decision in *Re Rizzo & Rizzo Shoes*, [1998] 1 S.C.R. 27 at page 41

ANALYSIS OF MODERN PRINCIPLE

> ***Introduction.*** *More than thirty years ago, in the first edition of the Construction of Statues, Elmer Driedger described an approach to the interpretation of statutes which he called the modern principle:*
>
> > *Today there is only one principle or approach namely, the words of an Act are to be read in their entire context, in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act, and the intention of Parliament.*
>
> *The modern principle has been cited and relied on in innumerable decisions of the Canadian courts, and in Re Rizzo Shoes Ltd. it was declared to be the preferred approach of the Supreme Court of Canada. It has been applied to interpretation of Quebec's Civil Code.*

[66] In considering the *Rizzo* case regard should be given to the decision of the Supreme Court of Canada in *Bell ExpressVu v. Rex*, [2002] 2 S.C.R. 559 per Iaccobucci J. at paragraphs 27 to 30:

27 *The preferred approach recognizes the important role that context must inevitably play when a court construes the written words of a statute: as Professor John Willis incisively noted in his seminal article "Statute Interpretation in a Nutshell" (1938), 16 Can. Bar Rev. 1, at p. 6, "words, like [page581] people, take their colour from their surroundings". This being the case, where the provision under consideration is found in an Act that is itself a component of a larger statutory scheme, the surroundings that colour the words and the scheme of the Act are more expansive. In such an instance, the application of Driedger's principle gives rise to what was described in R. v. Ulybel Enterprises Ltd., [2001] 2 S.C.R. 867, 2001 SCC 56, at para. 52, as "the principle of interpretation that presumes a harmony, coherence, and consistency between statutes dealing with the same subject matter". (See also Stoddard v. Watson, [1993] 2 S.C.R. 1069, at p. 1079; Pointe-Claire (City) v. Quebec (Labour Court), [1997] 1 S.C.R. 1015, at para. 61, per Lamer C.J.)*

28 *Other principles of interpretation -- such as the strict construction of penal statutes and the "Charter values" presumption -- only receive application where there is ambiguity as to the meaning of a provision. (On strict construction, see: Marcotte v. Deputy Attorney General for Canada, [1976] 1 S.C.R. 108, at p. 115, per Dickson J. (as he then was); R. v. Goulis (1981), 33 O.R. (2d) 55 (C.A.), at pp. 59-60; R. v. Hasselwander, [1993] 2 S.C.R. 398, at p. 413; R. v. Russell, [2001] 2 S.C.R. 804, 2001 SCC 53, at para. 46. I shall discuss the "Charter values" principle later in these reasons.)*

29 *What, then, in law is an ambiguity? To answer, an ambiguity must be "real" (Marcotte, supra, at p. 115). The words of the provision must be "reasonably capable of more than one meaning" (Westminster Bank Ltd. v. Zang, [1966] A.C. 182 (H.L.), at p. 222, per Lord Reid). By necessity, however, one must consider the "entire context" of a provision before one can determine if it is reasonably capable of multiple interpretations. In this regard, Major J.'s statement in CanadianOxy Chemicals Ltd. v. Canada (Attorney General), [1999] 1 S.C.R. 743, at para. 14, is apposite: "It is only when genuine ambiguity arises between two or more plausible readings, each equally in accordance with the intentions of the statute, that the courts need to resort to external interpretive aids" (emphasis added), to [page582] which I would add, "including other principles of interpretation".*

> ***30*** *For this reason, ambiguity cannot reside in the mere fact that several courts -- or, for that matter, several doctrinal writers -- have come to differing conclusions on the interpretation of a given provision. Just as it would be improper for one to engage in a preliminary tallying of the number of decisions supporting competing interpretations and then apply that which receives the "higher score", it is not appropriate to take as one's starting point the premise that differing interpretations reveal an ambiguity. It is necessary, in every case, for the court charged with interpreting a provision to undertake the contextual and purposive approach set out by Driedger, and thereafter to determine if "the words are ambiguous enough to induce two people to spend good money in backing two opposing views as to their meaning" (Willis, supra, at pp. 4-5).*

[67] Professor Sullivan at page 9 of her text expresses three guiding principles:

> *THE MODERN PRINCIPLE AND THE PLAIN MEANING RULE*
>
> ***The plain meaning rule.*** *In recent years statutory interpretation in Canada has featured a lively debate about the plain meaning rule – what it refers to, whether it is legitimate, and how it relates to Driedger's modern principle. The plain meaning rule means different things to different people, but its proponents generally agree on the following propositions:*
>
> > *1. Upon reading a legislative text it is possible to determine the meaning of the text and whether it is plain or ambiguous.*
> >
> > *2. If a text has a plain meaning, extra-textual evidence of legislative intent (like legislative history or presumed intent) is inadmissible to contradict that meaning. The plain meaning constitutes definitive evidence of legislative intent and it is impermissible to rely on other factors to contradict it. Furthermore, other factors may not be relied on the "create" ambiguity – that is, casts doubt on the meaning of a text that is otherwise plain.*
> >
> > *3. If a text is ambiguous, interpretation is required. In interpretation, extra-textual factors*

> *such as legislative history and presumed intent may be relied on to resolve the ambiguity.*

[68] From all this I derive that it is the duty of the Court to make some sense of a statutory or regulatory provision by reading it in context. The Court should not be distracted simply because some Counsel can suggest ambiguities or absurdities. The Court should do its best to make sense of the provisions.

[69] I repeat section 8 of the 1993 version of the *PMNOC Regulations*:

Remedies	*Conclusions*
8. (1) The first person is liable to the second person for all damage suffered by the second person where, because of the application of paragraph 7(1)(e), the Minister delays issuing a notice of compliance beyond expiration of all patents that are the subject of an order pursuant to subsection 6(1).	*8. (1) La première personne est responsable envers la second personne de tout préjudice subi par cette dernière lorsque, en application de l'alinéa 7(1)e), le ministre reporte la délivrance de l'avis de conformité au-delà de la date d'expiration de tous les brevets vises par une ordonnance rendue aux termes du paragraphe 6(1).*
(2) The court may make such order for relief by way of damages or profits as the circumstances require in respect of any damage referred to in subsection (1).	*(2) Le tribunal peut rendre toute ordonnance de redressement par voie de dommages-intérêts ou de profits que les circonstances exigent à l'égard de tout préjudice subit de fait de l'application du paragraphe (1).*

[70] The Minister is under a duty to issue a Notice of Compliance promptly. It would not be proper to construe section 8 so as to impose a liability on a first person simply because the Minister may unreasonably delay or neglect to issue a Notice of Compliance to a second person.

[71] A reasonable interpretation of section 8 would be to impose a liability on a first person if the cause of the delay in issuing a Notice of Compliance to a second person was that the patent that was the subject of the proceeding had "expired", that is by the natural end of its term, or by lapse such as failure to pay maintenance fees, or by operation of law such as a declaration of invalidity. If, for instance, the patent was declared invalid in the context of the relevant NOC application itself, then it can be said that the Minister had delayed in issuing the Notice of Compliance because the patent must be considered to have "expired". The extent of the delay could reasonably be considered to be the later of the day upon which the Minister says that the Notice of Compliance would otherwise have been issued if it were not for the application of the Court, or the filing date of that application with the Court. The end date would be the date that the Notice of Compliance was actually issued. In the present case the Minister has provided a letter (Trial Exhibit 2-13) stating that the Notice of Compliance would have issued on July 21, 1995 were it not for the application in this Court which was filed August 3, 1993 (Trial Exhibit 2-5). The Notice of Compliance was actually issued May 4, 1999 (Trial Exhibit 2-12). Thus the period would be between July 21, 1995 and May 4, 1999.

[72] However, in this case the Judgment holding the '671 patent to be invalid did not occur in the context of the *PMNOC Regulations* application but in the context of a separate action. That

Judgment issued on April 23, 1999, only a few days before May 4, 1999. The Order varying the prohibition Order and dismissing the *PMNOC* application was made April 30, 1999. There is no evidence as to the dates when the Minister was actually made aware of the Judgment or the Order. I find that there was no unreasonable delay by the Minister in issuing a Notice of Compliance to Apotex.

[73] Given the circumstances Apotex was, as of May 4, 1999, free to sell the drug in question. Can it also reach back and apply the finding of invalidity in the action so as to argue that the ’671 patent had “expired” within the meaning of section 8 of the 1993 *PMNOC Regulations* such that it can make a claim under that provision? I find that Apotex cannot.

[74] The basis for making such a finding is as expressed by Lord Justice Jacob in *Unilin supra*. The *PMNOC Regulations* application was fully argued on the issues raised, which did not include any allegation of invalidity of the ‘671 patent, at trial and on appeal.

[75] Apotex lost and a prohibition Order was granted. It was not until several years later that, in a separate action, Apotex prevailed in getting a declaration that the ’671 patent was invalid. I refer again to paragraphs 44 and 46 of Lord Justice Jacob’s reasoning in *Unilin* but will not repeat them. I also refer to the decision of the majority judges, Peter Gibson L.J. and Sir Martin Nourse in *Coflexip, supra,* where, on the basis that a patent had been held to be invalid in a subsequent proceeding, an injunction granted in an earlier proceeding was set aside but the award of damages remained. They wrote at paragraph 137 of their Reasons:

> *137. In any event we have no reason to think that Poulton was wrongly decided, despite Mr. Henderson's submissions to the contrary. The fact that Fletcher Moulton L.J. was wrong, as Jacob J. pointed out in para. 16 of his judgment, in expressing the view that an order for revocation only takes effect from the time of its pronouncement does not affect the ratio of this court's decision, and his error was not shared by the other members of the court. Mr. Henderson sought to rely on what he described as the anomaly that once the patent is revoked, that puts an end to an injunction granted in the earlier proceedings but does not undermine the claim for damages in an inquiry held after the revocation. However the logic of the distinction seems to us defensible. It is that the final decision in the earlier proceedings established, in a way which the defendant could not be allowed to challenge in subsequent proceedings, the fact of the infringement of a valid patent before the decision and the consequent loss to the owner of the patent, the inquiry doing no more than quantify the damages that had been suffered up to the time of the judgment. As Fletcher Moulton L.J. said ([1908] 2 Ch. 430 at p. 439):*
>
> > *"In point of fact such an inquiry takes time, but, as regards all legal consequences, it may be supposed to take place at the same instant as the determination of the other issues."*
>
> *An injunction, whilst granted because of the findings as to past infringements which the defendant cannot subsequently challenge, is expressed to restrain the party enjoined from future infringements. When the patent is subsequently revoked the court will not allow the injunction to continue because there is no patent then subsisting capable of being infringed. That does not undermine the correctness of the decision.*

[76] At no time during the period when the prohibition Order was made, including the period where that Order was affirmed on appeal, was the ’671 patent held to be invalid by the Court in that proceeding or any other Court in any other proceeding. The patent had not “expired” when the Order was made or affirmed on appeal. Immediately upon the “expiry” of the patent by a finding of invalidity in another proceeding the Minister issued a Notice of Compliance. There

was no delay. I find, therefore, that section 8 of the 1993 version of the *PMNOC Regulations* is not triggered in the circumstances of this action.

Issue #4: *If either the 1993 or 1998 version of the PMNOC Regulations* is applicable, is Apotex disentitled to any relief by its conduct in the prohibition Order proceedings?

[77] Roche has pointed to several procedural steps taken by Apotex in the several proceedings earlier referred to and invites this Court to find that such procedures disentitle Apotex to any relief in this action. Again because of my findings it is unnecessary for me to make a finding on this issue. However because of the possibility of an appeal, I will do so.

[78] Apotex was not reprimanded or criticized by any Court in any of the earlier proceedings in respect of any procedural or other steps that it took. It would be unacceptable for this Court now to look at what was done in any critical way and come to the conclusion that such conduct was so reprehensible or out of line so as to disentitle Apotex to any relief. On the scant evidence provided to me I cannot make any such finding.

[79] In any event the proceedings in question were in the earlier days of the *PMNOC Regulations* which were admittedly arcane and difficult to understand. Even today, several amendments later, those *Regulations* still present a puzzling minefield to even the most experienced litigant.

[80] I find no merit in Roche's submissions in this regard.

Issue #5: ***If Apotex is entitled to relief under either the 1993 or 1998 PMNOC Regulations what is the most appropriate beginning date for the period of liability?***

[81] Again, in view of my previous finding, it is unnecessary to provide an opinion on this issue. However, for the reasons previously expressed, I will do so.

[82] I have already expressed my opinion as to the starting date under the 1993 version of the *PMNOC Regulations*.

[83] As to the 1998 version of the *PMNOC Regulations*, section 8(1)(a) gives the Court the power to find another date than that certified by the Minister as being the date that the Notice of Compliance would have issued. As I wrote in *Apotex Inc. v. Merck & Co. Inc. et al.* October 21, 2008, 2008 FC 1185, I must be satisfied on the evidence that another date would be more appropriate. I wrote at paragraphs 106 to 109:

> ***106*** *With respect to subsection 8(1)(a) there is no provision for "*certification*" as such by the Minister or any definition in the* PMNOC Regulations *or elsewhere as to what such "*certification*" may mean. The parties have agreed, however, and I find that is reasonable to conclude that the date "*as certified by the Minister on which a notice of compliance would have been issued*", is the date of the letter sent by the Minister to the generic Apotex stating that the examination of its ANDS application has been completed but an NOC will not be issued until the requirements of the* PMNOC Regulations *are met, that is, until the then outstanding Court application T-844-03 is determined or withdrawn. In this case, that letter (Exhibit 1, Tab 7) is dated February 3, 2004. Thus, according to subsection 8(4)(a), the beginning date from which Apotex can claim compensation "*unless the court is satisfied on the evidence that another date is more appropriate*" is February 3, 2004.*

> ***107*** *Subsection 8(4)(b) provides that the period of compensation shall end, in this case, on the date of dismissal. Here that date is May 26, 2005, the date that this Court in T-844-03 dismissed Merck's application. There was no appeal. No provision is made in that subsection for any discretion in the Court to choose another date.*
>
> ***108*** *Thus the presumptive period over which compensation may be sought by Apotex is from February 3, 2004 to May 26, 2005.*
>
> ***109*** *The discretion that I am given in respect of that period is only with respect to the first date, February 3, 2004, the date that, to use the vernacular, the Minister has written to the generic to say that its application for an NOC is approved subject to "patent hold". I can only exercise my discretion under subsection 8(4)(a) if I am satisfied on the evidence that another date is more appropriate.*

[84] In the present case I have no evidence before me that satisfies me that any date other than that certified by the Minister, July 21, 1995 (Trial Exhibit 2-13) would be more appropriate.

SUMMARY OF CONCLUSIONS

[85] As to the issues presented for determination at this time I have found:

1. The 1993 version of the *PMNOC Regulations* applies in the circumstances of this action.
2. The 1998 version of the *PMNOC Regulations* does not apply but if it did the events respecting the dismissal of the application in which the prohibition Order was granted would trigger the provision of section 8 of those *Regulations.*
3. The 1993 version of the *PMNOC Regulations* applies but section 8 of the *Regulations* is not triggered by the events in this action.

4. If Apotex would otherwise be entitled to relief, its conduct would not disentitle it to such relief.
5. If the 1998 version of the *PMNOC Regulations* were to apply the relevant starting date is that certified by the Minister.

[86] As a result, I dismiss this action with costs to the Defendants.

[87] I must commend all Counsel for submitting this case on the basis of agreed facts and documents and for the concise and professional way in which their arguments were presented. They were most helpful.

COSTS

[88] Counsel for the parties had no special submissions as to costs and agreed that they should follow the disposition of this action. The Defendants are entitled to their costs to be assessed at the middle of Column IV. They are entitled to tax costs for one senior and one junior counsel at trial. I remain available if required to provide guidance as to how other costs and disbursements are to be taxed.

"Roger T. Hughes"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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