Court Nos. T-388-96 & T-793-96

BETWEEN:

GLAXO WELLCOME INC.,
- and -
THE WELLCOME FOUNDATION LIMITED,

Applicants,

- and -

THE MINISTER OF NATIONAL HEALTH AND WELFARE,
- and -
APOTEX INC.,

Respondents.

REASONS FOR ORDER

TEITELBAUM J:

INTRODUCTION

These two applications for judicial review both concern the medicine acyclovir. The applicants seek orders pursuant to the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, March 12, 1993 (the *"Regulations").* The applicants wish the Court to prohibit the respondent, the Minister of National Health and Welfare ("the Minister"), from issuing Notices of Compliance ("NOCs") to the respondent Apotex ("Apotex").

These cases are not formally joined but were heard at the same time. I have therefore prepared one comprehensive set of reasons because of the intertwining of the facts and issues.

FACTS

In essence, these proceedings hinge on the criteria for issuing a NOC. By way of background, I shall therefore briefly explain the significance and meaning of NOCs before

analyzing the particular issues and law. A NOC, which formally authorizes a drug to be sold, is issued by the Minister after a drug manufacturer has complied on two fronts. The first element of compliance concerns the overall safety and efficacy of the drug: (see regulation C.08.004 of the *Food and Drug Regulations*, C.R.C., c.870). The second element of compliance figures on the drug manufacturer's non-infringement of certain patents embodied in the drug. This second, rather more unexpected, patent-related requirement came into existence after changes to the compulsory licensing regime.[1] Formerly, under a compulsory license, a generic drug manufacturer could obtain a licensed supply of a patented drug from the patent owner. The NOC process did not then concern itself with questions of patent infringement. However, with the abolition of compulsory licenses under the *Patent Act Amendment Act*, 1992, S.C. 1993, c.2, (the "*Patent Act*") the regime for obtaining NOCs also changed. Generic drug manufacturers now seeking NOCs must file what is called a Notice of Allegation under Section 5 of the *Regulations*.

Section 5 of the *Regulations* states:

> 5.(1) Where a person files or, before the coming into force of these Regulations, has filed a submission for a notice of compliance in respect of a drug and wishes to compare that drug with, or make a reference to, a drug that has been marketed in Canada pursuant to a notice of compliance issued to a first person in respect of which a patent list has been submitted, the person shall, in the submission, with respect to each patent on the patent list,
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> (***a***) state that the person accepts that the notice of compliance will not issue until the patent expires; or
>
> (***b***) allege that
>
> (***i***) the statement made by the first person pursuant to paragraph 4(2)(***b***) is false,
> (***ii***) the patent has expired,
> (***iii***) the patent is not valid, or
>
> (***iv***) no claim for the medicine itself and no claim for the use of the medicine would be infringed by the making, constructing, using or selling by that person of the drug for which the submission for the notice of compliance is filed.
>
> (2) Where, after a second person files a submission for a notice of compliance, but before the notice of compliance is issued, a patent list is submitted or amended in respect of a patent pursuant to subsection 4(5), the second person shall amend the submission to include, in respect of that patent, the statement or allegation that is required by subsection (1).
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> (3) Where a person makes an allegation pursuant to paragraph (1)(***b***) or subsection (2) the person shall
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> (***a***) provide a detailed statement of the legal and factual basis for the allegation; and

[1] Margaret Smith, *Patent Protection for Pharmaceutical Products* (Ottawa: Library of Parliament Research Branch, 1994) at 4.

(***b***) serve a notice of the allegation on the first person and proof of such service on the Minister.

In effect, under Subsection 5(3) of the *Regulations*, in a "Notice of Allegation", the generic drug manufacturer, "the second person", signals its compliance with the patents embodied in a medicine. Under Section 4 of the *Regulations*, the patent owner or licensee, usually a brand name drug manufacturer like the applicants, submits a list of the patents that contain claims for the medicine itself or the use of the medicine.[2] Under Section 3 of the *Regulations*, the Minister compiles the patent lists into a public document called the "Patent Register".

The applicants are the owners or licensees of four patents in respect of acyclovir, the medicine at issue in the current proceedings. They are patent numbers 1,172,169 (the '"169 patent"), 1,062,257(the '"257 patent"), 1,096,863 (the '"863 patent") and 1,096,864 (the '"864 patent). The '169 patent relates to the medicine acyclovir in the particular form of a topical cream or ointment. The '257 patent concerns more general claims for the medicine. Both the '863 and '864 patents contain claims for the methods and processes for the manufacture of acyclovir itself (the '863 patent) and its intermediates (the '864 patent).

In the current proceedings, Apotex, a generic drug manufacturer, sent two Notices of Allegation to the applicants. The first Notice of Allegation was dated January 4, 1996. Apotex alleged that its manufacture and sale of acyclovir tablets would not infringe the '257, '863 and '864 patents because it intended to obtain its supply of acyclovir from Medichem Inc., a

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[2] Subsections 4(1) and 4(2) read:

4. (1) A person who files, or before the coming into force of these Regulations has filed a submission for or has been issued, a notice of compliance in respect of a drug that contains a medicine may submit to the Minister a patent list.

(2) A patent list submitted pursuant to subsection (1) must be certified by the person to be accurate, and must set out

(***a***) any Canadian patent that is owned by the person, or in respect of which the person has an exclusive licence or has obtained the consent of the owner of the patent for the inclusion of the patent on the patent list, that contains a claim for the medicine itself or a claim for the use of the medicine and that the person wishes to have included on the patent list;

(***b***) a statement that, in respect of each patent, the person applying for a notice of compliance is the owner, has an exclusive licence or has obtained the consent of the owner of the patent for the inclusion of the patent on the patent list;

company holding a compulsory license for acyclovir.[3] On February 19, 1996, in Court Action No. T-388-96 ("the 388 proceeding"), the applicants responded to Apotex's Notice of Allegation by issuing an Originating Notice of Motion for judicial review.

Apotex quickly responded to the issuance of the applicants' Originating Notice of Motion and Amended Notice of Motion in the '388 proceeding. Two days later, on February 21, 1996, Apotex sent a second Notice of Allegation to the applicants. The new Notice of Allegation also concerned the medicine acyclovir in tablet form, but in this instance, Apotex specifically cited only the '863 and '864 patents. Apotex asserted that it would not infringe those patents because the patents contained no claim for the medicine acyclovir or no claim for the use of the medicine. On April 4, 1996, in Court Action No. T-793-96 (the "793 proceeding"), the applicants issued a second Originating Notice of Motion in response to Apotex's Notice of Allegation dated February 21, 1996.

ISSUES

The burden is on the applicants to establish on the balance of probabilities that Apotex's allegations of non-infringement in its Notices of Allegation dated January 4, 1996 and February 21, 1996 were not justified: (see *Eli Lilly and Co.* v. *Novopharm Ltd.* (1995), 60 C.P.R. (3d) 417 at 430).

There are two overriding issues relating to the justification of the Notices of Allegations. The first issue concerns the expiry and relevancy of certain of the applicants' patents. A second issue centres on the question of whether a drug manufacturer must mention in its Notice of Allegation all of the patents found on the Patent Register for a particular drug.

DISCUSSION

I. The Expiry and Relevancy of the Patents.

To streamline discussion of the issues, I have decided to take the lead of counsel for Apotex and address in a systematic fashion the patents cited in Apotex's two Notices of Allegation. The first issue is whether the remedies sought by the applicants are now moot either because of the expiry or irrelevancy of their patents.

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[3] Under the *Patent Act*, *supra* , compulsory licenses granted before December 20, 1991, and not terminated before February 15, 1993, continued to exist, unless otherwise breached, as if the sections dealing with compulsory licensing had not been repealed.

(i) The Patents in the '388 Proceeding

In the '388 proceeding, the applicants have sought an order prohibiting the Minister from issuing a NOC until after the expiry of the '257, '863 and '864 patents. Apotex had cited those very patents in its Notice of Allegation dated January 4, 1996.

(a) The '257 Patent

I shall state from the outset that I can see no need for an order of prohibition in the '388 proceeding. The patents at issue have either expired or contain claims that are not encompassed under the *Regulations*. For instance, the '257 Patent expired on September 11, 1996. Nonetheless, the applicants argue that the Court should make a declaratory finding despite the expiry of the '257 patent. They also submit that the relevant date for assessing the validity of the allegation of non-infringement is the date the Notice of Allegation was issued or forty-five days after that date: (see *Merck Frosst Canada Inc.* v. *Canada (Minister of National Health and Welfare* (1996), 65 C.P.R. (3d) 483(F.C.T.D.) (*Merck Frosst*, (T-1306-93)).

With respect, I cannot agree with either submission. First, under Subsection 6(1) of the *Regulations*, the applicants can only "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**" (my emphasis). It would be the height of futility if the Court had to prohibit the Minister from issuing a NOC on the basis of an expired patent. On this issue of futility, in *Merck Frosst Canada Inc. et al.* v. *The Minister et al.*, Court Files Nos. T-304-96, T-306-96 and T-386-96, June 13, 1997 (*Merck Frosst*, (T-304-96)), Justice Nadon concluded at 22, "Clearly the generic manufacturer cannot be in violation of a patent which has expired".

Furthermore, on the second element of the timing of the allegation of non-infringement, in the recent case of *Merck Frosst Canada Inc. and Merck & Co., Inc* v. *The Minister of National Health and Welfare, Genpharm Inc. and Yamanouchi Pharmaceutical Co., Ltd.*, T-1312-96, May 27, 1997

(hereinafter *Yamanouchi*)[4], Justice Muldoon held at 18 that "the justification for the allegations is not frozen in time". In coming to this conclusion, Justice Muldoon analyzed *Merck Frosst,* (T-1306-93), *supra*. However, he found that the Federal Court of Appeal (reported at (1996), 67 C.P.R. (3d) 455) had affirmed *Merck Frosst,* (T-1306-93), *supra,* on an issue other than the relevant date for evaluating a notice of allegation. Justice Muldoon distinguished *Merck Frosst,* (T-1306-93), *supra,* on its facts and held at 12 that the optimum period for determining the justification of the allegation is at the time of the hearing. Justice Muldoon's reasoning was most recently cited with approval by Justice Nadon in *Merck Frosst*, (T-304-96), *supra.*

I also share and support Justice Muldoon's conclusion in *Yamanouchi, supra*. In other words, the Court cannot be blind to the fact that the '257 patent has expired. The relevant time for assessing Apotex's allegations of non-infringement is the date of the hearing. The '257 patent expired some eight months before the matter was heard before this Court in April, 1997. As counsel for the applicants himself acknowledged during the course of oral argument, these cases proceeded at a relatively rapid clip compared to the often painstakingly slow progress of claims for relief under the *Regulations.* Indeed, the parties appeared to recognize or were made aware of the doubtful viability of the '257 patent even prior to its expiry on September 11, 1996. In Apotex's Application Record dated August 29, 1996, Apotex accepted that no Notice of Compliance should issue to it prior to September 12, 1996, the day after the expiry of the '257 patent.

(b) The '863 and '864 Patents

As for the '863 and '864 patents, the applicants themselves conceded that neither patent contains claims that are encompassed by the *Regulations.* In paragraph 2 of their original Originating Notice of Motion dated February 19, 1996, and in paragraph 2 of their final Re-Amended Notice of Motion dated July 3, 1996, the applicants stated:

> The Wellcome Foundation is also the owner of Canadian Patent Nos. 1, 096, 863 and 1, 096, 864, both granted March 3, 1981. The former contains claims for methods and processes of manufacture of the medicine acyclovir while the latter contains claims for intermediates used in the preparation of the medicine acyclovir. **The Applicants do not rely upon these two patents in the present proceedings**.

[4] Appeal filed June 19, 1997 in Court No. A-450-97.

(my emphasis)

The status of the highlighted phrase, "the applicants do not intend to rely ..." in paragraph 2 of the applicants' Notices of Motion was the subject of controversy between the parties and a topic of judicial comment. The applicants had argued that the phrase was included in the original Originating Notice of Motion dated February 19, 1996 because of a non-binding administrative oversight. In contrast, Apotex submitted that the applicants had made an admission that should be read against them because it reflects the law on the irrelevancy of such process patents and patents devoted to intermediates.

For the sake of clarity, I shall now address in an abbreviated fashion the dispute surrounding the inclusion or deletion of the phrase beginning "the applicants do not rely upon ...". On February 20, 1996, the day after the issuance of the original Originating Notice of Motion, the applicants issued an Amended Originating Notice of Motion which deleted the phrase, "the applicants do not intend to rely ...". The applicants later sought leave to file and serve a Re-amended Originating Notice of Motion. However, during the course of the hearing before Justice Rouleau of the Federal Court, Trial Division, Apotex's objections to the validity of the deletion of the phrase in paragraph 2 became an issue. According to the applicants, they asked Justice Rouleau to validate the **deletion** of the phrase. However, in his Order dated June 11, 1996, Justice Rouleau characterized the motion in a different manner. He stated: "the verbal motion **to add** to paragraph no. 2 a clause which was included in the original Originating Notice of Motion and which had been deleted from the first amended Originating Notice of Motion is hereby denied" (my emphasis). In my opinion, the two characterizations - validating a deletion or rejecting an addition - amount to the same result.

However, the applicants asked Justice Rouleau to reconsider his June 11, 1996 Order and issue an express validation of the deletion. In their Notice of Motion in support of the reconsideration, the applicants argued that Justice Rouleau had overlooked or accidentally omitted to deal with certain amendments on consent

and the express validation of the deletion. By an Order dated June 28, 1996, Mr. Justice Rouleau varied the terms of his June 11 Order. He allowed the additional amendments on consent. However, he concluded that the amendments made in the Amended Originating Notice of Motion filed February 20, 1996 had not been overlooked nor omitted. The applicants apparently interpreted this Order to mean that Justice Rouleau had implicitly refused to validate the deletion of the phrase in the February 20, 1996 Amended Notice of Motion. Arguably, however, Justice Rouleau was simply stating in his June 28, 1996 Order that the matters had not been overlooked because he had already addressed the issue under a different guise or characterization by rejecting the addition of the phrase. However, because they had no express authority to sanction the deletion of the phrase from paragraph 2 of the original Originating Notice of Motion, the applicants issued a final Originating Notice of Motion on July 3, 1996 with the phrase intact. Justice Rouleau's Order of June 28, 1996 is not under appeal. The applicants and the Court are therefore bound by the contents of the Originating Notice of Motion issued on July 3, 1996.

The applicants have therefore expressly acknowledged in their Originating Notice of Motion for the '388 proceeding that they will not be relying upon the '863 and '864 patents. I can only conclude that the Court would accomplish little by issuing an order of prohibition based on patents that the applicants themselves do not invoke. Given this lack of reliance on the applicants' own part, the Court will not act to prohibit the Minister from issuing a NOC to Apotex until after the expiry of the '863 and '864 patents.

More importantly, even without the express statement in the Originating Notice of Motion, the applicants could not rely on the '863 and '864 Patents. The '863 and '864 patents describe methods and processes for the manufacture of acyclovir and its intermediates. In *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.), the Court held that such method or process patents were not the type of patents encompassed by the term "medicine or use of medicine" in Subsection 4(2) of the *Regulations*. In *Eli Lilly and Co.* v. *Apotex Inc.* (1995), 63 C.P.R. (3d) 245 (F.C.T.D.), affirmed (1996) 68 C.P.R. (3d) 126

(F.C.A), there was a similar conclusion in the case of intermediates, the type of claims embodied in the '864 patent in the cases at bar. Thus, according to Apotex, the applicants stated in their Originating Notice of Motion that they did "not rely upon [the '863 and '864] patents in the present proceedings" because they could not in law rely on these types of patents. I agree. It is clear that such process and intermediate patents are unquestionably irrelevant to the *Regulations*. Indeed, in *Merck Frosst* (T-304-96), *supra*, the issue before the Court was whether the Minister could unilaterally prune such process patents from the Patent Register. The Court held that the Minister could and should act in this fashion.

Moreover, in the Notice of Allegation at issue in the '793 proceeding, Apotex noted expressly that the '863 and '864 patents "have no claim for the medicine (acyclovir) itself or the use of the medicine" (page 165, Application Record of the applicants in the '793 proceeding). However, the applicants now argue that the Court must take the Notice of Allegation in the '388 proceeding as it stands and not read into it what Apotex might have or should have stated at the first opportunity. In contrast, Apotex argues that the scope of the patents embraced by the *Regulations* is a question of jurisdiction. Section 5 of the *Regulations* establishes allegations that may be made in the context of a Notice of Allegation but does not expressly outline an allegation of non-infringement based on the jurisdiction of the Court under the *Regulations*. Thus, according to Apotex, such an allegation need not be made in the allegation itself but can be raised at any point as a defence.

I accept Apotex's submission that the Court should not issue an Order of prohibition in relation to patents whose claims do not fall under the purview of the *Regulations*. As Justice Nadon stated at pages 19 and 20 in *Merck Frosst, (*T-304-96), *supra*, the issue of "whether pure process claims fall within the ambit of the *Regulations* has already been decided ... **a process only patent confers no rights on the patent-holder in the context of these *Regulations***" (my emphasis). While I am also reluctant to see the Notice of Allegation process become an endless and seemingly interminable revised series of Notices, Apotex insists that it issued the Second Notice of Allegation in

respect of the '863 and '864 patents only out of a "sense of precaution (paragraph 14, page 20, respondents' Record in the ‘388 proceeding). However, there are practical consequences to Apotex's second Notice of Allegation or its attempt to issue a comprehensive allegation of non-infringement for the ‘863 and 864 patents. After all, the second Notice of Allegation is but one more piece of paper to “gum up the works” and slow the approval process for the NOC, Apotex's ultimate goal.

In these particular circumstances, the Court has to go beyond the contents of the Notice of Allegation and decide whether it should grant an order of prohibition based on the ‘863 and ‘864 patents. It would be an absurdity if the Court had to issue such an order until after the expiry of such patents when it is conceded by the applicants themselves that the ‘863 and ‘864 patents are not encompassed by the *Regulations*. I am satisfied that an Order of prohibition should not be issued as it relates to the ‘863 and ‘864 patents because such method or process patents have no bearing on the medicine or the use of the medicine acyclovir under the *Regulations*. And as stated above, the ‘257 patent cited by the applicants in their claim for relief has already expired. I therefore conclude that the ‘388 proceeding should be dismissed.

However, in the '388 proceeding, the applicants also raise the issue of the validity of Apotex's arrangement with Medichem to obtain acyclovir. Apotex asserted in its Notice of Allegation dated January 4, 1996 that it would not infringe the '257, '863 and '864 patents because it could obtain the medicine used to make the drug from Medichem, a company holding a compulsory license for acyclovir. According to the applicants, the arrangement between Medichem and Apotex concerning the supply of acyclovir actually constitutes a sub-license or transfer by Medichem to Apotex of the compulsory license. The applicants argue that Apotex would be acting as the directing mind in its supply agreement with Medichem, a closely related company. In effect, the applicants submit that Apotex cannot find shelter behind a compulsory license in its allegation of non-infringement when the license has been implicitly converted into a sub-license.

The applicants argue that the cases at bar are analogous to the facts in several linked Federal Court of Appeal decisions: (see *Eli Lilly and Co.* v. *Apotex Inc.* (1996), 66 C.P.R. (3d) 329 (F.C.A), *Eli Lilly and Co. v. Novopharm Ltd.* (1996), 67 C.P.R. (3d) 377 and *Merck Frosst Canada Inc.* v. *Canada(Minister of National Health & Welfare)* (1996), 67 C.P.R. (3d) 455 ("the Court of Appeal decisions"))[5]. In the Federal Court of Appeal decisions, the issue was the status of a written agreement between Apotex and Novopharm, another generic drug manufacturer. Apotex and Novopharm agreed to provide each other with patented medicine under their respective compulsory licenses. The Court of Appeal held that this written agreement was in fact a sub-license of the compulsory license.

However, I am satisfied that I need not address the applicants' arguments on the compulsory license issue in depth. For the reasons stated above, namely the expiry and irrelevancy of the patents in the '388 proceeding, an Order of prohibition until after the expiry of the '257, '863 and '864 patents is not a viable remedy.

In any event, I am not convinced that the Court of Appeal decisions absolutely determine the status of Apotex's arrangements with Medichem. As Counsel for Apotex noted, Medichem's compulsory license was issued in December 1991 and implicitly provides for non-arm's length transactions (page 161, applicants' Record in the 388 proceeding). Sub-paragraph 1 (a) of the compulsory license sets out the royalty rate for "arm's length transactions". However, sub-paragraph 3(b) indicates a different rate for calculating the royalty when the transaction does not fall under sub-paragraph 1(a) or the "arms's length setting". The compulsory license itself does not foresee an incompatibility between non-arm's length transactions and the prohibition against sub-licensing. Surely then Medichem can deal in acyclovir with Apotex on a non-arm's length basis without necessarily violating the prohibition against sub-licensing found at paragraph 12 of the same compulsory license? While I am not prepared to make conclusions on the issue of the analogies between the Federal Court of

[5] Leave to appeal to the Supreme Court was granted on February 6, 1997 for the Court of Appeal decisions.

Appeal decisions and Medichem's arrangements with Apotex, the contents of the compulsory license and the significant points of difference are noteworthy.[6]

[6] Apotex's written arrangement with Novopharm at issue in the Federal Court of Appeal decisions was concluded in November, 1992. The background provisions of the agreement expressly recognize the approaching end of the compulsory licensing regime as the impetus for the agreement. In contrast, the arrangements between Medichem and Apotex for the supply of acyclovir are not formalized in writing and presumably exist independently of the specific events forming the backdrop of the Apotex and Novopharm agreement. Medichem's compulsory license itself is a result of a decision of the Commissioner of Patents stipulating that the applicants, the brand name drug manufacturer, must provide Medichem with a license for the '257, '863 and '864 Patents.

(ii) The Patents in the '793 Proceeding

As stated above, in the '793 proceeding, Apotex's Notice of Allegation dated February 21, 1996 cites both the '863 and '864 patents. Apotex stated that it would not infringe those patents because the patents have no claim for the medicine itself or the use of the medicine. However, the applicants in the '793 proceeding seek an order prohibiting the Minister from issuing a NOC not only until the expiry of the '863 and '864 patents but also in relation to all four of their patents on the Patent Register for acyclovir: namely, the '169, '257, '863 and '864 patents.

The applicants cite all four patents because they argue that the *Regulations* require a specific allegation from Apotex for each patent found on the Patent Register for a medicine. In the Notice of Allegation dated January 4, 1996, Apotex did not refer to the '169 patent but cited only the '257, '863 and '864 patents. The second Notice of Allegation dated February 21, 1996 equally did not refer to the '169 Patent. I have therefore examined the '169 Patent, the only patent that has yet to be discussed in these reasons, under the rubric of the second issue of referring to *each* patent on the Patent Register.

II. The Reference to Each Patent

(i) The '169 Patent

To buttress their claim that a generic drug manufacturer like Apotex must cite each and every patent on the Patent Register for a medicine, the applicants invoke the wording of Subsection 5(1) of the *Regulations*. Subsection 5(1) states that the "second person", in other words, the individual making the Notice of Allegation, "shall, in the submission, with **respect to each patent on the patent list...."**(my emphasis) make a specific allegation. As I noted in the introductory material describing the NOC process, the "first person", or patent owner or licensee, usually a brand name drug manufacturer like the applicants, submits a patent list to the Minister under Section 4 of the *Regulations*. The Minister compiles the patent lists into the Patent Register. The applicants argue that Apotex's Notice of Allegation dated February 21, 1996 was procedurally deficient because it failed to address the '169 patent even though this patent was on the Patent Register for acyclovir. According to the applicants, if a patent is

on the Patent Register, but remains conspicuously absent from the Notice of Allegation, then the Minister is left in the dark about the status of the patent. In essence, the applicants submit that Apotex has defeated the economy of the regulatory scheme by putting the onus on the Minister to examine the Notice of Allegation and the Patent Register with the proverbial "fine tooth comb".

However, I am satisfied that the applicants in this instance have misconstrued the contents of the Patent Register for acyclovir. They also appear to have underestimated the perspicacity of the Minister. While there is a reference to "each" in Subsection 5(1) of the *Regulations*, the subsection refers to "each patent on the patent list". Under the *Regulations*, Apotex must only give an allegation with respect to every patent on a patent list in respect of the particular form of the drug for which it seeks a NOC. In effect, the patent list is the building block for the Patent Register, the public document compiled by the Minister under Section 3 of the *Regulations*.

Turning now to the patent lists for acyclovir, it is clear that the applicants had to submit a separate list for each drug product or form of acyclovir embodied in the medicine (pages 152-157, applicants' Record in the 793 proceeding). In the pre-printed application form for submitting a patent list, the applicants had to indicate the "medicine/active substance", the "route of administration" (i.e. oral or topical), the "pharmaceutical dosage form" and the "strength per unit". Thus for acyclovir, in an oral, tablet dosage form of the 200 mg strength, the applicants cited the '257, '863 and '864 patents. It is important to note that the applicants did not refer to the '169 patent on this patent list. The applicants did not invoke the '169 patent because it contains claims for the medicine acyclovir in the topical route of administration. The applicants filed separate patent lists for acyclovir in other oral capsule or tablet dosages, but for all the oral routes of administration, the '169 patent was absent from the patent list. The applicants only cited the '169 patent in the separate patent list for ayclovir in the topical cream 50 mg strength.

More importantly, these distinctions in the patent lists are reflected in the Patent Register (pages 167-168, applicants' Record in the 793 proceeding). The

Patent Register organizes the information provided in the patent lists into columns with such titles as "medicine", "strength" "per unit" and "patent(s)". Under the heading "medicine" for acyclovir, there are eight entries, each with a different strength (i.e. 500 mg, 200 mg, etc.) or unit (i.e. "TAB", "CAP"). For seven of the entries, all associated with the oral route of administration, there are only three patents listed or associated with the medicine acyclovir (i.e. the '257, '863 and '864 patents) . In other words, the '169 patent is not listed for those forms of the medicine. Only the last entry for acyclovir in the topical route of administration cites the '169 patent. And this entry is set apart from the preceding eight because it is called "acyclovir 1" (my emphasis) and comes in the "GM" or topical, not oral unit.

From my examination of the Patent Register, I am satisfied that Apotex did not have to cite the '169 patent in the Notice of Allegation dated February 21, 1996. In the cases at bar, in both Notices of Allegation, Apotex expressly stated that it proposed to make "Acyclovir tablets: 200 mg, 400 mg and 800 mg" (my emphasis) (pages 163, 165, applicants' Record in the '793 proceeding). Apotex has made no application for a NOC for the topical solution or cream ointment form of acyclovir, and absent such an application, it could not manufacture those forms of acyclovir. It would therefore be odd and only confuse the issue if the Court had to issue an Order of prohibition based on a patent that was not encompassed by the proposed form of the medicine.

Apotex did make an application for a NOC for the oral tablet form of acyclovir in varying dosages. However, as stated above, the Patent Register clearly indicates that the '169 patent is only implicated in the manufacturer of acyclovir in a topical cream or ointment form. Since the Minister has the obligation under Section 3 of the *Regulations* to maintain the Patent Register, he is well-versed in its intricacies and can use it in his evaluation, for the purposes of issuing a NOC, of Apotex's Notice of Allegation concerning the tablet forms of acyclovir medicine. Justice Nadon in *Merck Frosst* (T-304-96), *supra*, held at 26 that the Minister is not a " mere pawn" in the process.

Furthermore, the applicants were unable to point to any jurisprudence holding that a mention of each patent on the Patent Register, no matter the proposed formulation, was obligatory. The *Regulations* and the Patent Register itself must be read and used in a purposive fashion. If every Patent had to be mentioned, no matter the content or significance of the patent on the Patent Register, then the Notice of Allegation would be an entirely formulaic document with little or no connection to the actual proposed form of the drug. What would be the practical utility of citing the '169 Patent implicated only in the topical formulation when one only seeks to manufacture the oral form of the medicine?

It is also interesting to note that the applicants, in their Notices of Motion, only specifically pleaded Apotex's alleged failure to cite the '169 patent in the later '793 proceeding, the judicial review application specifically triggered by the second February 21, 1996 Notice of Allegation. However, during the course of oral pleading, the applicants were at pains to argue that their submissions on the '169 patent equally applied to both the '388 and '793 proceedings. Nonetheless, I am struck by the fact that the applicants had a rather belated conversion to the principle that each and every patent had to be mentioned in the Notice of Allegation. The applicants' tardy embrace of this argument casts some doubt on its weight and significance. Certainly, the second February 21, 1996 Notice of Allegation also did not specifically cite the '257 patent. As I stated above, the '257 patent is now a moot point since it expired in September, 1996.

In conclusion, on the '793 proceeding, I find that the allegation of non-infringement in the Notice of Allegation dated February 21, 1996 was justified. The jurisprudence is clear that process or intermediate claims are not claims for the medicine itself or the use of the medicine under the ambit of the *Regulations*. Apotex's ostensible "failure" to cite the '169 patent is irrelevant to the issue of justified allegations of non-infringement.

CONCLUSION

For these reasons, the applications in the '388 and '793 proceedings are dismissed.

"Max M. Teitelbaum"

J.F.C.C.

OTTAWA

August 19, 1997