EB-2009-0172

IN THE MATTER OF the *Ontario Energy Board Act, 1998,* S.O. 1998, c. 15 (Schedule B), as amended;

AND IN THE MATTER OF an Application by Enbridge Gas Distribution Inc. for an order or orders approving or fixing just and reasonable rates and other charges for the sale, distribution, transmission and storage of gas commencing January 1, 2010.

SUBMISSION OF THE ASSOCIATION OF POWER PRODUCERS OF ONTARIO ("APPrO")

Overview

1. The Applicant Enbridge Gas Distribution Inc. ("EGD") seeks to interpret section 10.1 of the settlement agreement in Board Proceeding No. EB-2007-0615 (the "Settlement Agreement") in a way that will allow EGD to change the methodology it uses to calculate ROE for the purposes of the earnings sharing mechanism ("ESM") set out in that agreement.

2. APPrO does not agree that EGD is entitled to adjust its method of calculating ROE from that articulated in the Settlement Agreement. Rather, the terms of the Settlement Agreement are unambiguous in requiring that the ROE methodology be fixed for the entire term of the Settlement Agreement.

3. In light of this dispute, the Board issued Procedural Order No. 5 setting out the following question to be addressed in written submissions by the parties:

> Does the calculation of the earnings sharing referred to in Section 10.1 of the IRM Settlement Agreement require the use of an ROE based on the Board's cost of capital policy in effect at the time the IRM Settlement Agreement was entered into, or the 2009 Cost of Capital Report, which is in effect at the time the earnings sharing calculation will be performed? (the "ROE Issue").

4. APPrO has reviewed and agrees with the submissions of other intervenors on the ROE Issue.

The Provision is Unambiguous

5. A review of the Settlement Agreement reveals unambiguous language to the effect that the ROE to be used for the ESM is based on the policy in place at the time the Settlement Agreement was concluded. Section 10.1 provides:

> 10.1 Should an ESM be included in the IR plan?
>
> **Complete Settlement:** The Parties agree that the IR Plan shall include an earnings sharing mechanism ("ESM") that shall be used to calculate an earning sharing amount, as follows:
>
> (i) if in any calendar year, Enbridge's actual utility ROE, calculated on a weather normalized basis, is more than 100 basis points over the amount calculated annually by the application of the Board's ROE Formula in any year of the IR Plan, then the resultant amount shall be shared equally (i.e., 50/50) between Enbridge and its ratepayers;
>
> (ii) for the purpose of the ESM, Enbridge shall calculate its earnings using the regulatory rules prescribed by the Board, from time to time, and shall not make any material changes in accounting practices that have the effect of reducing utility earnings;
>
> (iii) all revenues that would otherwise be included in revenue in a cost of service application shall be included in revenues in the calculation of the earnings calculation and only those expenses (whether operating or capital) that would be otherwise allowable as deductions from earnings in a cost of service application, shall be included in the earnings calculation. ... (emphasis added)

6. The definition of "ROE Formula" is set out in section 2.4 of the Settlement Agreement:

> **2.4 Should the gas utilities ROE be adjusted in each year of the incentive regulation (IR) plan using the Board's approved ROE guidelines?**
>
> **Complete Settlement:** The Parties agree that, except as otherwise provided in this Agreement, the percentage rate of return on equity ("ROE") of 8.39% that is already included in the Company's rates for 2007 will not be adjusted under the Board's formula for setting the ROE ("ROE Formula") during the term of the IR Plan. (emphasis added)

7. Reading sections 2.4 and 10.1 together and in the context of the entire Agreement, it is clear that the methodology used to calculate ROE for the ESM is fixed for the entire term of the Settlement Agreement.

8. In the alternative, should the Board find that the provisions of the Settlement Agreement relating to this issue are genuinely ambiguous on their face, then reference may be made to extrinsic evidence relating to the negotiation and drafting of the Settlement Agreement in order to determine the contractual intent of the parties. The question of whether such documents may be filed in this proceeding is currently before the Board.

Eli Lilly & Co. v. Novopharm Ltd., [1998] 2 S.C.R. 129 at paras. 54-55.

EGD's Interpretation is Strained

9. EGD's interpretation of section 10.1 is strained and does not reflect what was contemplated by the parties to the Settlement Agreement or memorialized therein.

10. Contrary to EGD's proposed interpretation, the Settlement Agreement expressly provides that the ROE methodology is not subject to automatic adjustment using the Board's approved ROE guidelines, even if those guidelines change in subsequent years.

11. The precise circumstances that EGD relies on as the basis for changing the ROE methodology used in the ESM are addressed by the Settlement Agreement. In particular, section 6.1 makes it clear that any change to the ROE methodology used in the context of the Settlement Agreement must be effected by an application by EGD:

> ...
> **ROE Methodology**
>
> If a proceeding is instituted before the Board, before the term of this IR Plan expires, in which changes to the methodology for determining the ROE is requested, then all Parties, including Enbridge, will be free to take such positions as they consider appropriate with respect to that proceeding. Enbridge may apply to the Board to institute such a proceeding should a change in the methodology for determining return on equity be approved or adopted by the Board. If the Board determines that a change in methodology is appropriate, Enbridge or any other Party in this proceeding, may apply for determination of whether or not that change should be applied to Enbridge during the term of the IR Plan....(emphasis added)

12. Contrary to EGD's submissions, any change in ROE methodology adopted by the Board during the term of the Settlement Agreement will not automatically apply to EGD. Rather, EGD must apply to the Board in order for such an adjustment to take effect.

13. EGD has also argued that the use of terms such as "using the regulatory rules prescribed by the Board, from time to time" in section 10.1(ii) extends generally to all calculations relating to the ESM, including the ROE. The language of section 10.1 belies this argument.

14. Section 10.1(ii) clearly applies only to the calculation of earnings and not generally to all factors to be input into the ESM. The parties could have included language such as "from time to time" in those provisions relating to the ROE, but they did not do so. The omission of such terms from section 10.1(i) must be read in context and taken as an expression of the parties' intentions with regard to the fixed nature of the calculation method for ROE, particularly in light of the inclusion of such terms in section 10.1(ii).

Conclusion

15. EGD's interpretation of the Settlement Agreement is not straightforward or reflective of the clear meaning of the relevant provisions. Rather, EGD attempts to read into the Settlement Agreement a right for which it did not bargain; that is, the automatic right to change its ROE calculation method without making a new application to the Board.

16. APPrO submits that EGD's proposed interpretation is contrary to the intention of the parties as reflected in the clear language used in the Settlement Agreement and contravenes the underlying purpose of any negotiated settlement, which is to achieve certainty and predictability for the parties.

ALL OF WHICH IS RESPECTFULLY SUBMITTED

Christine Kilby
Counsel for APPrO

Eli Lilly & Co. *v.* Novopharm Ltd., [1998] 2 S.C.R. 129

Novopharm Limited *Appellant*

v.

Eli Lilly and Company and Eli Lilly Canada Inc. *Respondents*

and

The Minister of National Health and Welfare *Respondent*

and between

Apotex Inc. *Appellant*

v.

Eli Lilly and Company and Eli Lilly Canada Inc. *Respondents*

and

The Minister of National Health and Welfare *Respondent*

Indexed as: Eli Lilly & Co. *v.* Novopharm Ltd.

File Nos.: 25402, 25348.

1998: January 21; 1998: July 9.

Present: L'Heureux-Dubé, Gonthier, Cory, McLachlin, Iacobucci, Major and Bastarache JJ.

on appeal from the federal court of appeal

Patents -- Infringement -- Sublicensing -- Licensee agreeing to supply patented medicine to unlicensed third party -- Licence expressly prohibiting sublicensing -- Breach of licence terms grounds for termination of licence -- Whether supply agreement between licence holder and third party a sublicence or having legal effect of creating a sublicence.

Agency -- Supply agreement -- Licensed party to obtain patented bulk medicine for unlicensed party -- Whether licensed party acting as agent of unlicensed party in carrying out contractual obligations.

Patents -- Notice of allegation (NOA) -- Proper date for assessing NOA.

Jurisdiction -- Declaratory relief -- Whether declaration should issue as to patent holder's failure to show notice of allegation unjustified or that it was entitled to terminate compulsory licence -- Whether appropriate to declare that supply agreement not constituting sublicence or transfer of compulsory licence.

Patents -- Medicine -- Reformulation of patented product -- Bulk medicine reformulated into final-dosage form -- Whether reformulation of patented product amounting to infringement of patent.

Eli Lilly and Co. ("Eli Lilly") owned the Canadian patents for nizatidine and for its manufacturing process. It alone held a notice of compliance (NOC) to produce and market certain final-dosage forms of the medicine. Novopharm held a compulsory licence, obtained under the *Patent Act* (the "Act") as it existed prior to February, 1993, which permitted it to use the patented process to make nizatidine for the preparation or production of medicine and to import and/or sell medicine made by the process. The licence stipulated that it was non-transferable, prohibited Novopharm from granting any sublicence, and provided Eli Lilly with the option to terminate the licence upon any breach of its terms.

In anticipation of the 1993 amendments to the Act, which radically altered the procedures for the issuance of NOCs and eliminated the compulsory licensing regime entirely, Novopharm and Apotex entered a "supply agreement" in November, 1992. The agreement provided that, where one party held a licence for a patented medicine for which the other did not, the licensed party would obtain, at the request and direction of the unlicensed party, specified quantities of that medicine, and supply it to the unlicensed party at cost plus a four per cent royalty. In April, 1993, Apotex commenced efforts to obtain a NOC for certain final-dosage forms of nizatidine, and issued a notice of allegation ("NOA") alleging that no claim for nizatidine or for its use would be infringed. In support of this allegation, Apotex relied upon the licence issued to Novopharm and the "mutual understanding" with Novopharm. On the same date, Apotex notified Novopharm of its intention to request Novopharm to supply it with nizatidine. However, Apotex also indicated that, because it did not yet have a NOC to permit it to market nizatidine in Canada, it could not provide Novopharm with any specifics as to its requirements, but that it would advise in due course as to the required quantity and the manufacturer from whom the nizatidine should be purchased.

Eli Lilly and Eli Lilly Canada Inc. ("Eli Lilly Canada") brought an application (*Eli Lilly and Co. v. Apotex Inc.*, S.C.C., No. 25348 (*Apotex #1*)), under s. 6(1) of the *Patented Medicines (Notice of Compliance) Regulations* (the "Regulations"), for an order prohibiting the Minister from issuing a NOC to Apotex at all or, alternatively, until after December 31, 1997, ten years after the issuance of the NOC to Eli Lilly Canada, which, under the amended *Patent Act*, would be the first date on which Apotex, without a NOC, would be entitled to import nizatidine for consumption in Canada. On July 15, 1993, Eli Lilly purported to exercise its option to terminate Novopharm's compulsory licence, alleging that Novopharm had breached the terms of the licence by granting a sublicence to Apotex. Novopharm denied this allegation, stating that the commercial agreement into which it had entered with Apotex did not constitute a sublicence or any transfer of rights under the licence. The Federal Court--Trial Division found that the supply agreement between Novopharm and Apotex did not constitute a sublicence but nonetheless granted the prohibition order on the grounds that, because the reformulation of nizatidine for consumption in Canada would infringe Eli Lilly's patent, the NOA was not justified. The Federal Court of Appeal dismissed Apotex's appeal, but on the grounds that the agreement did constitute a sublicence.

In July 1993, Novopharm issued a NOA in support of its own application for a NOC in relation to nizatidine and relied on its own compulsory licence as the basis for the non-infringement of the patents. Eli Lilly and Eli Lilly Canada brought an application before the Federal Court--Trial Division (*Eli Lilly and Co. v. Novopharm Ltd.*, S.C.C., No. 25402 (the *Novopharm* proceeding)), requesting a prohibition order to enjoin the Minister from issuing the requested NOC to Novopharm on the grounds that Novopharm's licence had been terminated and that Novopharm could not, therefore,

obtain the bulk medicine in a non-infringing way. The application was dismissed at trial but this decision was reversed by the Federal Court of Appeal.

The issue common to both appeals is whether the agreement between Apotex and Novopharm constituted a sublicence, such as to justify Eli Lilly's purported termination of Novopharm's compulsory licence. If it did, then the NOAs issued by both Novopharm and Apotex were not justified and the requested prohibition order should issue. Each appeal also raises other discrete issues. Specifically, in the *Novopharm* proceeding, this Court is asked to determine: (1) whether the Federal Court of Appeal erred in applying its decision in *Apotex #1* to the *Novopharm* appeal, whether as *res judicata* or otherwise; (2) whether Novopharm's NOA was not justified, regardless of whether its compulsory licence was terminated by breach, because the licence did not permit the activities which the NOA proposed; and (3) whether the Federal Court had the jurisdiction to grant declaratory relief on a limited judicial review proceeding of this type. In *Apotex #1*, it is further alleged that, apart from the primary issue of infringement, Apotex's proposed reformulation into final-dosage form would itself constitute an infringement of the patents held by Eli Lilly, and that the prohibition order should therefore have issued regardless of whether or not the supply agreement constituted a sublicence.

Held: The appeals should be allowed.

A sublicence amounts to a grant by a licensee of certain licensed rights to a third party, the sublicensee. By the grant of a licence, the patentee grants to the licensee the right to act in a certain way *vis à vis* the patented article, a right which, but for the licence, the licensee would not enjoy. Thus, for Novopharm to have granted a

sublicence to Apotex, it must have granted, either expressly or impliedly, the right to do something which Apotex would otherwise be prohibited from doing, and which Novopharm was permitted to do only by virtue of its compulsory licence. This may have been accomplished either by virtue of some express provision or provisions of the agreement, or by virtue of its actual legal effect (even if this runs contrary to the subjective intentions of the parties).

The ultimate goal of contractual interpretation should be to ascertain the true intent of the parties at the time of entry into the contract. The contractual intent of the parties is to be determined by reference to the words they used in drafting the document, possibly read in light of the surrounding circumstances which were prevalent at the time. Evidence of one party's subjective intention has no independent place in this determination. It is unnecessary to consider any extrinsic evidence at all when the document is clear and unambiguous on its face. Here, there was no ambiguity to the contract entered into between Apotex and Novopharm and further interpretive aids were therefore unnecessary. The evidence as to the subjective intentions of the principals at the time of drafting was thus inadmissible by virtue of the parol evidence rule especially since it did not go to the circumstances surrounding the making of the contract.

Nothing in the wording of the document suggested that the parties intended to grant sublicences to each other. Rather, every indication was that they intended to establish a commercial arrangement whereby the unlicensed party would enjoy the right to require the licensed party to use its various licences for the benefit of the unlicensed party by acquiring, potentially at the direction of the unlicensed party, and subsequently reselling to the unlicensed party, various patented medicines. While no express words of grant are required to create a sublicence, clearly the supply agreement, to have this

character, must have transferred to Apotex more than simply the right to compel Novopharm to use its licence in a given way. But there was no indication that Apotex acquired any other independent rights under the compulsory licence. In fact, such an interpretation would be inconsistent with the combined effect of certain express provisions of the agreement.

To prove the existence of a sublicence, it must be established that the agreement was, in substance if not form, more than merely an elaborate arrangement under which future contracts for purchase and sale might be completed. The sale of a licensed article, while it does transfer to the purchaser the rights of use and alienation, does not have the automatic effect of constituting the purchaser a sublicensee; thus, the fact that a third party enjoys these rights cannot alone be indicative of the existence of a sublicence. Any number of ways exist in which a licensee can sell a licensed article to a third party with the complete range of ordinary incidents of ownership, without constituting that party a sublicensee. The rights of use and alienation can only be determinative of the existence of a sublicence where there has been no sale of the licensed article to the third party. In such a case, a right of use could only be derived from a sublicence of some type. Where the rights of the unlicensed party are derived from a sale of licensed material, it would be misleading to rely on the rights of use and alienation as a basis for the conclusion that a sublicence has been or is to be granted. This situation was plainly contemplated by the supply agreement here, under which the only way Apotex could acquire bulk nizatidine was by purchasing it from Novopharm, not directly from Novopharm's supplier.

Further, because legitimate transfers were to take place between separate entities, dealing at arm's length, the contemplated transactions could not be

characterized, *ex ante*, as shams. While it was theoretically possible that the agreement could be implemented in an infringing way, it had not yet been implemented at all and thus any suggestion of infringement was speculative. The agreement did not, on its face or in its actual legal effect, amount to a sublicence.

The degree of control likely to be exercised by Apotex over the acquisition of nizatidine would not result in a situation where Novopharm in reality would be acting as Apotex's agent. Nor would Novopharm, because of its allegedly standing in the shoes of Apotex, become an unlicensed entity. Under the supply agreement, any contractual relations that might be established for the purchase of nizatidine would be between Novopharm and the third-party supplier. Apotex would not be a party to the contract; Novopharm would not be entering into the contract "on behalf of" Apotex in any sense. The notion of an agent's entering into contractual relations with the third party is inimical to the entire concept of agency, which contemplates the agent's binding the principal, not itself, to contractual relations and obligations.

Given that the agreement was properly characterized as a supply agreement and given that the agreement had not been implemented at the material time, it was not necessary to decide if the Federal Court of Appeal erred in applying its decision in *Apotex #1* to its decision in *Novopharm*.

Since the appropriate date for assessment of a NOA, where a prohibition order is sought by a patentee, is the date of hearing and not the date on which the NOA was issued (see *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare*, S.C.C., No. 25419 (*Apotex #2*)), Novopharm's NOA was not premature and therefore unjustified. Pursuant to s. 39.14 of the *Patent Act*, it was entitled to

manufacture the medicine itself or through Canadian agents seven years after the date of the issue of the first NOC to Eli Lilly Canada. As this seven-year period had expired before the date the application was heard, Novopharm was entitled, as of the date of hearing, to manufacture or have made the drug for its own use, for sale for consumption in Canada. The NOA did not specify that the nizatidine was to be imported and not produced in Canada, and so, at the date of hearing, there existed at least one non-infringing way for Apotex to obtain the necessary medicine.

In light of its other findings, it was not necessary for the Court to grant declaratory relief to the effect that Eli Lilly failed to show either that the NOA was not justified, or that it was entitled to terminate the compulsory licence. Moreover, in light of the limited nature of these judicial review proceedings, it would be inappropriate for this Court to declare conclusively, and for purposes other than those of these appeals, that the supply agreement did not constitute a sublicence or a transfer of the compulsory licence from Novopharm to Apotex. Accordingly, the requested declaratory relief was denied.

Absent express conditions to the contrary, a purchaser of a licensed article is entitled to deal with the article as he or she sees fit, so long as such dealings do not infringe the rights conferred by the patent. The reformulation of nizatidine into final-dosage form would not have the effect of creating a new article, such as to infringe Eli Lilly's patent. Rather, reformulation is more akin to repackaging the substance into a commercially usable form, which is not a violation of any rights under the patents. The right of use and sale which Apotex would acquire inherently, through its acquisition of nizatidine from Novopharm, encompasses the right to use and sell things produced with this nizatidine, including capsules in final-dosage form. This is, in reality, the only

practical use of bulk medicine in the hands of a purchaser, which may explain why reformulation was implicitly contemplated by the compulsory licence held by Novopharm. Apotex therefore would not infringe the patents held by Eli Lilly simply by selling the medicine in the form contemplated by the NOA. This is particularly so when the exclusive rights enjoyed by the patentee under the patent are limited, in essence, to the formulation of bulk medicine according to the patented process. Nothing in the reformulation process can be seen as infringing upon this right. Thus, in the absence of some express prohibition in the compulsory licence, the right to reformulate should be seen as inherent to the purchaser's right to deal with licensed material as he or she sees fit. Eli Lilly accordingly failed in its various efforts to establish that Apotex's NOA was not justified and that a prohibition order should thus be issued.

Cases Cited

Distinguished: *E.I. du Pont de Nemours & Co. v. Shell Oil Co.*, 227 USPQ 233 (1985); **referred to:** *Apotex Inc. v. Merck Frosst Canada Inc.*, [1998] 2 S.C.R. 193; *Glaxo Wellcome Inc. v. Canada (Minister of National Health and Welfare)* (1997), 75 C.P.R. (3d) 129; *David Bull Laboratories (Canada) Inc. v. Pharmacia Inc.*, [1995] 1 F.C. 588; *Consolidated-Bathurst Export Ltd. v. Mutual Boiler and Machinery Insurance Co.*, [1980] 1 S.C.R. 888; *Merck & Co. v. Apotex Inc.* (1994), 59 C.P.R. (3d) 133, rev'd in part [1995] 2 F.C. 723; *Carey v. United States*, 326 F.2d 975 (1964); *Howard and Bullough, Ld. v. Tweedales and Smalley* (1895), 12 R.P.C. 519; *Lampson v. City of Quebec* (1920), 54 D.L.R. 344; *Joy Oil Co. v. The King*, [1951] S.C.R. 624; *Indian Molybdenum Ltd. v. The King*, [1951] 3 D.L.R. 497; *Badische Anilin und Soda Fabrik v. Isler*, [1906] 1 Ch. 605; *Gillette v. Rea* (1909), 1 O.W.N. 448; *Betts v. Willmott* (1871), L.R. 6 Ch. App. 245; *Intel Corp. v. ULSI System Technology Inc.*, 995 F.2d 1566 (1993);

Cyrix Corp. v. Intel Corp., 77 F.3d 1381 (1996); *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)* (1994), 55 C.P.R. (3d) 302; *National Phonograph Co. of Australia, Ltd. v. Menck*, [1911] A.C. 336; *Libbey-Owens-Ford Glass Co. v. Ford Motor Co. of Canada, Ltd.*, [1970] S.C.R. 833, aff'g [1969] 1 Ex. C.R. 529; *Rucker Co. v. Gavel's Vulcanizing Co.* (1985), 7 C.P.R. (3d) 294.

Statutes and Regulations Cited

Food and Drug Regulations, C.R.C., c. 870, s. C.08.004.

Patent Act, R.S.C., 1985, c. P-4, s. 39(4), 39.11 [ad. c. 33 (3rd Supp.), s. 15], 39.14 [*idem*].

Patent Act Amendment Act, 1992, S.C. 1993, c. 2, s. 11(1).

Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, ss. 4(1), 5, 6, 7.

Authors Cited

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Fridman, G. H. L. *The Law of Contract in Canada*, 3rd ed. Scarborough, Ont.: Carswell, 1994.

Melville, Leslie W. *Forms and Agreements on Intellectual Property and International Licensing*, vol. 1, 3rd ed. rev. New York: West Group, 1997 (loose-leaf updated August 1997, release 29).

APPEAL (*Eli Lilly and Co. v. Novopharm Ltd.*, S.C.C., No. 25402) from a judgment of the Federal Court of Appeal (1996), 67 C.P.R. (3d) 377, 197 N.R. 291, [1996] F.C.J. No. 576 (QL), allowing an appeal from a judgment of McGillis J. (1995), 60 C.P.R. (3d) 181, 91 F.T.R. 161, [1995] F.C.J. No. 238 (QL), granting an application

for judicial review and prohibiting the Minister from issuing a notice of compliance. Appeal allowed.

APPEAL (*Eli Lilly and Co. v. Apotex Inc.*, S.C.C., No. 25348) from a judgment of the Federal Court of Appeal (1996), 66 C.P.R. (3d) 329, 195 N.R. 378, [1996] F.C.J. No. 425 (QL), dismissing an appeal from a judgment of McGillis J. (1995), 60 C.P.R. (3d) 206, 91 F.T.R. 181, [1995] F.C.J. No. 237 (QL), dismissing an application for judicial review. Appeal allowed.

Harry B. Radomski, *Richard Naiberg* and *David Scrimger*, for the appellant Apotex Inc.

Donald N. Plumley, *Q.C.*, *Mark Mitchell* and *Stephanie Chong*, for the appellant Novopharm Limited.

Anthony G. Creber and *David Watson*, *Q.C.*, for the respondents Eli Lilly and Company and Eli Lilly Canada Inc.

The judgment of the Court was delivered by

I IACOBUCCI J. -- A single agreement entered into by Novopharm Limited ("Novopharm") and Apotex Inc. ("Apotex"), competitors in the pharmaceutical industry, has given rise to litigation resulting in no fewer than three appeals to this Court. In addition to the two instant cases, which I shall refer to as "*Novopharm*" and "*Apotex #1*", reasons in *Apotex Inc. v. Merck Frosst Canada Inc.*, [1998] 2 S.C.R. 193 ("*Apotex #2*"), are also being released today. The issue common to all three is whether the agreement

in question constitutes a simple supply agreement, as alleged by the two parties to the agreement, or, as alleged by the various respondents, a sublicence to exercise the rights acquired by Novopharm pursuant to compulsory licences obtained prior to recent changes to the legislative regime which governs patented medicines. This determination is key to the resolution of the issues in these appeals because, as shall be discussed, the grant of a sublicence by Novopharm could justify the termination by the patentee of the compulsory licence in question and render the supply agreement useless.

2 Owing to the intertwining nature of the lower court decisions in *Novopharm* and *Apotex #1*, I shall deal with these two appeals in one set of reasons. In addition to the common issue of interpretation, each case raises a number of other issues, which I shall endeavour to deal with appropriately as they arise.

I. Background

A. *The Patents and the Compulsory Licence*

3 Prior to February, 1993, there existed in Canada a compulsory licensing regime with respect to patents for pharmaceuticals. Under s. 39(4) of the *Patent Act*, R.S.C., 1985, c. P-4, as it then existed, in respect of any patent intended or capable of

being used for medicine or for the preparation or production of medicine, any person could make an application for a licence:

> **39**....
>
> (4)...
>
> (*a*) where the invention is a process, to use the invention for the preparation or production of medicine, import any medicine in the preparation or production of which the invention has been used or sell any medicine in the preparation or production of which the invention has been used, or
>
> (*b*) where the invention is other than a process, to import, make, use or sell the invention for medicine or for the preparation or production of medicine. . . .

According to the terms of s. 39(4), the Commissioner of Patents was obliged to grant to the applicant a licence to do the things specified in the application unless there existed a good reason not to grant such licence.

4 These appeals relate to two Canadian patents owned by Eli Lilly and Company ("Eli Lilly") in respect of the medication nizatidine: one in respect of the medicine itself and one in respect of the process by which the medicine is made. On December 31, 1987, the Department of National Health and Welfare granted a notice of compliance ("NOC") to Eli Lilly Canada Inc. ("Eli Lilly Canada"), pursuant to s. C.08.004 of the *Food and Drug Regulations*, C.R.C., c. 870, thereby permitting Eli Lilly Canada to market 150 mg and 300 mg final-dosage form capsules of nizatidine for consumption in Canada. To date, no other company has been issued a NOC in respect of nizatidine.

5 On January 17, 1990, Novopharm applied under s. 39(4) of the *Patent Act* for a compulsory licence under the patents owned by Eli Lilly. The application was

vigorously contested by Eli Lilly, but, it was found that none of the objections constituted a valid reason to refuse the application and the Commissioner of Patents accordingly granted the licence, as he was obliged to do under the Act as it then existed. The licence, which, unless validly terminated by Eli Lilly (a very contentious issue in the instant appeals), is still in force, permits Novopharm to use the patented process to make nizatidine for the preparation or production of medicine, and to import and/or sell medicine made by the process. It also permits Novopharm to make, use, sell and import either or both of the invention for medicine and the invention for the preparation or the production of medicine. The royalty rate to be paid by Novopharm to Eli Lilly Canada on sales of the medicine in final-dosage form is fixed at six percent of the selling price. The Commissioner of Patents, in a decision dated October 21, 1991, found that the licence is not restricted to the forms of medicine listed by Novopharm in its application, as such "would place unnecessary limits on [Novopharm's] operations under the licence".

6 Certain other specific terms and conditions of the licence are also relevant. Paragraph 1 contains terms and conditions pertaining to the calculation of royalties for the sale of nizatidine to arm's length purchasers and contemplates the sale of the medication by Novopharm in both final-dosage and bulk forms, stipulating royalty rates for each. Novopharm is also required, under paragraphs 3 and 4, to obtain quarterly statements showing the descriptions, quantities, net selling prices and royalty computations resulting from the operations of arm's length purchasers of the medicine, non-arm's length purchasers of the medicine in final-dosage form, and any subsequent non-arm's length purchasers from the latter.

7 Paragraph 9 of the licence, which is of paramount importance to this appeal, provides Eli Lilly with the option to terminate the licence upon any breach of its terms by Novopharm by giving notice in writing. In the event that Novopharm fails to rectify the breach within 30 days, the licence is terminated automatically. However, under paragraph 10, if Novopharm disputes the breach by written notice to Eli Lilly, the licence is not terminated pending adjudication by the courts or arbitration as agreed upon by the parties. Finally, paragraph 12 stipulates that the licence is non-transferable, and that Novopharm is prohibited from granting "any sublicence".

B. *The Supply Agreement Between Novopharm and Apotex*

8 On November 27, 1992, Novopharm and Apotex entered into what they described as a "supply agreement", in anticipation of proposed changes to the *Patent Act*, then embodied in Bill C-91. It was expected that this bill, if passed, would both eliminate the then-existing compulsory licensing regime and threaten the existing licences and licence applications of both companies. The agreement was drafted, apparently without the advice of counsel, by Dr. Bernard Sherman, the president of Apotex, and Mr. Leslie Dan, the president of Novopharm, and reads as follows:

> WHEREAS THE Federal Government has introduced Bill C-91 which, if passed, would eliminate compulsory licensing under the Patent Act,
>
> AND WHEREAS Apotex and Novopharm have various licences and licence applications pending which are threatened by Bill C-91,
>
> AND WHEREAS, depending on the cut-off dates that will pertain when Bill C-91 is finalized, it is expected that the parties hereto each may hold valid licences for products for which the other may not hold valid licences, details of which cannot be predicted at this time,

AND WHEREAS for their mutual benefit in relation to other competitors, the parties wish to ensure that they have available for use licences on the maximum number of products,

AND WHEREAS the parties have thus agreed that they will share their rights under licences for any product for which only one of the parties may hold a useable licence,

NOW THEREFORE in consideration of the premises and the mutual covenants and other good and valuable consultations, receipt of which is hereby acknowledged, the parties hereto agree as follows:

1. At any time subsequent to the date upon which Bill C-91 or any Bill derived therefrom is enacted and proclaimed, for any product for which one party (hereinafter the "licensed" party) shall hold a useable licence and the other party (hereinafter called the "unlicensed party") shall not, the licensed party shall, at the request of the unlicensed party, use its licence for the benefit of the unlicensed party in the manner hereinafter set out.

2. In the event that the licence is a licence to import, the licensed party shall import from such source, in such quantity, and on such terms as the unlicensed party shall direct, and shall resell the imported goods to the unlicensed party at the cost thereof together with such royalties as shall be payable under the terms of the licence.

3. In the event that the licence is a licence to manufacture in Canada, the licensed party shall enter into such contracts with Canadian chemical manufacturers as the unlicensed party shall direct for the manufacture of the relevant material and shall sell the manufactured materials to the unlicensed party at the cost thereafter together with such royalties as shall be payable under the terms of the licence.

4. In the event that the licensed party has a source of material from which it imports or in the event that the licensed party is producing the material under a licence to manufacture, and in the event that it is not possible for the unlicensed party to find another source from which to import, or at which to arrange for the manufacture of material, then the licensed party shall supply material to the unlicensed party from the licensed party's source at a price equal to the fair market price of the material together with such royalties as shall be payable under the terms of the licence. Any disagreement as to fair market price shall be settled by binding arbitration.

5. In addition to the payments provided for in paragraphs 2, 3 and 4 hereof, the unlicensed party shall pay to the licensed party a fee equal to 4% of the unlicensed party's net sales of product

covered by any unexpired patent included in the licensed party's licence and purchased from the licensed party.

Within 60 days of the end of each quarter year the unlicensed party shall deliver to the licensed party payment of the fee on sales made during the previous quarter along with a statement certified by an independent auditor setting out the quantities sold, the net dollar sales, and the fee payable thereon.

6. The licensed party shall comply with the terms of the licence.

7. The licensed party shall not be excused from performing any act as directed by the unlicensed party pursuant to paragraphs 2 or 3 or 4 hereof, on the grounds that there is doubt as to whether or not the licence has remained in force or permits the requested acts, nor on the basis of litigation or threatened litigation by the patentee, provided that the unlicensed party shall undertake to defend any lawsuit against the licensed party resulting from such act and hold the licensed party harmless for the costs of such lawsuit any damage award arising therefrom.

8. For greater clarity, the foregoing paragraphs shall not be limiting, and the licensed party shall cooperate fully with the unlicensed party and follow the directions of the unlicensed party to enable the unlicensed party to enjoy the use of the licence to the same extent that would be possible if the unlicensed party itself held such licence, so long as the licensed party is held harmless from any such use.

9. The unlicensed party shall resell any product purchased from the licensed party only under its own label and shall not sell the product for resale under a label other than that of the unlicensed party.

10. Neither party will engage in preventing or blocking the accessability [*sic*] of HPB clearance of any raw material affecting present and future pharmaceutical products.

11. This agreement shall expire on December 31, 1994 unless extended by mutual agreement.

12. Notwithstanding paragraph 11 hereof, if Bill C-91 is passed into law with an amendment that permits companies to continue to apply for and obtain compulsory licenses for any product for which a licence was issued to any one or more licence [*sic*] prior to December 20, 1991, then this agreement shall be terminated.

13. Notwithstanding paragraph 11 hereof, in relation to any specific licence in respect of which the unlicensed party shall have on or before December 31, 1994, advised the licensed

> party of an intention to utilize such licence, this agreement shall continue in force until expiry of the last patent covered by such licence.

9 On February 15, 1993, most of the provisions of the *Patent Act Amendment Act, 1992*, S.C. 1993, c. 2, were proclaimed into force. On March 12, 1993, the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the "Regulations"), came into force and radically altered the procedures governing the issuance of NOCs, strengthening the monopoly position of the patentee by eliminating the compulsory licensing scheme and curtailing the ability of generic drug companies to obtain approval to market a patented medicine until the expiry of all relevant product and use patents. The new NOC regime is lucidly summarized in the following excerpt from the judgment of Teitelbaum J. in *Glaxo Wellcome Inc. v. Canada (Minister of National Health and Welfare)* (1997), 75 C.P.R. (3d) 129 (F.C.T.D.), at pp. 131-32:

> 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. 1978, 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. 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*, ... (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*.
>
> ...
>
> 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. Under Section 3 of the *Regulations*, the Minister compiles the patent lists into a public document called the "Patent Register".

10 As required under s. 4(1) of the new Regulations, Eli Lilly Canada submitted a patent list, dated April 6, 1993, to the Minister of National Health and Welfare, which included the patents for nizatidine for which it held the NOC.

11 Apotex commenced efforts to obtain a NOC for 150 mg and 300 mg capsules of nizatidine under the new scheme, and accordingly sent a letter to Eli Lilly Canada, dated April 28, 1993, which constituted a Notice of Allegation ("NOA") as required by s. 5(3)(*b*) of the Regulations. In the NOA, Apotex alleged that no claim for the patented medicine itself or for the use of the medicine would be infringed by its making, constructing, using or selling the specified nizatidine capsules. In support of this allegation, Apotex relied upon the licence issued to Novopharm for nizatidine and upon the "mutual understanding" whereby Novopharm, the licensed party, would supply Apotex with raw materials obtained pursuant to its licence. Apotex stated that it had given Novopharm notice of its intention to obtain nizatidine, and undertook not to obtain, use, or sell any nizatidine other than from Novopharm until such time as the patents had expired.

12 The letter of intention referred to, also dated April 28, 1993, indicated that, because Apotex did not yet have a NOC to permit it to market nizatidine in Canada, it could not provide Novopharm with any specifics as to its requirements, but that it would advise in due course as to the required quantity and the manufacturer from whom the

nizatidine should be purchased. Although Apotex did apparently locate a source for the nizatidine, it had not, by the date of the hearing of this appeal, disclosed the identity of the source to Novopharm, and the evidence remained sealed as confidential information.

13 Eli Lilly and Eli Lilly Canada brought an application, under s. 6(1) of the Regulations, for an order prohibiting the Minister from issuing a NOC to Apotex at all or, alternatively, until after December 31, 1997, ten years after the issuance of the NOC to Eli Lilly Canada, which, under s. 39.11 of the *Patent Act*, would be the first date on which Apotex, without a NOC, would be entitled to import the patented medicine for consumption in Canada. This application forms the basis of the litigation in *Apotex #1*, upon which I shall elaborate shortly.

14 On July 15, 1993, Eli Lilly purported to exercise its option to terminate Novopharm's compulsory licence by providing 30 days' notice in writing to Novopharm. In support of the notice of termination, Eli Lilly alleged that Novopharm had breached the terms of the licence by granting a sublicence to Apotex. Novopharm denied this allegation, stating that the commercial agreement into which it had entered with Apotex did not constitute a sublicence or any transfer of rights under the licence. Novopharm apprised the Commissioner of Patents of the purported termination and its having disputed the allegations of breach.

C. *The Novopharm Proceeding*

15 On July 30, 1993, Novopharm issued a NOA in support of its own application for a NOC in relation to 150 mg and 300 mg capsules of nizatidine. It relied on its own compulsory licence as the basis for the non-infringement of the patents owned

by Eli Lilly. On September 15, 1993, Eli Lilly and Eli Lilly Canada brought an application before the Federal Court--Trial Division, requesting a prohibition order to enjoin the Minister from issuing the requested NOC to Novopharm, on the grounds that Novopharm's licence had been terminated and that Novopharm could not, therefore, obtain the bulk medicine in a non-infringing way.

16 Meanwhile, Eli Lilly also brought a separate application in the Ontario Court of Justice (General Division), seeking a declaration that Novopharm's licence was terminated by virtue of its granting a sublicence to Apotex, contrary to the terms of the licence. Forget J. found that that court had concurrent jurisdiction with the Federal Court--Trial Division to grant the relief sought, but, applying the convenient forum test, held that the matter ought to be decided by the Federal Court in the context of the prohibition proceedings. Eli Lilly and Eli Lilly Canada then brought an interlocutory motion in the Federal Court to amend the originating notice of motion by adding a claim for declaratory relief. Pinard J. dismissed the motion, stating that, in dealing with the originating notice of motion (i.e., the prohibition application), the Court had jurisdiction to make an incidental finding that the compulsory licence in question had been terminated, which would be sufficient to justify an order prohibiting the Minister from issuing a NOC.

17 On July 20, 1993, Mr. Dan of Novopharm wrote to Dr. Sherman of Apotex, stating that the two companies did not have an agreement to transfer licences or to sublicence, and asking Apotex to refrain from claiming in its applications for NOCs that licences would be transferred. He confirmed that the supply agreement contemplated that Novopharm would supply Apotex, as a third party customer, with specific licensed products, but stipulated that Novopharm never intended to create a sublicence, given that

such would be "contrary to the standard conditions of all compulsory licenses". Dr. Sherman responded by letter the next day, stating that Apotex had never suggested that any transfer of rights or sublicensing would occur, only that Novopharm would be supplying materials to Apotex, as a third-party purchaser.

18 Mr. Dan also filed an affidavit concerning his intentions as to the nature of the agreement with Apotex. On cross-examination, he testified that Novopharm and Apotex had intended to create a supply agreement, and that the statement in the preamble as to sharing of rights was improperly worded. He further testified that Apotex had not yet requested Novopharm to supply it with nizatidine, but that, if and when a request was made to obtain nizatidine from a foreign source, it would be Novopharm which would approach various sources, obtain quotations, import the bulk material, and finally sell it to Apotex on the terms agreed upon with the supplier. He stated that, if there was only one supplier for a given medicine, the accepted commercial practice would be that "if we have access, they should have access". Also, responding to a question concerning provisions of the *Patent Act* which would prohibit the importation and manufacture of nizatidine until December 31, 1997 and December 31, 1994, respectively, Mr. Dan asserted that "[w]e have to abide by the regulations".

19 McGillis J. of the Federal Court--Trial Division dismissed Eli Lilly's application for judicial review, finding that the agreement between Novopharm and Apotex did not constitute a sublicence, that the licence, therefore, could not be terminated on that ground by Eli Lilly, and, accordingly, that Eli Lilly had failed to prove that Novopharm's notice of allegation was not justified. This decision was reversed by a unanimous panel of the Federal Court of Appeal, which, relying on its earlier decision

in *Apotex #1*, *infra*, held that a sublicence had in fact been conferred by virtue of the supply agreement.

D. *The Apotex #1 Proceeding*

20 In cross-examination on the hearing of the application for a prohibition order in *Apotex #1*, the background of which is detailed above, Dr. Sherman of Apotex testified that the supply agreement with Novopharm did not enable Apotex to import or manufacture nizatidine, but only to require Novopharm to import or manufacture the medicine under the terms of its licence and to sell the material to Apotex. He testified that Apotex would in fact be acquiring the nizatidine from Novopharm and, if the NOC were granted, formulating it into 150 mg and 300 mg capsules for sale in Canada. He was of the view that this would not constitute an infringement of Eli Lilly's patents, given that no further licence would be necessary once the licensed material was purchased from Novopharm. However, he did appear to make reference at one point to Apotex's "having rights" under the licence.

21 Relying on her analysis in *Novopharm*, McGillis J. of the Federal Court--Trial Division found that the supply agreement between Novopharm and Apotex did not constitute a sublicence. Nonetheless, she granted the prohibition order on the basis that Apotex's allegations of non-infringement were not justified, as its formulation of nizatidine capsules for consumption in Canada would infringe Eli Lilly's patents.

22 The Federal Court of Appeal, Pratte J.A. dissenting, dismissed Apotex's appeal, but on different grounds. It found that, despite the parties' apparent intention to avoid conferring sublicences on one another, this was in fact the legal effect of the

written contract which they had completed. Therefore, Novopharm's licence was properly terminated and thus Apotex had no non-infringing means by which to obtain the nizatidine. While it was not necessary to decide the question, it was nevertheless unanimously held, contrary to the view of McGillis J., that Apotex's reformulation of nizatidine into final-dosage form would not have infringed the patents.

II. Relevant Statutory Provisions

23 *Patent Act*, R.S.C., 1985, c. P-4

> **39.11** (1) Subject to this section but notwithstanding anything in section 39 or in any licence granted under that section, no person shall under a licence granted under that section in respect of a patent for an invention pertaining to a medicine, regardless of when the licence was granted, have or exercise any right,
>
> > (*a*) where the invention is a process, to import the medicine in the preparation or production of which the invention has been used, if the medicine is for sale for consumption in Canada; or
> >
> > (*b*) where the invention is other than a process, to import the invention for medicine or for the preparation or production of medicine, if the medicine is for sale for consumption in Canada.
>
> (2) The prohibition under subsection (1) expires in respect of a medicine
>
> ...
>
> > (*c*) ten years after the date of the notice of compliance that is first issued in respect of the medicine where that notice of compliance is issued after June 27, 1986.
>
> **39.14** (1) Notwithstanding anything in section 39 or in any licence granted under that section, where the notice of compliance that is first issued in respect of a medicine is issued after June 27, 1986, no person shall, under a licence granted under that section in respect of a patent for an invention pertaining to the medicine, have or exercise any right,
>
> > (*a*) where the invention is a process, to use the invention for the preparation or production of medicine, or

(*b*) where the invention is other than a process, to make or use the invention for medicine or for the preparation or production of medicine

for sale for consumption in Canada, until the expiration of seven years after the date of that notice of compliance.

Patented Medicines (Notice of Compliance) Regulations, SOR/93-133

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,

(*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).

(3) Where a person makes an allegation pursuant to paragraph (1)(*b*) or subsection (2) the person shall

(*a*) provide a detailed statement of the legal and factual basis for the allegation; and

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

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.

(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 if it finds that none of those allegations is justified.

(3) The first person shall, within the 45 days referred to in subsection (1), serve the Minister with proof that an application referred to in that subsection has been made.

(4) Where the first person is not the owner of each patent that is the subject of an application referred to in subsection (1), the owner of each such patent shall be made a party to the application.

7. (1) The Minister shall not issue a notice of compliance to a second person before the latest of

(*a*) the expiration of 30 days after the coming into force of these Regulations,

(*b*) the day on which the second person complies with section 5,

(*c*) subject to subsection (3), the expiration of any patent on the patent list 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 any allegation pursuant to paragraph 5(3)(*b*) in respect of any patent on the patent list,

(*e*) subject to subsections (2), (3) and (4), the expiration of 30 months after the receipt of proof of the making of any application referred to in 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.

(3) Paragraphs (1)(*c*), (*d*) and (*e*) do not apply in respect of a patent if the owner of the patent has consented to the making, constructing, using or selling of the drug in Canada by the second person.

> (4) Paragraph (1)(*e*) ceases to apply in respect of an application referred to in subsection 6(1) if the application is withdrawn or is finally dismissed by the court.
>
> (5) A court may shorten or extend the time limit referred to in paragraph (1)(*e*) in respect of an application where the court has not yet made an order pursuant to subsection 6(1) in respect of that application and where the court finds that a party to the application failed to reasonably cooperate in expediting the application.

III. Judicial History

A. *Novopharm Ltd. v. Eli Lilly and Co.*

(1) Federal Court--Trial Division (1995), 60 C.P.R. (3d) 181

24 As a preliminary matter, McGillis J. considered the nature of the proceedings before the court. She observed that an application for prohibition under s. 6(1) of the *Regulations* is a judicial review proceeding which is intended to determine expeditiously whether a NOC should be issued. In this connection, she referred to *David Bull Laboratories (Canada) Inc. v. Pharmacia Inc.*, [1995] 1 F.C. 588 (C.A.), where Strayer J.A. held that the issues to be decided in such proceedings are of a limited or preliminary nature, only for the limited purpose above stated, and that, if a full trial of validity or infringement issues is required, it is to be obtained in the usual way, by commencing an action.

25 Turning to the question of whether the allegations of non-infringement made by Novopharm in requesting the NOC were justified, McGillis J. noted that, since Novopharm's position was premised on its licence, the key issue was the proper interpretation to be given the November, 1992 agreement between Apotex and

Novopharm. If the agreement was in substance a sublicence, then the licence would have been properly terminated by Eli Lilly, and Novopharm would have been left with no non-infringing way in which to obtain the medication for which the NOC was requested.

26 Relying on the decision of this Court in *Consolidated-Bathurst Export Ltd. v. Mutual Boiler and Machinery Insurance Co.*, [1980] 1 S.C.R. 888, McGillis J. identified the task at hand (at p. 197) as ascertaining the "true intent of the parties at the time of the entry into the contract". She rejected the submissions by Eli Lilly that the evidence of Mr. Dan, both in his affidavit and his cross-examination, as to his intention at the time the supply agreement was drafted, was inadmissible on the basis of the parol evidence rule. In her view, Mr. Dan was entitled to tender direct evidence concerning his intention at the time of drafting. As to the exchange of letters between Mr. Dan and Dr. Sherman, McGillis J.A. declined to rule on their admissibility, inasmuch as even if they were admissible, she would have accorded them no weight on the basis that they were written to clarify the intent of the parties long after the supply agreement had been signed, and apparently only in response to the threatened termination of the licence held by Novopharm.

27 With regard to the intentions of Mr. Dan at the time of drafting, McGillis J. concluded on the basis of his direct evidence that he intended to enter into a supply agreement with Apotex. However, she recognized (at p. 199) the need to examine the agreement as a whole in order to determine whether the words used by the parties reasonably expressed their intent, bearing in mind that "a sublicence could only have been created if Novopharm granted some or all of its rights under the licence to Apotex". In her view, at p. 199, the true nature of the agreement was that of "a supply agreement

dressed up to look like a sublicence". In other words, despite the presence in the supply agreement of wording which might tend to suggest the conferral of a sublicence, the actual operative provisions of the agreement did not amount to the granting of any of Novopharm's licensed rights to Apotex.

28 In the view of McGillis J., the plain fact that the supply agreement contemplated Novopharm's entering into contracts with third parties at the direction of Apotex did not itself amount to a sublicence. Indeed, if the licensed rights had in fact been sublicensed to Apotex, Novopharm's continued involvement in the transactions would have been unnecessary. On balance, McGillis J. was of the view that none of the provisions of the agreement conferred any of Novopharm's licensed rights upon Apotex, and that paragraph 6, by stipulating that the licensed party must comply with the terms of its licence, including the prohibition against sublicensing, strongly suggested that the parties did not intend to create a sublicence.

29 Therefore, McGillis J. found that no sublicence was granted by Novopharm to Apotex. In her view, this interpretation served to promote the true intent of the parties at the time of entry into the supply agreement and to produce a sensible commercial result from their perspective, which she viewed as an important interpretive goal, based on *Consolidated-Bathurst, supra.* Indeed, she stated that to find that a sublicence had been created would have defeated the parties' entire objective in entering into the supply agreement, as the compulsory licences could then have been terminated by the patentees. She also stipulated that, even had she not considered the extrinsic evidence given by Mr. Dan as to his intention, she would have reached the same conclusion based on the plain wording of the agreement as a whole. On this basis, McGillis J. concluded that Eli Lilly and Eli Lilly Canada had failed to establish, on a balance of probabilities, that the

allegation of Novopharm in its NOA was not justified within the meaning of s. 6(2) of the Regulations. Accordingly, she dismissed the application for a prohibition order.

30 As to the question of whether the licence had been terminated, McGillis J. declined jurisdiction to decide this matter, despite the earlier orders of Forget J. and Pinard J. She felt bound by the subsequent ruling in *David Bull Laboratories, supra*, that the court lacks jurisdiction, in the context of a judicial review proceeding to determine an application for a prohibition order of this kind, to determine ancillary or incidental questions which pertain solely to the rights of two private parties. However, in the event that she was wrong in this conclusion, she expressed the opinion that her finding that Novopharm had not granted a sublicence to Apotex necessarily led to the conclusion that the licence had not been breached.

(2) Federal Court of Appeal (1996), 67 C.P.R. (3d) 377

31 In oral reasons delivered from the bench, Stone J.A. (MacGuigan and McDonald JJ. A. concurring) dismissed the appeal. The appeal was heard three weeks after the hearing of the appeal in *Apotex #1*, *infra*, and at the hearing, the court invited submissions as to the possible application of that decision to the outcome of the instant appeal. Eli Lilly argued that the decision was dispositive, in that the court there held that the supply agreement contravened the sublicensing prohibition in the compulsory licence, and that, by notice, Eli Lilly had succeeded in terminating the licence. For its part, Novopharm argued that the decision should not be applied because the facts of the instant appeal differed materially from the facts in the previous case, and also because, while a decision on a prohibition order application binds the parties to the specific litigation, it has little precedential value for other cases.

32 The court held that, while the previous decision was not *res judicata*, it was nonetheless binding on the court unless it could be distinguished on its facts or was manifestly wrong owing to the failure of the court to consider a relevant legal rule. The latter was not alleged. As to the former, while the court recognized that there were some factual differences and that some of the evidence which was before the court in *Apotex #1* was not part of the record in the instant case, the same compulsory licence and the same supply agreement were at issue and in evidence in both cases. To the extent that it was unaffected by evidence unique to its own record, the analysis of the supply agreement in *Apotex #1* could therefore be applied to *Novopharm*. While it was true that paragraph 6 of the supply agreement required Novopharm to act in compliance with the terms of its licence, the court concluded that this clause was to be read together with the other clauses of the agreement, leading to the conclusion that a sublicence had indeed been granted. Accordingly, the appeal was allowed.

B. *Apotex Inc. v. Eli Lilly and Co.*

(1) Federal Court--Trial Division (1995), 60 C.P.R. (3d) 206

33 In this proceeding, the basis for Eli Lilly's claim of non-justification was that Novopharm's licence for nizatidine had been terminated by virtue of its grant of a sublicence to Apotex, and that Apotex therefore had no non-infringing way of obtaining the bulk nizatidine in order to formulate the capsules that were the subject of the NOC request. Alternatively, it was argued that the formulation of the capsules would itself constitute an infringement of Eli Lilly's patent rights.

34 In concluding in *Novopharm*, *supra*, that the arrangement between Apotex and Novopharm was not a sublicence but merely a supply agreement, McGillis J. had considered the evidence of Mr. Dan of Novopharm concerning his intent at the time he drafted the agreement with Dr. Sherman. While this evidence was not part of the record in the instant matter, McGillis J. had indicated in *Novopharm* that she would have reached the same conclusion even without considering that evidence. Accordingly, she was of the view that her conclusion as to the nature of the agreement in *Novopharm* applied equally to the case at bar.

35 Turning, then, to the question of whether the formulation of capsules from the bulk material would infringe Eli Lilly's patent rights, McGillis J. considered the decision of MacKay J. in *Merck & Co. v. Apotex Inc.* (1994), 59 C.P.R. (3d) 133 (F.C.T.D.), and agreed with his conclusion that this processing activity would in fact constitute an infringement, as "an unlicensed third party purchaser acquires none of the exclusive rights granted to a patentee merely by virtue of the fact that he has purchased bulk material from a licensed supplier" (p. 218).

36 Therefore, McGillis J. found that Eli Lilly had established, on a balance of probabilities, that the allegation of non-infringement made by Apotex in its notice of allegation was not justified within the meaning of s. 6(2) of the Regulations. Accordingly, she allowed the application for judicial review and prohibited the Minister from issuing a NOC to Apotex until after the expiry of Eli Lilly's patents.

(2) Federal Court of Appeal (1996), 66 C.P.R. (3d) 329

(a) *MacGuigan J.A. (Robertson J.A. concurring)*

37 In reviewing the facts and the evidence, MacGuigan J.A. observed that, on several occasions, Dr. Sherman had emphasized that all decisions under the supply agreement would be made by Apotex and communicated to Novopharm. Apotex's stated intention was to deal with a Canadian manufacturer, independent of Novopharm, and it in fact refused to communicate to Novopharm the identity of this manufacturer until such was convenient for Apotex. But Dr. Sherman insisted that Novopharm, not Apotex, would purchase the material and sell it to Apotex, within the terms of its licence.

38 MacGuigan J.A. noted that the conclusion of McGillis J. in *Novopharm* as to the proper characterization of the Apotex-Novopharm agreement was premised, to some extent, on the evidence of Mr. Dan as to his intention at the time the agreement was drafted. He observed not only that this evidence did not form part of the record in the case before him, but also that any direct evidence as to the intention of the parties was to be excluded from consideration under the parol evidence rule. In his view, the question as to the meaning of the agreement was a legal one which was to be determined from its text. Although McGillis J. had made clear that she would have reached the same conclusion even absent the extrinsic evidence, MacGuigan J.A. observed that she also appeared to have been influenced in her decision by two particular legal propositions: that a sublicence could only have been created if Novopharm had granted some or all of its rights under the licence to Apotex, and that, when interpreting a contract, courts should favour an interpretation which promotes a sensible commercial result: see *Consolidated-Bathurst, supra.*

39 MacGuigan J.A. relied on the decision of the Delaware Supreme Court in *E.I. du Pont de Nemours & Co. v. Shell Oil Co.*, 227 USPQ 233 (1985) ("*du Pont*"),

which, although it dealt with somewhat different facts, considered what was in his view essentially the same type of transaction, that is, one in which the patented product was produced not for the licensed party but for an unlicensed party. In that case, the court, relying on *Carey v. United States*, 326 F.2d 975 (Ct. Cl. 1964), held that the test for a sublicence is whether the production of the licensed item is by or for the use of the original licensee or the alleged sublicensee, and concluded that the application of this test revealed a sublicence in a situation where an unlicensed party purported to manufacture a patented item as the agent of the licensee, only to purchase the item from the licensee immediately upon its manufacture, each transfer of property being nothing more than a paper transaction.

40 In the view of MacGuigan J.A., a similar form of "legerdemain" occurred in the present case. He found that, under the supply agreement, the separate contracts between Novopharm and its suppliers and Novopharm and Apotex were to be maintained only to avoid a direct contractual link between Apotex and the suppliers. He viewed this as a matter of form only. Because Apotex was in reality the directing mind, with Novopharm using its licence for Apotex's benefit, he found that the arrangement between the two was, contrary to the view of McGillis J., "a sublicence dressed up to look like a supply agreement" (p. 338). While he recognized that the subjective intention of the parties was to avoid creating a sublicence, he found that this was at odds with the objective intention of the document they executed. The legal effect of the contract, in other words, was to create a sublicence.

41 MacGuigan J.A. also found that, in accordance with his reading of *Consolidated-Bathurst, supra*, any consideration of whether this interpretation would promote a "sensible commercial result" must be accorded only a "tertiary status", behind

the "primary" rule of interpretation -- the objective analysis of the actual words used by the parties -- and the application of the *contra proferentum* doctrine to interpret any ambiguity against the drafting party. In his view, at p. 338, the primary rule governed in the present case, as there was no ambiguity in "the words they used, as I interpret the reality behind them".

42 Therefore, MacGuigan J.A. dismissed Apotex's appeal, finding that Novopharm's licence had been properly terminated by Eli Lilly. Although he found it unnecessary to decide the issue of infringement by formulation, he stated that he would have agreed with the reasons of Pratte J.A. on the matter.

(b) *Pratte J.A., dissenting*

43 Pratte J.A. differed from the majority on the issue of contractual interpretation. In his view, there was nothing obscure in the text of the supply agreement such as to require further interpretation. Although both the intention and the effect of the contract was to afford the parties, as far as possible, the same benefits they would have obtained under mutual sublicences, the supply agreement did not provide for the granting of any sublicence. As to Eli Lilly's contention that the agreement did not disclose the true nature of the arrangement -- that each party would give sublicences to each other and then, for the sake of appearances, act as the sublicensee's agent in procuring the drug -- there was, in the view of Pratte J.A. at p. 342, "absolutely no evidence that the parties ever intended to enter into such a surrealistic arrangement". In his view, Eli Lilly had not succeeded in proving that the arrangement was a sham merely by showing that the parties could have obtained the same advantages by entering into a

different agreement. Therefore, he concluded that Novopharm had not breached the terms of its licence.

44 Turning to the question of non-infringement by Apotex's actual activities, Pratte J.A. was of the view, at pp. 342-43, that "Apotex, by purchasing from Novopharm bulk nizatidine manufactured or imported by that company under its compulsory licence, would acquire the right to use that drug and, as an incident of that right, the right to make capsules from it". He found that, by selling a patented article, a patentee transfers the ownership of that article to the purchaser. The patentee no longer has any right with respect to the article, and the purchaser, as the new owner, "has the exclusive right to possess, use, enjoy, destroy or alienate it" (p. 343) without fear of infringing the vendor's patent. The patentee, in other words, has impliedly renounced his exclusive right of use and sale. In the view of Pratte J.A., with whom the majority concurred on this point, the same principles apply to the sale of a patented article by a licensee who is entitled by the licence to sell without restrictions, and therefore, Apotex was entitled to make capsules from the nizatidine obtained from Novopharm without infringing Eli Lilly's patent. For these reasons, Pratte J.A. would have allowed the appeal.

IV. Issues

45 As I have already stated, the issue common to both appeals is whether the supply agreement between Apotex and Novopharm constituted a sublicence, such as to justify the termination by Eli Lilly of Novopharm's compulsory licence for nizatidine. If it did, then the NOAs issued by both Novopharm and Apotex were not justified and the requested prohibition order should issue. However, each appeal also raises other discrete issues, which I shall consider in turn.

46 Specifically, in the *Novopharm* proceeding, this Court is asked to determine: (1) whether the Federal Court of Appeal erred in applying its decision in *Apotex #1* to the *Novopharm* appeal, whether as *res judicata* or otherwise; (2) whether Novopharm's NOA was not justified, regardless of whether its compulsory licence was terminated by breach, because the licence did not permit the activities which it proposed; and (3) whether the Federal Court had the jurisdiction to grant declaratory relief on a limited judicial review proceeding of this type. In *Apotex #1*, it is further alleged that, apart from the primary issue of infringement, Apotex's proposed reformulation of the nizatidine into final-dosage form would itself constitute an infringement of the patents held by Eli Lilly, and that the prohibition order should therefore have issued regardless of whether or not the supply agreement constituted a sublicence.

V. Analysis

A. *The Agreement Between Apotex and Novopharm*

47 The primary argument advanced by Eli Lilly is that the supply agreement constituted the grant of a sublicence by Novopharm to Apotex in direct violation of paragraph 12 of Novopharm's compulsory licence for nizatidine. It is undisputed that such a breach would, pursuant to paragraph 8 of the licence, entitle Eli Lilly to terminate the licence, which would in turn preclude Novopharm from manufacturing, using, importing or selling nizatidine without infringing Eli Lilly's patent. In this event, neither Novopharm's nor Apotex's NOA would be justified.

(1) The Nature of a Sublicence

48 Relatively little argument was directed at defining what a sublicence is. As a general matter, a sublicence amounts to a grant by a licensee of certain licensed rights to a third party, the sublicensee. That is, the licensee in effect transfers or licenses some or all of his or her rights to the sublicensee, which means that the sublicence has similar incidents to the primary licence, including the right to exercise independently certain rights enjoyed by the licensee pursuant to its licence. It has been said, in fact, that "a sublicence is simply another name for the indirect granting of a licence": see Leslie W. Melville, *Forms and Agreements on Intellectual Property and International Licensing*, vol. 1 (3rd ed. rev. 1997 (loose-leaf)), at §3.18.

49 To understand the nature of a sublicence, then, it is first necessary to appreciate the nature of a licence. In Harold G. Fox, *The Canadian Law and Practice Relating to Letters Patent for Inventions* (4th ed. 1969), the concept is expressed as follows (at p. 285):

> A licence, even though exclusive, does not give the licensee all the rights of the patentee. A licence does not set up rights as between the licensee and the public, but only permits him to do acts that he would otherwise be prohibited from doing. He obtains merely a right of user. But a licence is a grant of a right and does not merely confer upon the licensee a mere interest in equity. A licence is the transfer of a beneficial interest to a limited extent, whereby the transferee acquires an equitable right in the patent. A licence prevents that from being unlawful which, but for the licence, would be unlawful; it is a consent by an owner of a right that another person should commit an act which, but for that licence, would be an infringement of the right of the person who gives the licence. A licence gives no more than the right to do the thing actually licensed to be done. [Emphasis added.]

In other words, by the grant of a licence, the patentee grants to the licensee the right to act in a certain way *vis à vis* the patented article, a right which, but for the licence, the

licensee would not enjoy. The licensee's rights, however, are not necessarily equivalent to those of the patentee; rather, they are limited to, and qualified by, the express terms of the licence.

50 Moreover, I should note, as an aside, that, unless the intention is expressed or implied in the licence, a licensee is not at liberty to grant a sublicence without the permission of the licensor: see, for example, *Howard and Bullough, Ld. v. Tweedales and Smalley* (1895), 12 R.P.C. 519, at p. 528. This may be viewed as an effort by the law to protect the property rights of the owner of the property, notwithstanding that the exclusive nature of these rights has been compromised by the granting of a licence. Thus, even without the express prohibition against sublicensing in the compulsory licence, Novopharm would not have been permitted to grant a sublicence to Apotex. The effect of the express prohibition, however, in the context of this licence as a whole, is that the grant of a sublicence by Novopharm would occasion a breach which could lead to the termination of the compulsory licence at the instance of Eli Lilly.

51 For Novopharm to have granted a sublicence to Apotex by means of the supply agreement, it must have transferred some or all of its rights under its compulsory licence to Apotex. Simply put, the question comes down to this: did Novopharm grant to Apotex, either expressly or impliedly, the right to do something which Apotex would otherwise be prohibited from doing, and which Novopharm was permitted to do only by virtue of its compulsory licence for nizatidine? This may have occurred in one of two ways: either some express provision or provisions, apparent on the face of the agreement, may reveal that the intentions of the parties was to create a sublicensing arrangement, or the legal effect of the document may be such that a sublicence was created in spite of the parties' contrary intentions. I will examine each of these possibilities in turn.

(2) Contractual Interpretation and the Intentions of the Parties

52 In order to ascertain whether the supply agreement conferred or had the effect of conferring a sublicence upon Apotex, it is first necessary to consider the proper approach to the interpretation of such a contract, and, in particular, the evidence which may be considered in this respect. In *Consolidated-Bathurst, supra*, at p. 901, Estey J., writing for himself and Pigeon, Dickson, and Beetz JJ., offered the following analysis:

> Even apart from the doctrine of *contra proferentem* as it may be applied in the construction of contracts, the normal rules of construction lead a court to search for an interpretation which, from the whole of the contract, would appear to promote or advance the true intent of the parties at the time of entry into the contract. Consequently, literal meaning should not be applied where to do so would bring about an unrealistic result or a result which would not be contemplated in the commercial atmosphere in which the insurance was contracted. Where words may bear two constructions, the more reasonable one, that which produces a fair result, must certainly be taken as the interpretation which would promote the intention of the parties. Similarly, an interpretation which defeats the intentions of the parties and their objective in entering into the commercial transaction in the first place should be discarded in favour of an interpretation ... which promotes a sensible commercial result.

53 From this passage emerge a number of important principles of contractual interpretation. Not all of these, however, apply to the instant appeal. One which surely does not is the doctrine of *contra proferentem*. *Contra proferentem* operates to protect one party to a contract from deviously ambiguous or confusing drafting on the part of the other party, by interpreting any ambiguity against the drafting party. When both parties are in agreement as to the proper interpretation of the contract, however, it is not open to a third party to assert that *contra proferentem* should be applied to interpret the contract against both contracting parties. Indeed, a third party has no basis at all upon

which to rely upon *contra proferentem*: see G. H. L. Fridman, *The Law of Contract in Canada* (3rd ed. 1994), at p. 471. Therefore, I would, as a preliminary matter, reject the suggestion that the doctrine should apply to read any ambiguity in the contract against the drafting parties, in this case both Novopharm and Apotex.

54 The trial judge appeared to take *Consolidated-Bathurst* to stand for the proposition that the ultimate goal of contractual interpretation should be to ascertain the true intent of the parties at the time of entry into the contract, and that, in undertaking this inquiry, it is open to the trier of fact to admit extrinsic evidence as to the subjective intentions of the parties at that time. In my view, this approach is not quite accurate. The contractual intent of the parties is to be determined by reference to the words they used in drafting the document, possibly read in light of the surrounding circumstances which were prevalent at the time. Evidence of one party's subjective intention has no independent place in this determination.

55 Indeed, it is unnecessary to consider any extrinsic evidence at all when the document is clear and unambiguous on its face. In the words of Lord Atkinson in *Lampson v. City of Quebec* (1920), 54 D.L.R. 344 (P.C.), at p. 350:

> . . . the intention by which the deed is to be construed is that of the parties as revealed by the language they have chosen to use in the deed itself .... [I]f the meaning of the deed, reading its words in their ordinary sense, be plain and unambiguous it is not permissible for the parties to it, while it stands unreformed, to come into a Court of justice and say: "Our intention was wholly different from that which the language of our deed expresses. . . ."

56 When there is no ambiguity in the wording of the document, the notion in *Consolidated-Bathurst* that the interpretation which produces a "fair result" or a

"sensible commercial result" should be adopted is not determinative. Admittedly, it would be absurd to adopt an interpretation which is clearly inconsistent with the commercial interests of the parties, if the goal is to ascertain their true contractual intent. However, to interpret a plainly worded document in accordance with the true contractual intent of the parties is not difficult, if it is presumed that the parties intended the legal consequences of their words. This is consistent with the following dictum of this Court, in *Joy Oil Co. v. The King*, [1951] S.C.R. 624, at p. 641:

> . . . in construing a written document, the question is not as to the meaning of the words alone, nor the meaning of the writer alone, but the meaning of the words as used by the writer.

57 In my view, there was no ambiguity to the contract entered into between Apotex and Novopharm. No attempt was made to disguise the true purpose of the arrangement, or the circumstances surrounding its drafting. Clearly, the agreement was meant to minimize the deleterious effects of the amendments to the *Patent Act*, which were expected to and did eventually place severe restrictions on the former scheme of compulsory licensing, by maximizing the access of each party to as wide a variety of patented medicines as possible. This was to be accomplished by obliging each party to obtain such material for the other in the event that one party possessed a licence which the other lacked and could no longer readily obtain. All of this is evident on a plain reading of the recitals to the supply agreement. Leaving aside the question of circumventing the legislation, which has no bearing on the interpretation of the contract, the parties' intentions are clear on the face of the agreement. Accordingly, it cannot properly be said, in my view, that the supply agreement contains any ambiguity that cannot be resolved by reference to its text. No further interpretive aids are necessary.

58 More specifically, there is no need to resort to any of the evidence tendered by either Apotex or Novopharm as to the subjective intentions of their principals at the time of drafting. Consequently, I find this evidence to be inadmissible by virtue of the parol evidence rule: see *Indian Molybdenum Ltd. v. The King*, [1951] 3 D.L.R. 497 (S.C.C.), at pp. 502-3.

59 Moreover, even if such evidence were required, that is not the character of the evidence tendered in this case, which sheds no light at all on the surrounding circumstances. It consisted only of the subjective intentions of the parties: Mr. Dan's subjective intention at the time of drafting and Dr. Sherman's subjective intention to implement the agreement in a certain way.

60 Therefore, I am of the opinion that the trial judge erred, in the *Novopharm* proceeding, in considering the evidence of Mr. Dan as to his intention at the time the contract was made. However, I am also cognizant of her clear statement that she would have reached the same conclusion even without considering the evidence and thus I would not reject her interpretation of the supply agreement for this reason alone. Appropriately, McGillis J. did not appear to consider the evidence of Dr. Sherman in *Apotex #1*, although the same cannot be said for MacGuigan J.A. in his disposition of that case. Indeed, he seemed to have been influenced heavily by this evidence, which necessarily casts doubt on the validity of his conclusions.

61 Having established that no extrinsic evidence is admissible, what does the text of the agreement say about the intentions of the parties? Despite the somewhat strident submissions to the contrary by Eli Lilly, one thing which it most assuredly does not say is that, pursuant to its terms, Apotex is entitled to the independent use of any

compulsory licence owned by Novopharm for its own benefit. Nor does it say that Apotex is entitled to exercise any right enjoyed by Novopharm pursuant to any such licence. Rather, it simply provides, in paragraph 1, that Novopharm will, at the direction of Apotex, "use its licence for the benefit of" Apotex. To my mind, this does not satisfy the definition of a sublicence, as previously set out. The only right acquired by Apotex pursuant to this provision is the right to require Novopharm to exercise its licensed rights in a particular way, that is, to enable it to set in motion and benefit from Novopharm's exercise of its own rights to obtain and sell certain patented medicines. Apotex acquires no right to obtain these medicines independently of Novopharm. Indeed, it remains abundantly clear that Novopharm is still the only party actually entitled to act pursuant to the licence.

62 Thus, it is really of no consequence that the agreement gives Apotex the right to direct Novopharm as to who should make the medicine, from whom it should be purchased, and at what price, or that Novopharm is contractually obliged to follow these directions. Nor does it matter that Novopharm is to receive a royalty for supplying to Apotex the licensed materials so obtained. In some ways, these provisions create nothing more than an elaborate agreement to agree. That is, the agreement sets out a procedure by which the unlicensed party may require the licensed party to enter into another agreement, one of purchase and sale, the specific terms of which may be set substantially by the unlicensed party except that the licensed party is always entitled to the same rate of return: four percent of the cost of the material sold. In this way, the royalty does no more than assure the licensed party a certain margin of profit in consideration of its role in these anticipated future transactions. The arguments of the respondent notwithstanding, I do not see how this can be indicative of either an intention to confer, or the actual conferral of, a sublicence.

63 It is true that, in the recitals, the parties refer to a mutual intention to "share their rights", which itself might well be taken to suggest an intention to create a sublicence. However, this provision must be read in light of the rest of the agreement, which clearly discloses the intention not to create a sublicence. In particular, the requirement in paragraph 6 that the licensed party comply with the terms of its licence militates against the conclusion that the parties intended by the agreement to grant sublicences to one another. It simply would not be possible for Novopharm to grant a sublicence while still complying with the terms of its compulsory licence for nizatidine, given the express prohibition in that licence against the conferral of sublicences. On the evidence, there is no reason to conclude that Novopharm intended to breach both the supply agreement and its compulsory licence by granting a sublicence to Apotex.

64 Moreover, I do not read paragraph 7 of the agreement, which provides that "[t]he licensed party shall not be excused from performing any act as directed by the unlicensed party ... on the grounds that there is doubt as to whether or not the licence ... permits the requested acts" (emphasis added), provided also that the unlicensed party is obliged to defend the licensed party from any ensuing litigation, as either permitting or requiring the conferral of a sublicence in this case. If paragraph 6 is to have any meaning at all, it must at least be seen as prohibiting acts which would be in clear violation of the licence held by the licensed party. I can conceive of no clearer violation than the conferral of a sublicence. There is no "doubt" as to whether the licence permits such an act; rather, it is expressly prohibited by paragraph 12 of the licence. Consequently, I do not believe that paragraph 7 has any application in the circumstances; certainly, it does not oust the effect of paragraph 6.

65 Paragraph 8, which requires the licensed party to "cooperate fully with the unlicensed party and follow the directions of the unlicensed party to enable the unlicensed party to enjoy the use of the licence to the same extent that would be possible if the unlicensed party itself held such licence" (emphasis added), is admittedly an unusual and arguably unfortunately worded clause. Indeed, if anyone were to question whether the supply agreement was actually drafted without the benefit of counsel, as asserted by both Novopharm and Apotex, this paragraph would stand as cogent evidence in support of that claim. However, it too must be read in light of the rest of the agreement, which simply does not permit the unlicensed party to "enjoy the use of the licence" in the active sense, that is, to actually use it. Rather, it permits only indirect enjoyment: the enjoyment of the licensed party's use of the licence. It is certainly true that the licensed party is obliged to follow the directions of the unlicensed party and to take all legal steps possible to enable the unlicensed party to benefit from the existence of the license, when requested. However, this stops short of actually permitting the unlicensed party to exercise licensed rights independently of the licensed party, which is the essence of a sublicence.

66 In short, I can find nothing in the wording of the document to suggest that the parties intended to grant sublicences to each other. Rather, every indication is that they intended to establish a commercial arrangement whereby the unlicensed party would enjoy the right to require the licensed party to use its various licences for the benefit of the unlicensed party by acquiring, potentially at the direction of the unlicensed party, and subsequently reselling to the unlicensed party, various patented medicines. Indeed, it is worth noting that the creation of sublicences really would not have been in the parties' commercial interests, as this would have justified the termination of the various compulsory licences held by each company and thereby not only rendered the

supply agreement itself useless but also jeopardized the business operations of both. While it is true, as submitted by Eli Lilly, that no express words of grant are required to create a sublicence, clearly the supply agreement, to have this character, must have transferred to Apotex more than simply the right to compel Novopharm to use its licence in a given way. But it is apparent that, in the context of the agreement as a whole, this is all that was meant by sharing rights.

(3) The Legal Effect of the Supply Agreement

67 Eli Lilly contends that the legal effect of the agreement was that a sublicence was granted by each party to the other, despite what they may have intended. In light of the foregoing analysis, however, I do not see how this argument can be sustained. Apotex and Novopharm intended to create a specific type of supply agreement, not a sublicence, and I believe they succeeded in doing so. However, to the extent that Eli Lilly's argument may be premised upon some confusion as to the distinction between a sublicence and an ordinary agreement of purchase and sale, that distinction does merit some brief examination at this stage.

(i) *Sublicence Versus Purchase and Sale*

68 By virtue of its compulsory licence, Novopharm is entitled to manufacture and/or import bulk nizatidine, subject to the temporal restrictions imposed by the *Patent Act*, and to sell the nizatidine so obtained to Apotex or any other third party. Apotex, having acquired the nizatidine from Novopharm, would then be free to use it in any way that did not infringe the patents held by Eli Lilly. Thus, no sublicence could have been created by an agreement that was confirmatory of these rights and simply conferred upon

Apotex the additional right to require Novopharm to acquire and sell to it bulk nizatidine at a certain rate. In other words, to prove the existence of a sublicence, it must be established that the agreement was, in substance if not form, more than merely an elaborate arrangement under which future contracts for purchase and sale might be completed.

69 As I have said, a sublicence requires the conferral of licensed rights by a licensee upon a third party, the sublicensee. This may create some confusion between a sublicence and an ordinary contract of purchase and sale, though, as a third party may acquire similar rights under each of these arrangements. That is, just as a sublicensee can obtain the rights to use and sell a patented article if this right is enjoyed by the licensee and transferred accordingly, so too is the sale by a licensee of a patented article presumed to give the purchaser the right "to use or sell or deal with the goods as the purchaser pleases": see *Badische Anilin und Soda Fabrik v. Isler*, [1906] 1 Ch. 605, at p. 610; see also *Gillette v. Rea* (1909), 1 O.W.N. 448 (H.C.); *Betts v. Willmott* (1871), L.R. 6 Ch. App. 245. In other words, unless otherwise stipulated in the licence, a licensee is generally entitled to pass to a purchaser the right to use or resell the patented article without fear of infringing the patent.

70 But the sale of a licensed article obviously does not have the automatic effect of constituting the purchaser a sublicensee, and thus the fact that a third party enjoys rights of use and alienation cannot alone be indicative of the existence of a sublicence. Indeed, as Apotex points out, both the case law and common sense disclose any number of ways in which a licensee can sell a licensed article to a third party with the complete range of ordinary incidents of ownership, without constituting that party a sublicensee. These range from the ordinary casual purchase to the licensee's manufacturing, at the

purchaser's instigation and direction, and according to the purchaser's own design specifications, products which incorporate the subject matter of the licence: see *Intel Corp. v. ULSI System Technology Inc.*, 995 F.2d 1566 (Fed. Cir. 1993).

71 Thus, practically speaking, the rights of use and alienation can only be determinative of the existence of a sublicence in cases in which it is clear that no transfer of property rights has occurred, i.e., that there has been no sale of the licensed article to the third party. In such a case, a right of use could only be derived from a sublicence of some type, and an untrammelled right of alienation could not be enjoyed at all, as it would be impossible for a third party to transfer good title without first having any proprietary right in the article. Where the rights of the unlicensed party are derived from a sale of licensed material, however, it would be misleading to rely on the rights of use and alienation as a basis for the conclusion that a sublicence has been or is to be granted.

72 In the present case, it is plainly the latter situation which is contemplated by the supply agreement between Novopharm and Apotex. Under the agreement, any right Apotex might enjoy to sell nizatidine would obviously emanate from its first having purchased such material from Novopharm. As I have stated, the possibility that the material might be acquired by Novopharm at and subject to Apotex's direction is of no consequence. What is important, rather, is that the supply agreement in no way permits Apotex to exercise rights licensed to Novopharm in order to manufacture, or otherwise acquire independently, patented material for which it is not itself licensed. If the agreement were in substance a sublicence, Novopharm's involvement would be entirely unnecessary; Apotex could deal directly with the manufacturer or exporter of the material, or manufacture the drugs itself. But no such rights in fact exist under the supply agreement.

73 A number of recent U.S. cases support the view that establishing the existence of a sublicence in situations analogous to the one before us will typically depend on demonstrating that the unlicensed party is exercising the licensee's right to manufacture or import the licensed material. For example, in *Intel*, *supra*, it was held that the sale of microchips by the licensee, Hewlett-Packard ("HP"), to a third party, ULSI, did not constitute a sublicence, notwithstanding that the chips were built by HP according to the design and specifications of ULSI and were then resold by ULSI. The court in that case did acknowledge, however, that HP's empowering ULSI to make the chips itself would have constituted a sublicence.

74 In the instant appeals, the Federal Court of Appeal relied on *du Pont*, *supra*, for the proposition that, in effect, a sublicence is created whenever a patented product is made for the benefit of the unlicensed party rather than the licensee. However, with respect, I view *du Pont* as readily distinguishable from the cases before us, and do not, in any event, believe that it stands for the legal principle propounded. In *du Pont*, it was more significant that the unlicensed party actually manufactured the licensed article, allegedly as the agent of the licensee, only then to "purchase" the article from the licensee immediately upon its manufacture. This arrangement was characterized by the Delaware Supreme Court as a sham, and rightfully so. The only factor which distinguished it from an overt situation of an unlicensed party's manufacturing a patented article strictly for its own benefit was a series of paper transactions carried out between a subsidiary corporation and its parent for the purpose of obscuring the true character of the arrangement.

75 But the situation is manifestly different in a case where the manufacturer and the end user are embodied in two different legal *personnae*, and legitimate transfers of property do, in fact, take place. In *Cyrix Corp. v. Intel Corp.*, 77 F.3d 1381 (Fed. Cir. 1996), the licensed party agreed to supply a third party with microprocessors which it was entitled to manufacture pursuant to a licence conferred upon it by the patentee. The licensed party, in turn, had the processors made by another corporation (affiliated but not a subsidiary), which then sold them to the licensed party for resale to the third party. It was argued that this arrangement constituted in essence a sublicence granted by the licensed party to the third-party manufacturer, and that the licensed party's "have made" rights under the licence extended only to the manufacture of goods for its own benefit. The court rejected this argument, finding that the licensed party was entitled to have the licensed products made by an agent and to resell them as it saw fit. It distinguished *du Pont*, *supra*, on the basis that the manufacturer and the end user were two completely separate entities, and so the arrangement could not be characterized as a sham.

76 In my view, *Cyrix* is much more closely analogous than *du Pont* to the instant appeal, a case in which two arm's-length companies, one licensed and the other unlicensed, have contracted for the prospective purchase and sale of patented goods. They have agreed that the licensed party, in this case Novopharm, will, at and according to the direction of the unlicensed party, Apotex, either manufacture or import the goods, acquire property rights in them, and sell them to Apotex. The only real difference is that, where in *Cyrix* the licensee presumably had the chips made on such terms as would ensure that a profit would be earned on the agreement of purchase and sale previously completed with the third party, in the present circumstances, the profit of which Novopharm is assured is based not on its arrangement with its supplier, but from the

guaranteed four percent royalty payable by Apotex. This distinction alone cannot transform the supply agreement into a sublicence.

77 Because the supply agreement has not yet been implemented, the evidence certainly does not establish that this is a case where the unlicensed party is manufacturing the goods itself, as in *du Pont*. Consequently, I need not decide whether a sublicence would be granted in this hypothetical situation. Indeed, it has not been argued, and I cannot simply presume that the supply agreement has been or is intended to be carried out in this manner. Moreover, I note again that the supply agreement expressly provides, in paragraph 6, that the licensed party must comply with the terms of the licence, which, *inter alia*, precludes it from granting sublicences. Therefore, while it is theoretically possible that this arrangement could someday be implemented in a way that would result in the grant of a sublicence, it must be presumed for the present purposes that, if the agreement is ever actually acted upon, the parties will act in accordance with the law.

78 Pursuant to the terms of the contract as it stands, Apotex is simply permitted to direct Novopharm to the third party manufacturer which it favours and with whom it has negotiated terms, which would then oblige Novopharm to deal with that manufacturer and acquire the patented medicine on the terms negotiated. Despite this considerable degree of control by Apotex, it remains the case that separate entities are involved, that Apotex is in no way ultimately responsible for the supply of the goods that Novopharm will eventually sell to it, and that a legitimate and *de facto* transfer of property must occur between Novopharm and the third party before any proprietary rights can be acquired by Apotex. Therefore, only if Apotex's designation of a preferred

source or manufacturer would necessarily render it a sublicensee of Novopharm would the agreement between the two companies amount to a breach of the terms of the compulsory licence. Since it is possible for Apotex to exercise this contractual right without the benefit of licensed rights transferred to it by Novopharm, it would be incorrect to say that the supply agreement necessarily infringes the licence.

79 As I have already made clear, Apotex enjoys no rights of its own under the licence as a consequence of the supply agreement with Novopharm, regardless of the parties' apparent intention to "share their rights". At bottom, the agreement amounts to nothing more than an agreement to agree, a mutual obligation for the parties to enter into future contractual arrangements with one another. Neither the text of the agreement nor the manner in which the parties purported to implement it supports the conclusion that it is in substance a sublicence.

(4) The Agency Argument

80 In the alternative, Eli Lilly submitted that the supply agreement ought to be interpreted as a sublicence because the degree of control likely to be exercised by Apotex over the acquisition of nizatidine would result in a situation where Novopharm in reality would be acting as Apotex's agent. Novopharm would not be acting on its own behalf in the acquisition but rather on behalf of Apotex, which would imply that Apotex has acquired licensed rights from Novopharm. As a variation on this theme, it is suggested that Novopharm would in effect be unlicensed to make these acquisitions because it would be standing in the shoes of Apotex, an unlicensed entity. The latter submission, then, stands as an alternative to the sublicence argument, and remains even if the supply agreement is not considered a sublicence.

81 To my mind, both forms of this argument must fail, for one very simple reason. It is abundantly clear that, under the supply agreement, any contractual relations that might be established for the purchase of nizatidine would be between Novopharm and the third-party supplier. Apotex would not be a party to the contract; Novopharm would not be entering into the contract "on behalf of" Apotex in any sense. The notion of an agent's entering into contractual relations with the third party is inimical to the entire concept of agency, which contemplates the agent's binding the principal, not itself, to contractual relations and obligations. The completion of a contract between Novopharm and a third-party supplier would prevent the formation of an agency relationship because, even if contemplated, such a relationship could not be embodied by a transaction which resulted in the completion of a contract between the third party and the agent rather than the principal.

(5) Conclusion as to the Nature of the Supply Agreement

82 The arrangement entered into by Apotex and Novopharm is not a sublicence. Regardless of the level of control that might be exercised by Apotex over arranging and facilitating the acquisition of licensed materials for its own benefit, no actual acquisition is itself possible without the involvement of Novopharm. The agreement does not grant Apotex the right to do independently of Novopharm anything which only Novopharm is licensed to do, nor does it purport or disclose any contractual intent to do so. In other words, no licensed rights are transferred by Novopharm to Apotex. Thus, the substance of the arrangement, while perhaps resulting in an unconventional commercial situation, is ultimately inconsistent with the grant of a sublicence. To the extent that the Federal Court of Appeal held otherwise, it was, with respect, in error.

83 That is not to say, however, that it would be impossible to implement the agreement in such a manner as to create a sublicence. For example, while I need not decide this hypothetical issue, I would again observe that, if the domestic supplier from which Apotex directed Novopharm to obtain the nizatidine were found to be Apotex itself, the agreement would likely be seen as a sham, just as in *du Pont, supra.* Similarly, if Novopharm were to be less than vigilant in enforcing the terms of the agreement and permit Apotex to contract directly with a third party supplier for the purchase of nizatidine, this relaxation of terms might well be shown to result in the effective conferral of a sublicence. But these are hypotheticals, not our facts. Indeed, there can be no possible evidence in this case of the manner in which the agreement was implemented by the parties because, at the time of the hearing, it had not been implemented at all. On the other hand, if the agreement has subsequently been implemented so as to create a sublicence, or if it is so implemented in the future, it would certainly then be open to the patentee to move to terminate the compulsory licence or to seek whatever other relief might be appropriate under the *Patent Act* or otherwise. However, this has no bearing on the justification of the NOAs here at issue.

84 Accordingly, I would emphasize that the conclusions reached in this case should not be taken to characterize every supply agreement similar to the one here at issue as insulating the parties to it from any allegation of sublicensing. Rather, this decision is to be substantially confined to its facts: a case in which an agreement has been entered into between companies dealing at arm's length, which is not on its face a sublicence, and which had not been implemented at any time material to the litigation. Depending on the implementation of the agreement, the identities of the parties, or any

number of other distinguishing factors, it is entirely possible that a different result might be reached on the specific facts of another case.

B. *Other Issues in the Novopharm Appeal*

(1) Did the Federal Court of Appeal Err in Applying its Decision in *Apotex #1* to its Decision in *Novopharm*?

85 Novopharm submits that, even if the supply agreement were properly interpreted by the Federal Court of Appeal as conferring a sublicence upon Apotex, it nonetheless should not be considered a sublicence for the purposes of the *Novopharm* appeal. The reason advanced for this distinction is that nothing on the face of the agreement can be seen as constituting a sublicence, and, whereas the conclusion of the court in *Apotex #1* may have been premised in part on Dr. Sherman's evidence as to the manner in which Apotex expected the agreement to be implemented, no steps had actually been taken to implement the agreement. Thus, it is argued that, while it might have been open to the court to grant the requested prohibition order in *Apotex #1* if Dr. Sherman's proposed implementation would have resulted in the conferral of a sublicence, this evidence was not before the court in *Novopharm* and, in fact, was inconsistent with Mr. Dan's evidence as to his understanding of the agreement. To the extent that the Federal Court of Appeal failed to take into consideration this material evidentiary difference, it is suggested, this constituted an error of law.

86 It is certainly true that each case must be considered on its own facts, and I have already expressed the view that the implementation of the agreement in a certain way might well result, hypothetically, in the creation of a sublicence. As such, I agree that it would have been inappropriate for the Federal Court of Appeal to apply its

decision in the first appeal to the second, whether as *res judicata* or otherwise, without considering any material factual differences which might have existed between the two cases. However, in light of my earlier conclusion as to the character of the supply agreement, together with the fact that the agreement had not been implemented at the material time, it is not necessary to decide this issue. None of the parol evidence considered by the Federal Court of Appeal has had any bearing on the conclusions I have reached.

(2) Was Novopharm's Notice of Allegation Premature and Therefore not Justified?

87 Even the unequivocal conclusion as to the character of the supply agreement does not put the *Novopharm* matter to rest. Still to be determined is whether, as alleged by Eli Lilly, Novopharm's NOA was not justified regardless of whether its compulsory licence for nizatidine was successfully terminated.

88 Pursuant to s. 39.11(2)(*c*) of the *Patent Act*, Novopharm was prohibited from importing, under its compulsory licence, medicine in respect of which a previous NOC had been granted after June 27, 1986, until 10 years after the date of the issuance of that NOC. While this section was repealed by the *Patent Act Amendment Act, 1992*, s. 11(1) of that Act provides that licences granted under the former s. 39 prior to December 20, 1991, continue in effect according to their terms, and ss. 39 to 39.14 of the former Act continue to apply to such licences as if those sections had not been repealed.

89 A NOC in respect of nizatidine was granted to Eli Lilly Canada on December 31, 1987. Accordingly, it is submitted by Eli Lilly that Novopharm's NOA, which was issued on July 30, 1993, could not have been justified before December 31, 1997, the

first date on which it would have been entitled, under its compulsory licence, to import nizatidine. Thus, Eli Lilly argues that, even if no sublicence was granted and the termination of Novopharm's licence was not therefore justified, Novopharm would nonetheless have infringed Eli Lilly's patents if it had received a NOC for nizatidine, as it had no non-infringing way in which to obtain the bulk medicine.

90 However, this submission appears to ignore the fact that Novopharm's NOA does not seem to disclose any specific intention to import the nizatidine. Rather, the request was for a NOC to make, construct, use, and/or sell nizatidine in 150 mg and 300 mg capsules. No mention was made of how Novopharm proposed to obtain the bulk medicine, and no evidence was led to suggest that it was to be imported. Indeed, while Mr. Dan acknowledged in his written answers to undertakings on cross-examination that, at the time of the hearing, Novopharm's suppliers were located outside of Canada, he also indicated that Novopharm was aware of the prohibition against its importing nizatidine before December 31, 1997, and intended to abide by the relevant provisions of the *Patent Act*. Further, he indicated that Novopharm might locate a Canadian supplier between December 31, 1994, and December 31, 1997, and expressly disavowed any intention to import nizatidine prior to the latter date.

91 Pursuant to s. 39.14 of the *Patent Act*, Novopharm was entitled to use the patented invention for the preparation or production of medicine -- that is, to manufacture the medicine itself or through Canadian agents -- after the expiration of seven years after the date of the issue of the first NOC to Eli Lilly Canada. This seven-year period expired on December 31, 1994, and while Novopharm served its NOA on Eli Lilly Canada on July 30, 1993, the application was not heard until January 30, 1995.

Thus, as of the date of hearing, Novopharm was entitled to manufacture or have made the drug for its own use, for sale for consumption in Canada.

92 In *Apotex #2*, *supra*, the companion to the instant appeals, I have held that the appropriate date for assessment of a NOA, where a prohibition order is sought by a patentee, is the date of hearing and not the date on which the NOA was issued. Accordingly, I cannot conclude that Novopharm's NOA was premature and therefore not justified. As of the date of hearing, it did indeed have a non-infringing way to obtain bulk nizatidine, and, in the absence of evidence to the contrary, I presume that its intention was, as Mr. Dan asserted, to operate within the restrictions of the *Patent Act* by obtaining the medicine either from a Canadian supplier or not at all.

(3) Jurisdiction to Grant Declaratory Relief

93 The final issue to be determined with respect to the *Novopharm* appeal is whether this Court has the jurisdiction, on a summary judicial review proceeding concerning an application for a prohibition order against the issuance of a NOC, to grant declaratory relief. Specifically, Novopharm asks that this Court declare: (1) that Eli Lilly has failed to show that the notice of allegation was not justified; (2) that Eli Lilly has failed to show that it was entitled to terminate the compulsory licence; and (3) that the supply agreement does not constitute a sublicence or a transfer of the compulsory licence from Novopharm to Apotex.

94 In my view, the first two requests are unnecessary. The finding that the supply agreement was not a sublicence necessarily leads to the conclusion, at least for the purposes of this appeal, that Eli Lilly was not entitled to terminate Novopharm's

compulsory licence. Indeed, no other breach was alleged, such as to trigger paragraph 9 of the licence. Similarly, this finding, in combination with the finding that Novopharm's NOA was not premature, leads to the conclusion that Eli Lilly has failed to show that the NOA was not justified. I can see no reason to grant what would be superfluous declaratory relief on these issues, when all that is necessary is to determine whether or not the Federal Court of Appeal erred by granting the prohibition orders as requested.

95 As for the third request, I am of the view that it would be inappropriate for this Court to grant the requested relief in light of the nature of these proceedings. As McGillis J. correctly observed, the summary judicial review that is to be conducted on an application for a prohibition order under the Regulations is highly fact-specific and is generally considered to be binding only on the parties in the specific litigation. This is only appropriate, given the limited nature of the proceedings, the question that is to be answered, and the record generated for this limited purpose. In *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)* (1994), 55 C.P.R. (3d) 302 (F.C.A.), at pp. 319-20, Hugessen J.A. made this point in the following terms, with which I agree:

> In determining whether or not the allegations are "justified" (s. 6(2)), the court must then decide whether, on the basis of such facts as have been assumed or proven, the allegations would give rise in law to the conclusion that the patent would not be infringed by the respondent.
>
> In this connection, it may be noted that, while s. 7(2)(*b*) seems to envisage the court making a declaration of invalidity or non-infringement, it is clear to me that such declaration could not be given in the course of the s. 6 proceedings themselves. 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. [Emphasis added.]

96 This point was reinforced more recently by Strayer J.A. in *David Bull Laboratories, supra*, at p. 600:

> 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 their 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. [Emphasis added.]

97 While the relief requested of the Federal Court of Appeal in these cases touched on issues pertaining to the infringement and/or invalidity of the actual patents, not the effect of an external agreement, I believe that the reasoning involved is also applicable to the *Novopharm* appeal. The nature of the inquiry on this judicial review proceeding requires only a determination as to whether or not the NOA was justified in the circumstances of this case. While this necessarily entails a decision as to whether, in these particular circumstances, the supply agreement constituted a sublicence and thus justified the termination of the licence, this is not to be taken as a final decision on the nature of the agreement for all purposes. For this Court to make a binding declaration concerning the private rights and obligations of the parties to the agreement would go well beyond the limited scope of the proceeding. Accordingly, I would deny the declaratory relief requested by Novopharm.

C. *Other Issues in the Apotex #1 Appeal*

(1) Would the Reformulation of Nizatidine by Apotex into Final-dosage Form Infringe the Patent Held by Eli Lilly?

98 Even assuming that the supply agreement did not constitute a sublicence, that Novopharm's licence remains in force, and that Apotex is therefore able to purchase bulk nizatidine under the supply agreement as a third-party purchaser, the possibility remains that the use to which Apotex proposes, in its NOA, to put the drug would infringe Eli Lilly's patent. In this vein, Eli Lilly submits that the Federal Court of Appeal erred in holding that the formulation of final-dosage capsules by Apotex would not infringe the patent. Specifically, it is submitted that the rights of use and sale that are inherent in the unrestricted purchase of a licensed article do not permit the making of a new article.

99 In the Federal Court of Appeal, Pratte J.A., with whom the majority agreed on this point, disposed of this argument in the following concise and useful passage, at p. 343 with which I agree:

> If a patentee makes a patented article, he has, in addition to his monopoly, the ownership of that article. And the ownership of a thing involves, as everybody knows, "the right to possess and use the thing, the right to its produce and accession, and the right to destroy, encumber or alienate it".... If the patentee sells the patented article that he made, he transfers the ownership of that article to the purchaser. This means that, henceforth, the patentee no longer has any right with respect to the article which now belongs to the purchaser who, as the new owner, has the exclusive right to possess, use, enjoy, destroy or alienate it. It follows that, by selling the patented article that he made, the patentee impliedly renounces, with respect to that article, to [*sic*] his exclusive right under the patent of using and selling the invention. After the sale, therefore, the purchaser may do what

> he likes with the patented article without fear of infringing his vendor's patent.
>
> The same principles obviously apply when a patented article is sold by a licensee who, under his licence, is authorized to sell without restrictions. It follows that, if Apotex were to purchase bulk Nizatidine manufactured or imported by Novopharm under its licence, Apotex could, without infringing Lilly's patents, make capsules from that substance or use it in any other possible way. [Emphasis added.]

100 Perhaps the principles underlying this well-founded statement of the law merit some brief elaboration at this stage. As I have already noted in connection with the distinction between a sublicence and an ordinary agreement of purchase and sale of a patented or licensed article, the sale of a patented article is presumed to give the purchaser the right "to use or sell or deal with the goods as the purchaser pleases": see *Badische Anilin und Soda Fabrik v. Isler*, *supra*, at p. 610. Unless otherwise stipulated in the licence to sell a patented article, the licensee is thus able to pass to purchasers the right to use or resell the article without fear of infringing the patent. Further, any limitation imposed upon a licensee which is intended to affect the rights of subsequent purchasers must be clearly and unambiguously expressed; restrictive conditions imposed by a patentee on a purchaser or licensee do not run with the goods unless they are brought to the attention of the purchaser at the time of their acquisition: see *National Phonograph Co. of Australia, Ltd. v. Menck*, [1911] A.C. 336 (P.C.).

101 Therefore, it is clear that, in the absence of express conditions to the contrary, a purchaser of a licensed article is entitled to deal with the article as he sees fit, so long as such dealings do not infringe the rights conferred by the patent. On this score, Eli Lilly alleges that the reformulation of nizatidine would in this case exceed the scope of the rights obtained by the purchaser because it would constitute not simply the resale of the material purchased, but rather, the creation of a new article in violation of Eli

Lilly's patent. However, I can find no basis, either in the evidence or in the case law cited by Eli Lilly, for this submission. In my view, the reformulation of nizatidine into final-dosage form does not have the effect of creating a new article. Rather, it is more akin to repackaging the substance into a commercially usable form, which I do not view as violating any rights under the patents.

102 No specific evidence was led in the instant appeal concerning the nature of the process by which bulk medicine is reformulated into final-dosage form. However, in *Merck & Co. v. Apotex Inc.*, *supra*, at p. 155, MacKay J. offered a useful summary of the process. While it is possible that the process employed in the reformulation of nizatidine may differ slightly from the reformulation of the medicine at issue in that case, namely enalapril maleate, the gist of MacKay J.'s description is nonetheless apposite: the basic patented compound at issue, that is, the bulk medicine produced by the patentee or licensee, remains unchanged throughout the reformulation process. It exists in the same chemical form in the final-dosage product as in the bulk product. However, the two products are substantially different, in that the bulk form is essentially a powder without other form or shape, while the final-dosage form is a coloured tablet, consisting of the bulk medicine and other ingredients and shaped in a form associated with a particular dosage. Indeed, in the view of MacKay J., the process so described was such a significant transformation that the final-dosage form of enalapril maleate sold by Apotex was not protected by s. 56 of the *Patent Act*, which authorizes the use and sale of a "specific" patented article by a party who purchased, constructed, or acquired the article before the patent application became open to the inspection of the public. In other words, MacKay J. was unwilling to accept that the final-dosage form was the same "specific article" as the bulk enalapril maleate purchased by Apotex prior to the date on which Merck's patent application became open for inspection.

103 However, this conclusion was rejected by the Federal Court of Appeal, in a judgment reported at [1995] 2 F.C. 723. At p. 738, MacGuigan J.A., writing for a unanimous court, expressed the view that "the right to use or sell the 'specific article, etc.' is independent of the form in which the invention is purchased: any form of the invention may be used or sold within the immunity conferred by s. 56" (emphasis in original). In so holding, MacGuigan J.A. relied on the following statement of Hall J. in *Libbey-Owens-Ford Glass Co. v. Ford Motor Co. of Canada, Ltd.*, [1970] S.C.R. 833, at p. 839, affirming the judgment of Thurlow J. (as he then was) in the court below (reported at [1969] 1 Ex. C.R. 529):

> The question in this case is with respect to the extent of the meaning of "using" and it arises because with respect to "vending" the right of the owner of the specific machine or other thing is expressed as that of vending it, not as that of vending its output. However, it is obvious that in the case of a machine designed for the production of goods, there would really be no worthwhile protection allowed by s. 58 [now s. 56] if the owner could not put it to the only use for which it is usable without being liable for infringement. [Emphasis added.]

104 Accordingly, MacGuigan J.A. concluded, at p. 741, that:

> The use and sale of the product of a machine, particularly if production is the only possible use of the machine, is accorded protection under section 56 as a use of the machine itself. . . . In my view, use must be given the same sense in the case of a chemical invention. [Emphasis added.]

105 The *Merck & Co. v. Apotex Inc.* decision highlights the fact that there is really no commercial use for bulk medicine other than its reformulation into final-dosage form, for consumption by the ultimate consumer. In order to realize any utility from the acquisition, then, the purchaser must take steps to convert it into this commercially

usable form. In my view, MacGuigan J.A.'s conclusion that the right to use and sell an article includes the right to use and sell things produced with the article, though reached in the specific context of a s. 56 defence, applies with equal force to the case at bar. That is, the right of use and sale which Apotex would acquire inherently, through its acquisition of nizatidine from Novopharm, must be seen as encompassing the right to use and sell things produced with this nizatidine, including capsules in final-dosage form. It follows, therefore, that Apotex would not infringe the patents held by Eli Lilly simply by selling the medicine in the form contemplated by the NOA. This is particularly so when, as in the case at bar, the exclusive rights enjoyed by the patentee under the patent are limited, in essence, to the formulation of bulk medicine according to the patented process. Nothing in the reformulation process can be seen as infringing upon this right.

106 Any doubt as to this conclusion of non-infringement must, in my view, be eliminated by an examination of Novopharm's compulsory licence, which specifically contemplates the sale of the licensed material in bulk form by providing a formula for calculating royalties on product thus sold. As I see it, because there is no other practical use for bulk medicine, this must also be taken to contemplate and implicitly permit the reformulation of the product by the purchaser into final-dosage form. This conclusion is only reinforced, in my view, by the fact that the contemplated royalty rates are based on the amounts received by subsequent purchasers in consideration of the sale of final-dosage forms to the retail trade. Had the Commissioner of Patents intended to restrain such use of the medication, he would have provided for this expressly, or, at least, would not have specifically delineated the procedure that is to compensate the patentee for such use.

107 Therefore, Eli Lilly is incorrect to assert that the reformulation proposed by Apotex would either have to be carried out pursuant to a sublicence granted by Novopharm, which would justify the termination of Novopharm's compulsory licence and, therefore, the sublicence, or would be entirely unauthorized and infringe Eli Lilly's patents. The better view, as I have stated, is that the right to reformulate is premised on the inherent right of an owner of property to deal with that property as he or she sees fit. In the absence of some express term in the compulsory licence, prohibiting purchasers of bulk nizatidine from Novopharm from reformulating it into final-dosage form, the weight of the case law supports the view that Apotex, having validly acquired the bulk medicine, would be free to reformulate it for resale without fear of infringing any right under Eli Lilly's patents.

108 I would emphasize, however, that this conclusion is in no way premised upon, and should not be taken to have any bearing on, the well-established rules concerning the acceptable limits on the repair of a patented article: see, for example, *Rucker Co. v. Gavel's Vulcanizing Ltd.* (1985), 7 C.P.R. (3d) 294 (F.C.T.D.). Here, we are not considering the repair of a patented article, but its resale in a somewhat different form. I would also add that I am unconvinced by the authorities cited by Eli Lilly in support of the proposition that the rights of the purchaser do not include the right to reformulate.

109 In light of the foregoing, I am in agreement with Pratte J.A. and the majority of the Federal Court of Appeal, and conclude that the reformulation of the bulk nizatidine into final-dosage form would not infringe Eli Lilly's patent. Accordingly, I conclude that Eli Lilly has failed in its various efforts to establish that Apotex's NOA was not justified and that a prohibition order should thus be issued.

VI. Disposition

A. *Novopharm Ltd. v. Eli Lilly and Co.*

110 For the foregoing reasons, I would allow the appeal, set aside the judgment of the Federal Court of Appeal, and restore the judgment of the Federal Court--Trial Division, with costs to the appellant throughout. However, I would deny the appellant's request for declaratory relief.

B. *Apotex Inc. v. Eli Lilly and Co.*

111 Also for the foregoing reasons, and after a full consideration of the factual differences existing between the two appeals considered herein, I would allow the appeal, set aside the judgment of the Federal Court of Appeal, and dismiss the application for an order of prohibition. The appellant shall have its costs throughout.

Appeals allowed with costs.

Solicitors for the appellant Apotex Inc.: Goodman, Phillips & Vineberg, Toronto.

Solicitors for the appellant Novopharm Limited: Ridout & Maybee, Toronto.

Solicitors for the respondents Eli Lilly and Company and Eli Lilly Canada Inc.: Gowling, Strathy & Henderson, Ottawa.