Federal Court of Canada
Trial Division

Section de première instance de
la Cour fédérale du Canada

T-1273-97

OCT 23 1997

Between:

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MERCK FROSST CANADA INC.
- and -
MERCK & CO., INC.,

Applicants

-and-

THE MINISTER OF HEALTH,
THE ATTORNEY GENERAL FOR CANADA,
APOTEX INC.,
and APOTEX FERMENTATION INC.

Respondents

REASONS FOR ORDER

MACKAY J.:

These Reasons concern my disposition of four motions set down for hearing in Ottawa on September 25, 1997. Then a motion was heard on behalf of the respondents Apotex Inc. and Apotex Fermentation Inc. (hereinafter collectively referred to as "Apotex"), pursuant to s-s. 18.4(2) of the *Federal Court Act*, R.S.C. 1985, c. F-7, as amended (the" *Act*"), that this proceeding be treated and proceeded with as an action, and that it be joined or otherwise heard with an action initiated by the applicants against the respondents Apotex in Court file T-1272-97. Also heard that day was a motion filed September 19, 1997 by the applicants Merck Frosst Canada Inc. and Merck & Co. Inc. (hereinafter collectively referred to as "Merck"), for leave to file an amended originating notice of motion in this proceeding.

Two other motions before the Court that day, on behalf of the applicants Merck seeking orders to compel Mary Elizabeth Carman, and Dr. Bernard

Sherman, respectively, to re-attend for further cross-examinations and to provide answers to questions earlier objected to or refused arising from affidavits filed, were not heard on September 25 and orders now issue that these motions be adjourned. I note that all parties consider that these two motions may be dealt with at a case management conference scheduled for October 6, 1997 to consider issues arising in preparation for hearing of this matter (T-1273-97) and those arising in interlocutory injunction proceedings and in the action in Court file T-1272-97. The orders adjourning these motions indicate they are returnable on October 6 with the approval of the presiding judge.

I turn to the motions heard and now dealt with, after a brief overview of the background to provide the context of these proceedings.

The background

Apotex Inc. was granted a Notice of Compliance (NOC) under the *Food and Drug Regulations,* C.R.C., c.870, by the respondent Minister of Health in relation to Apo-lovastatin tablets on March 26, 1997. That drug product is a generic version of the Merck lovastatin medicine sold in Canada under the trade-mark MEVACOR® for which Merck had earlier obtained an NOC in 1988 for treatment of elevated levels of cholesterol, and subsequent NOC's for other treatments.

The NOC was granted to Apotex after the Court had dismissed an application by Merck for an order of prohibition under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the "*Regulations*"). The decision of my colleague Mr. Justice Rothstein, dated March 26, 1997, (Court file T-1305-93) was made following expiry of the 30 month statutory stay under s.7 of the *Regulations*. In accord with those *Regulations* Apotex had applied for an NOC and by notice of allegation had advised Merck that Apotex' generic product

would not infringe Merck's patents in relation to its lovastatin product. Apotex had later issued a second notice of allegation, in relation to its application for an NOC, which led to a second application for a prohibition order by Merck under the *Regulations*, but Apotex subsequently withdrew the second notice of allegation in February 1997.

From subsequent inquiries, through access to information requests, and by requests to the Ministry of Health, it appeared to Merck that the product monograph for Apo-lovastatin, approved with Apotex' NOC on March 26, 1997, referred to the Apotex product utilizing a microorganism, *Aspergillus obscurus*, which is said by Merck to be essentially the same as that which is the subject of Merck's patents. Thereafter, the Health Department advised that the product monograph for Apo-lovastatin was in error, since the process by which the product was produced, at the time of the grant of the NOC, was one that utilized another microorganism, *Coniothyrium fuckelii*. The department indicated an amended product monograph would be issued correctly identifying the microorganism used by Apotex. On July 11, 1997 after this proceeding had commenced the Minister issued a letter to Apotex enclosing a new cover page and page 1 for the product monograph earlier approved, correcting what were considered clerical errors.

On June 12, 1997, the applicants Merck filed a statement of claim alleging infringement of their patents, for their lovastatin product, by Apotex in its production and sale of Apo-lovastatin. In that action (T-1272-97) the respondents Apotex are defendants. In that action Merck seeks various declaratory orders concerning infringement by Apotex, concerning the validity of Merck's patents, concerning unfair competition and passing off by Apotex, and also a permanent injunction against the defendants, delivery up of infringing product, damages or an accounting of profits, punitive damages, costs and interest. All forms of relief sought are directed against the defendants Apotex, and the Minister and the

Attorney General, respondents in this proceeding, are not joined as parties or intervenors in the action.

On the same day, June 12, 1997, this proceeding by originating notice of motion was filed by the applicants Merck against the respondent Ministers, and Apotex respondents were subsequently joined as parties. The application as filed seeks judicial review of the decision of the Minister of Health made on March 26, 1997 to issue the NOC to Apotex in respect of its Apo-lovastatin product. The application seeks four interim and interlocutory orders against the Minister of Health, directing, until final determination of this application, that the Minister revoke or suspend the NOC issued March 26, 1997 to Apotex, and also an order prohibiting him from issuing a new or amended NOC to Apotex for lovastatin until the Minister requires Apotex to file a new submission for that product and Apotex has sent a new notice of allegation to Merck in respect of lovastatin in accord with the *Regulations*. An order prohibiting review of any further or amended submission of Apotex until it has filed a new submission and complies with the *Regulations* is also sought, as is a permanent order revoking or suspending the NOC granted March 26, 1997, presumably after hearing of this application. Generally similar interim relief but directed to the Apotex corporations was sought by Merck in its action in T-1272-97 and by motion. Merck sought, in both this application and in its action, interim injunctive relief. That was denied by my colleague Mr. Justice Dubé, by Orders dated July 2, 1997.

Affidavits were filed, three by Merck in support of its application, one on behalf of the respondent Minister of Health by Mary Elizabeth Carman, Director of the Bureau of Pharmaceutical Assessment of the Therapeutic Products Directorate of Health Canada, and two on behalf of Apotex Inc. by Dr. Bernard Sherman, Chairman of that corporation. Apparently in the course of cross-examination of Ms. Carman, responses to questions and to requests for production

of documents were extensive, and the Department of Health was prepared to be open and frank in its disclosure of matters related to the decision of March 26, here in question. From that and from cross-examination of Dr. Sherman on his affidavit, the Merck applicants believe there are additional facts which would strengthen their case. That development, and the form of their initial originating notice of motion, which, under grounds for the application, sets out a detailed statement of allegations of fact upon which Merck applicants rely, led Merck to move for leave to amend the originating notice of motion. The draft of the amendments proposed and Merck's applications, filed at the same time, for orders for the affiants Ms. Carman and Dr. Sherman to re-attend and answer further questions earlier refused or objected to, led to the respondents Apotex' motion to convert these proceedings to an action. Two days after that motion was filed and the day before this application was heard, Merck filed an amended statement of claim in the action in file T-1272-97, as they were entitled to do, no defence having yet been filed by Apotex. Those amendments delete from the statement of claim, references in the earlier version which duplicated, or at least reflected, some of the matters dealt with in this application for judicial review.

Apotex' motion that this proceeding be treated as an action

On behalf of Apotex the Court is asked to order that this application proceed as an action. Section 18.4 of the *Act* provides as follows:

> 18.4(1) Subject to subsection (2), an application or reference to the Trial Division under any of sections 18.1 to 18.3 shall be heard and determined without delay and in a summary way.
>
> (2) The Trial Division may, if it considers it appropriate, direct that an application for judicial review be treated and proceeded with as an action.

It is urged that factual matters raised by this proceeding cannot be established satisfactorily by affidavit evidence, that the complexity and nature of this proceeding does not accord with the purposes and expeditious nature of judicial review proceedings, and further that the Merck action against the Apotex corporations concerning alleged infringement also raises as issues matters raised

in this application. Those arguments arise in substantial part from the perceptions of counsel for Apotex that their counterparts for Merck treat these proceedings as an action. Those perceptions arise from the form of the originating notice of motion and Merck's approach to cross-examination on affidavits which is said to be akin to the process of discovery in an action. The perceptions of counsel for Apotex are said to be reinforced by the motions on behalf of the Merck applicants which were before the Court, for leave to file an amended originating notice of motion and to direct affiants to re-attend for further examination, purportedly on their affidavits.

The arguments of Apotex arise also without regard to the amended statement of claim in the action in Court file T-1272-97, which was filed late on the day before these motions were heard. The changes introduced in the amended statement of claim, in substantial part, appear to deal with provisions in the original version which Apotex had already proposed, by motion, not yet heard, should be struck out. Whether or not the changes introduced are a response to Apotex' earlier objections, they do substantially eliminate any serious claim that the action relates to matters arising in this proceeding. It is true the issue in this proceeding, i.e., the lawfulness of the Minister's decision to issue the NOC to Apotex on March 26, 1997, may appear at first glance to have some significance for the action in T-1272-97, but that decision, whether lawful or not, has no real relevance for the issues concerning alleged infringement of Merck patent interests or alleged unfair practices by Apotex.

In my opinion, in view of the amended statement of claim, it is no longer arguable that evidence of key matters raised in this application is similar to evidence on key matters raised in the action by Merck, even if the two proceedings arise from the same history.

As for Apotex' submissions that this proceeding is not properly a matter for judicial review, so far as these are based on perceptions of Merck's approach to this proceeding as though it were an action, these perceptions do not provide a basis for treating this application as an action. It is true the form of the originating notice of motion is unusual, both in the original and in the proposed amended versions. Grounds for the application in both versions include some 80 paragraphs setting out detailed allegations of fact and of error, as perceived by the Merck applicants, much like the detailed pleading in a thorough statement of claim, and the allegations originally made, Merck now proposes, would be amended in light of alleged facts learned from affidavits and cross-examination upon them since this proceeding commenced. Counsel for Merck may or may not treat cross-examination on affidavits as though it were discovery in an action. In an application for judicial review where evidence is offered by affidavit, cross-examination is not discovery. Counsel for the respondents can prevent their witnesses from being discovered, other than by appropriate cross-examination on matters relevant to the issue in the originating notice of motion or otherwise arising from affidavits.

Apotex urges the applicants Merck cannot present the record before the Minister at the time of his decision and, absent that record, it is inappropriate to proceed by judicial review. With respect, I believe this misunderstands "the record". The record before the Minister is one that he can establish pursuant to Rule 1613, with any necessary explanation by means of affidavit evidence. The application record that the Merck applicants must file in accord with the rules may comprise affidavits in support of their position, and perhaps transcripts of relevant cross-examinations of the respondents' affiants. Some of the record before the Minister at the time of his decision may well be in the exhibits with the applicants' affidavits, but not necessarily all of it.

Finally, Apotex urges that allegations of Merck, about actions of Apotex Inc. and of Apotex Fermentation Inc. and about alleged errors on the part of the Minister or his staff, raise serious issues, even suggestions of fraud. It is urged that the Court, in dealing with issues raised in this application, will be required to determine whether the Apotex product in question is produced in accord with the process disclosed by Apotex in its application for an NOC and as approved by the Minister. It is urged that would involve issues of credibility and expert evidence in complex scientific fields, issues only satisfactorily dealt with at a trial with witnesses subject to cross-examination. I am not persuaded that the Court, in considering whether the Minister has acted lawfully, within the terms of s-s. 18.1(4) of the *Act*, does have to consider the serious, and somewhat complex questions suggested. Nor, in my opinion, is this a case where the need for opportunity to cross-examine witnesses in open court, as in an action, is required for purposes of the issue that this proceeding raises. Thus, for example, the desire of parties to respond to perceptions that they are maligned by allegations of the applicants, as Apotex Fermentation here urges, does not warrant conversion of these proceedings to an action. That opportunity is not important for this proceeding for the matters of concern to that party are not central to the relatively narrow issue of whether the Minister acted within his lawful discretion in granting the NOC to Apotex. The same may be said of any concern the Minister may have in regard to allegations about alleged errors in decision-making, for those will ultimately be resolved on the facts, that can readily be set out in one or more affidavits, and on the applicable law.

I add one comment, which arises more directly in relation to Merck's motion for leave to file the amended originating notice of motion, that is, that this application for judicial review will be directed to consideration of the decision of the Minister on March 26, 1997 to issue the NOC. It will not be directed to detailed review of the entire process of consideration by the Minister's department

of Apotex' submissions in relation to Apo-lovastatin from 1993 to 1997, except so far as events and documents prior to the grant of the NOC may be relevant, under the applicable regulations and practices of the department, as essential bases for the Minister's decision here in question.

In *Del Zotto* v. *Minister of National Revenue et al.* (1995), 103 F.T.R. 150 at 157, (reversed on other grounds, (1996) 195 N.R. 74, 96 D.T.C. 6222 (F.C.A.)), my colleague Mr. Justice McKeown reviewed recent Court of Appeal decisions concerning conversion of a judicial review proceeding into an action, referring in particular to *Drapeau* v. *Canada (Minister of National Defence)* (1995), 179 N.R. 398 (F.C.A.) and *MacInnis* v. *Canada (Attorney General) et al.*, [1994] 2 F.C. 464; 166 N.R. 57; 113 D.L.R. (4th) 529, 25 Admin. L.R. (2d) 294 (F.C.A.). Among factors to be considered, as McKeown J. noted, are:

> ...(1) the undesirability of multiple proceedings; (2) the desirability of avoiding unnecessary costs and delays; (3) whether the particular issues involved require an assessment of demeanour and credibility of witnesses; and (4) the need for the court to have a full grasp of all the evidence.

While argument for Apotex relates in part to avoidance of multiple proceedings, I note that these proceedings are directed to relief against the respondent Minister, while the action by Merck, as the amended statement of claim clarifies, is directed to relief against the respondents Apotex Inc. and Apotex Fermentation Inc. Two proceedings primarily against different parties, for quite different forms of relief, are not readily facilitated, in my view, by converting this application for judicial review to an action, even if then it follows that the two actions be dealt with together.

Among other factors raised in this case is concern on behalf of the respondent Minister of Health that the issue raised by the application for judicial review be resolved as quickly as possible. Finally, the applicants, who commenced these proceedings to question the Minister's decision are opposed to

converting the proceedings. They believe this process has a reasonable prospect of relatively quick resolution. An action, however expedited, is likely to take considerably longer to resolve, particularly if it be ordered to be treated with the action in Court file T-1272-97 where the issues of infringement and unfair competition will require substantial time for preparation, and for hearing.

In my opinion, in light of all the factors raised that seem to me relevant, I am not persuaded that this proceeding should be ordered to be treated and to proceed as an action. To do so, particularly when that is opposed by the applicant, would require special reasons, none of which are here persuasive. Thus, an order goes dismissing the application by the respondents Apotex.

The motion for leave to amend the originating notice of motion

The motion of the applicants Merck seeks leave to file an amended originating notice of motion. The changes sought to be introduced are:

1) to the orders sought as relief in this proceeding by
   a) striking references to interim and interlocutory orders originally requested, now that the request for interim relief has been dismissed,
   b) adding a request for an order revoking or suspending the decision of the Minister of July 11, 1997 modifying the NOC earlier issued,
   c) adding precision to the request earlier made for an order of prohibition precluding the grant of an NOC to Apotex for lovastatin until Apotex files a new submission and again goes through the entire process for approval,
   d) an order for costs against the respondents on a solicitor and client basis.

2) to the detailed statement of facts alleged in the body of the originating notice of motion, additional allegations of fact said by Merck to arise from the affidavits filed by Ms. Carman for the

Minister of Health and by Dr. Sherman on behalf of Apotex and from cross-examination on those affidavits.

An amendment of an originating notice of motion may be allowed, in the discretion of the Court, where that will assist in determining the real issues between the parties and where it will not be prejudicial to the party or parties seeking relief. (See *SNC-Lavalin Inc.* v. *Canada (Minister of Public Works)* (1994), 79 F.T.R. 113 at 122; *Pfizer Canada Inc.* v. *Apotex Inc. et al.*, [1997] F.C.J. No. 1023 (July 25, 1997, Court file T-422-96) (F.C.T.D.). Where a proposed amendment is unnecessary or inappropriate, leave to amend has been refused (*Eli Lilly & Co.* v. *Novopharm Ltd.* (1994), 54 C.P.R. (3d) 402 (F.C.T.D.)).

After consideration of the amendments here proposed these are my conclusions. In relation to the amendments to the relief sought by the applicants, it is unnecessary to strike out reference to the interim and interlocutory relief originally claimed, and to do so would ignore the record of the earlier proceedings before Mr. Justice Dubé in regard to the applicants' motion for interim relief, now a part of the record in these proceedings. Even if that relief is not to be further pursued by the applicants, deleting reference to that relief originally claimed, and partly disposed of at this stage, is unnecessary.

Adding a request for an order to revoke or suspend the decision of the Minister of July 11, 1997, in my opinion, would be inappropriate. An application for judicial review by the Court's Rule 1602(4) is to be with regard to a single decision, or failure to decide, and here the original and the amended notice of motion already seek review of the Minister's decision of March 26, 1997 to issue an NOC to Apotex with regard to its Apo-lovastatin product. At the hearing of this application counsel for Merck confirmed that the decision of March 26 is the

key decision here sought to be set aside. While it was urged at the hearing that the amended detailed allegations of fact sought to be introduced make clear that Merck seeks to challenge in this proceeding the whole series of decisions made on behalf of the Minister leading to the issue of the NOC and its subsequent amendment, this would only be relevant to the extent the prior process is by law, or practice of the Minister, an integral aspect of the decision in question. Judicial review is not a proceeding to review an ongoing and continuous process; rather, its purpose, aside from declaratory relief, is to review a particular decision or action, or lack of decision or action if that is required by law.

The proposed amendment to provide details of an order of prohibition sought against the Minister in relation to any future decision on an NOC for Apotex with regard to lovastatin, in my opinion is inappropriate at this stage. The description of the order sought, as set out in the proposed amended originating notice of motion, is based upon a particular view or interpretation of the legal effects of a decision that the Minister erred in law in issuing the NOC to Apotex in March 1997. If the judge hearing the originating motion is persuaded an order of prohibition should issue, the detailed application of such an order can best be dealt with on the basis of submissions related to the evidence and argument that may ultimately be adduced. The originating motion originally filed does ask for an order of prohibition. That request remains and only the details of the application of that order would be changed if the amended version were now filed. In my opinion, the detailed terms of the order, if granted, will be resolved by the hearing judge.

Among the amendments to the relief sought the last is for an order for an award of costs against the respondents, presumably all four respondent parties, on a solicitor/client basis. The applicants may have a major task to persuade the hearing judge that such an award is merited, particularly in light of the fact that

Rule 1618 requires special reasons for any award of costs, even on a party and party basis, in judicial review proceedings. Yet, the applicants ought not to be precluded from amending the originating motion to argue that the circumstances here merit costs on the basis now requested. An amendment to the originating notice of motion requesting costs on a solicitor and client basis, as set out in the proposed clause E of the orders sought in the amended originating notice of motion, may be filed by the applicants.

I turn to the amendments proposed to the detailed statement of facts and submissions set out in the body of the proposed amended originating notice of motion as grounds for the motion. In my opinion, those amendments are totally unnecessary and leave to amend the originating notice of motion in this manner proposed, is denied. It is unnecessary to set out detailed allegations of fact in the text of the originating notice of motion. Those are matters primarily of evidence, and to some extent of argument based on the evidence. The evidence in an application for judicial review is provided by sworn affidavit, with documents exhibited as may be appropriate, and supplemented by relevant evidence in the transcripts of cross-examinations on affidavits. Argument based on that evidence, in the usual course, is then set out in the "concise memorandum of the points to be argued by the applicant", to be included in the applicants' application record, as Rule 1606 provides. Including detailed allegations of fact and of argument in the body of the originating notice of motion gives the facts no status; the facts alleged have significance only if adduced through sworn affidavit or through cross-examination on an affidavit.

Denying leave to amend the detailed allegations of fact does not preclude the applicants from relying on any of those facts if they are adduced by sworn affidavit or from cross-examination of affiants. When the applicants' application record is filed, and the argument is outlined by their "concise memorandum",

Merck's view of the facts may then lead the respondents to file further affidavit evidence in response, as they are entitled to do pursuant to Rule 1608. It may be appropriate for a schedule to be established by agreement or by the Court to ensure the application records are completed sufficiently in advance of the tentative date set for hearing of this application for judicial review, but I leave that for discussion as a matter for possible consideration at the case management conference scheduled for October 6, 1997.

Conclusion

For the reasons here set out the following Orders are issued.

1. The motion of the Apotex corporations, that this proceeding be ordered to be treated and proceed as an action, is dismissed.

2. The Merck corporations' application for leave to file an amended originating notice of motion is dismissed, except that an amendment to seek costs on a solicitor and client basis against the respondents shall be allowed if Merck decides to file an amended originating notice of motion with that amendment only.

3 and 4. The motions by the Merck corporations for orders directing Mary Elizabeth Carman and Bernard Sherman, respectively, to re-attend for further cross-examination on their affidavits, are adjourned for consideration, with approval of the presiding judge, at a case management conference scheduled for October 6, 1997.

"W. Andrew MacKay"
Judge

Toronto, Ontario
October 1, 1997.

FEDERAL COURT OF CANADA

Names of Counsel and Solicitors of Record

COURT NO:	T-1273-97
STYLE OF CAUSE:	MERCK FROSST CANADA INC. - and - MERCK & CO., INC., - and - THE MINISTER OF HEALTH, THE ATTORNEY GENERAL FOR CANADA, APOTEX INC., and APOTEX FERMENTATION INC.
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