Court File No.: A-167-14

FEDERAL COURT OF APPEAL

BETWEEN:

DR. GABOR LUKACS

Applicant

and

CANADIAN TRANSPORTATION AGENCY

Respondent

RECORD OF THE RESPONDENT
CANADIAN TRANSPORTATION AGENCY

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TAB 1

Court File No.: A-167-14

FEDERAL COURT OF APPEAL

BETWEEN:

DR. GABOR LUKACS

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Respondent

WRITTEN REPRESENTATIONS OF THE CANADIAN TRANSPORTATION AGENCY

PART I - STATEMENT OF FACTS

1. This motion is made in the context of a judicial review application, brought by the Applicant, Mr. Gabor Lukacs. In his application, Mr. Lukacs is seeking an order in mandamus requiring the Agency to render a decision in his February 24, 2014 complaint, according to subsection 29(1) of the Canada Transportation Act (CTA).

2. In his February 24, 2014 letter to the Canadian Transportation Agency (the Agency), Mr. Lukacs alleged that Expedia, Inc. has been advertising prices of air services on its Canadian website, expedia.ca, contrary to section 135.8 of the Air Transportation Regulations ("ATR"). Mr. Lukacs argued that Expedia, Inc. has been advertising prices on its Canadian Website, expedia.ca, contrary to ss. 135.8 of the ATR by:

   (a) failing to include fuel surcharges in "Air Transportation Charges"; and

   (b) improperly including and listing airline-imposed charges in "Taxes, Fees and Charges" under the name "YR - Service Charge."

3. Mr. Lukacs asked that the Agency order Expedia, Inc. to amend its Canadian Website to comply with Part V.1 of the ATR.

4. On March 27, 2014, Mr. Geoffrey C. Hare, Chair and Chief Executive Officer of the Agency, wrote in a letter addressed to the Applicant, among other things, that:

> Enforcement of the air pricing advertising provisions of the ATR is being achieved by application of administrative monetary penalty provisions of the Canada Transportation Act (CTA). The Canadian Transportation Agency Designated Provisions Regulations (Designated Provisions Regulations) were amended specifically for that purpose. The DEO is empowered to exercise discretion and judgement in deciding how to best achieve compliance and where necessary enforce through the imposition of administrative monetary penalties.
>
> For your information, the approach has been highly successful in achieving compliance with the regulations amongst advertisers of air services.

> To be clear, no decision by an Agency Panel is required for the DEO to undertake an investigation of a potential contravention of a provision listed in the Designated Provisions Regulations. Therefore, the Agency will not be conducting an inquiry into the matter you have raised.

5. Mr. Lukacs brought this application for judicial review on March 28, 2014.

6. On May 20, 2014, Ms. Simona Sasova, Manager of the Enforcement Division, filed an affidavit in regard to the application. In her affidavit, Ms. Sasova describes the Enforcement Division's efforts in ensuring compliance by advertisers of air services with the ATR.

7. In particular, she describes how a Designated Enforcement Officer conducted an online compliance verification following receipt of Mr. Lukacs' February 24 letter to the Agency.

8. Cross-examinations of Ms. Sasova on her affidavit were scheduled for June 9, 2014. On June 6, 2014, following disagreement about the relevancy of documents requested by Mr. Lukacs, the parties agreed to postpone the cross-examinations to a later date.

Exhibit "N" to the Affidavit of Mr. Gabor Lukacs
Applicant's Motion Record, p. 102

9. On June 6, 2014, the parties entered into settlement discussions. On June 13, 2014, Mr. Lukacs wrote to the Court to ask that the application be held in abeyance pending the settlement discussions.

Affidavit of Mr. Gabor Lukacs, para. 16
Applicant's Motion Record, p. 16

10. On July 3, 2014, on the Direction of Sharlow J.A., the following Order was issued:

> The applicant has requested that this matter be held in abeyance pending settlement discussions.
>
> The time for filing the applicant's record is extended to September 30, 2014.

Exhibit "O" to the Affidavit of Mr. Gabor Lukacs
Applicant's Motion Record, p. 107

11. On August 21, Mr. Lukacs wrote to Agency counsel to say that since Expedia's Canadian website continues to be non-compliant with the ATR, that he intended to proceed with the application. Mr. Lukacs enclosed a Direction to Attend to cross examine Ms. Sasova on her affidavit.

Exhibit "P" to the Affidavit of Mr. Gabor Lukacs
Applicant's Motion Record, p. 109

12. On September 5, 2014, cross-examinations of Ms. Sasova on her affidavit by Mr. Lukacs were conducted.

13. At the cross-examinations, Ms. Sasova produced documents in accordance with the Direction to Attend, (Exhibits 5, 6 and 7). Mr. Lukacs expressed his dissatisfaction with Ms. Sasova's document disclosure and eventually adjourned the examinations on the basis of his view that full production had not been made.

> Transcript of the September 4, 2014 cross-examination of Simona Sasova on her Affidavit sworn May 20, 2014, p. 91-92;
> Applicant's Motion Record, p. 230-231

14. On September 7, Agency counsel wrote to Mr. Lukacs informing him that Ms. Sasova would be sending Mr. Lukacs a complete package of documents in response to his Direction to Attend. Agency counsel stated:

> This is further to cross-examination of Ms. Sasova on her May 20, 2014 affidavit held September 4, 2014.
>
> Ms. Sasova will be sending you a complete package of documents on Monday that responds to your Direction to Attend. Most of those are copies and duplicates of documents already provided to you at the cross-examination on September 4th.
>
> However, to avoid further confusion, they are being sent to you as a complete package responding to your Direction to Attend.
>
> The email exchange dated May 27 from Paul Lynch to Paul de Bois and Simona Sasova is related to the two page document you were provided at the cross-examination and that started at page 2, which lead to some discussion.
>
> Although Ms. Sasova had not brought this first page to the cross-examination since it includes exchanges dated May 26 and 27 (and past the date she attested her affidavit), she is providing this document as it is relates to paragraph 14 of her affidavit.

> If you require further cross-examinations with respect to a document not provided at cross-examinations on September 4, then we could reconvene cross-examinations for that limited purpose at your convenience. Ms. Sasova will not be available to answer any additional questions on matters that have already been subject to cross-examination.
>
> Exhibit "Q" to the Affidavit of Mr. Gabor Lukacs
> Applicant's Motion Record, p. 113

15. On September 15, 2014, further cross-examinations of Ms. Sasova on her affidavit were conducted by Mr. Lukacs. During the cross-examinations, Agency counsel objected to Mr. Lukacs' questions relating to documents that had been provided to Mr. Lukacs at the September 4 cross-examinations. Mr. Lukacs adjourned the cross-examination of Ms. Sasova for failure to produce documents and refusal to answer questions.

16. No further request was made by Mr. Lukacs to Ms. Sasova to re-attend for cross-examination. On October 14, 2014, the Agency was served with Mr. Lukacs Motion Record.

PART II - ISSUES

17. The issues to be determined in this matter are:

1) whether Ms. Sasova should be required to produce additional documents and to re-attend for further cross-examination on her Affidavit.

2) whether the Agency should be required to pay the Applicant his costs of the September 15, 2014 continuation of Ms. Sasova's cross-examination; and

3) whether the Agency should pay the Costs of this Motion.

PART III - ARGUMENTS

1) Whether Ms. Sasova should be required to produce additional documents and to re-attend for further cross-examination on her Affidavit.

18. It is respectfully submitted that the issue of whether Expedia's online advertisement is, or is not, in compliance with the ATR is not relevant to whether the CTA requires the Agency to render a decision in Mr. Lukacs' February 24, 2014 complaint.

19. Mr. Lukacs argues as justification for the document production that, in the application, he will be required to establish the sixth condition in *Apotex Inc. v. Canada* (Attorney General) (C.A.), (1994) 1 F.C. 742 (para. 45) that mandamus will have "some practical value or effect" as support for the requested document.

20. In making this argument, Mr. Lukacs incorrectly states Ms. Sasova's position in paragraphs 14-16 of her May 20, 2014 affidavit that Expedia's Website had become compliant with the ATR as a result of enforcement actions taken by Agency staff.

Applicant's Notice of Motion, para. 23
Applicant's Motion Record, p. 9

21. In paragraph 16 of her affidavit, Ms. Sasova describes her enforcement efforts with respect to the matter of Expedia's failure to include fuel surcharges in "Air Transportation Charges". In paragraph 16 of her affidavit, she states:

> ...If a breakdown of these charges is provided in writing in the advertisement, it must appear under the heading "Air Transportation Charges", not under "Taxes, Fees and Charges". In this case, Expedia listed the "Airline Fuel Surcharge" separately, which is acceptable because it makes it clear to the consumer that it is not a third party charge. Nevertheless, Expedia was requested to physically move the "Airline Fuel Surcharge" heading so that it appears under the "Air Transportation Charges", which Expedia has done. Attached hereto and marked as Exhibit "K" to my Affidavit is a screenshot of an Expedia online ad taken on May 20, 2014.

22. In this paragraph (and as represented in the screen shot Exhibit "K" to her affidavit), Ms. Sasova acknowledges that Expedia's online advertisement was non-compliant with the requirement that air transportation charges must be displayed in an advertisement of air services, but this non-compliance was acceptable to her because it makes it clear to the consumer that it is not a third party charge.

23. In cross-examinations Ms. Sasova repeats several times her statement that Expedia's advertisement is non-compliant, but that it is acceptable.

> Transcript of the September 4, 2014 cross-examination of Simona Sasova on her Affidavit sworn May 20, 2014, p. 48, line 25; p 49, lines 1-15; p. 52, lines 6, 15, 22;
> Applicant's Motion Record, p. 187, 188, 191

Transcript of the September 15, 2014 cross-examination of Simona Sasova on her Affidavit sworn May 20, 2014, p. 120, line 18; p. 121, lines 15, 19, 24; p. 122, line 1; p. 138, line 11;
Applicant's Motion Record, p. 279, 280, 281, 297

24. Ms. Sasova explains her decision as being based on the exercise of her discretion as an enforcement officer. Neither the enforcement practices of the Enforcement Division, nor the exercise of discretion by Designated Enforcement Officers, are at issue in this application.

Transcript of the September 4, 2014 cross-examination of Simona Sasova on her Affidavit sworn May 20, 2014, p. 59, line 8.
Applicant's Motion Record, p. 198.

25. While, in response to questions posed by Mr. Lukacs in the September 15 cross-examination, Ms. Sasova testified that she worked with Expedia to try to find a way of achieving full compliance with this provision in the interests of settling the application, neither Ms. Sasova's affidavit, nor the subsequent evidence provided in cross-examination establish that Expedia has come into full compliance with subsection 135.8(3) of the Regulations since Ms. Sasova's May 20 affidavit was sworn.

Transcript of the September 15, 2014 cross-examination of Simona Sasova on her Affidavit sworn May 20, 2014, p. 135, line 18.
Applicant's Motion Record, p. 294

26. Ms. Sasova's affidavit demonstrates the Enforcement Division's responsiveness to information provided by members of the public regarding non-compliance with the ATR. It also illustrates the value of the compliance-based approach to enforcement of the ATR, whereby the DEO exercises discretion and judgement through the imposition of administrative monetary penalties, as described by Mr. Geoffrey C. Hare in his March 27, 2014 letter to Mr. Lukacs.

27. However, in the present circumstances, it establishes that Mr. Lukacs' concern expressed in his February 24, 2014 letter that Expedia failed to include fuel surcharges in "Air Transportation Charges" remains an outstanding issue – no further cross-examinations are required for that purpose.

28. With respect to Mr. Lukacs' second concern with Expedia's ad, expressed in his February 24, 2014 letter to the Agency (Expedia's service charges listed under the heading "Taxes, Fees and Charges") Ms. Sasova states in paragraph 13 and 14 of her May 20, 2014 affidavit that she had issued a warning letter to Expedia stating that it was in contravention of s. 135.92 of the ATR.

29. Ms. Sasova then states in paragraph 15 that "Expedia has since rectified the problem; the issue has now been resolved; and therefore, Expedia has complied with the requirements identified in the warning letter".

30. Mr. Lukacs has exhibited a tacit acceptance of Ms. Sasova's conclusions in this regard. In cross-examinations, his attention has been directed solely at the first ground identified in his February 24, 2014 letter to the Agency, regarding the requirement that Air Transportation Charges mentioned in Expedia's advertisements be placed under that heading.

> Exhibit No. A for Identification to the Transcript of the September 15, 2014 cross-examination of Simona Sasova on her Affidavit sworn May 20, 2014
> Applicant's Motion Record, p. 413

31. It is respectfully submitted that there is no reason to require Ms. Sasova to answer additional questions on her May 20 affidavit, given that in her May 20 affidavit, she accepts Mr. Lukacs' position that Expedia's advertisements were non-compliant with the requirement of s. 135.8(3) of the ATR. Her evidence is consistent with that conclusion and there is no reason to challenge her credibility.

32. Additional cross-examinations of Ms. Sasova in regard to her testimony would be unnecessary, repetitive, and add needless costs. The Federal Court has stated "cross-examination is not examination for discovery" and "even when a fact has been sworn to in the proceeding, it does not have legal relevance unless its existence or non-existence can assist in determining whether or not the remedy sought can be granted."

> Merck Frosst Canada Inc v Canada (Minister of Health), [1997] F.C.J. No. 1847 at paras 4-8.
> Tab 2 of the Agency's Motion Record

Specific Document Requests

33. In his written representations in this motion, Mr. Lukacs makes other points that he argues require Ms. Sasova to produce additional documents and to re-attend for further cross-examination on her Affidavit, which will be addressed below:

a) Communications between the Agency and Expedia after May 20, 2014

334. Mr. Lukacs argues that communications between Agency staff and Expedia about the need to make changes to Expedia's Website, dated after May 20, 2014, are relevant to his judicial review application.

35. Cross-examinations of Ms. Sasova on her affidavit occurred more than three months after her May 20, 2014 affidavit was sworn. This delay between Ms. Sasova's affidavit being sworn and cross-examinations occurring resulted from the application being put in abeyance by Court Direction at the request of Mr. Lukacs, on consent of Agency counsel, and in a good faith effort to settle the litigation.

36. It is respectfully submitted that this should not result in Ms. Sasova being subject to an ongoing and continuous obligation to produce documents that were created after her affidavit was sworn. Nor should it require her to provide testimony and documents on matters not attested to in her affidavit.

b) July 28, 2014 email exchange with Paul Lynch, Enforcement Support Officer

37. Mr. Lukacs specifically requests that all emails sent by Mr. Paul Lynch to Expedia on July 28, 2014, including those that were allegedly sent in error, be provided and that Ms. Sasova answer questions in relation to them.

38. The issue raised in Mr. Lynch's e-mail of July 28, 2014 which Expedia (Mr. de Blois) refers to as the "Subsequent Pages Project", is irrelevant to statements made by Ms. Sasova in her May 20, 2014 affidavit since this issue did not form the basis of her March 27, 2014 warning letter, nor was it in respect of her verification of the manner in which the Air Transportation Charges were displayed in that advertisement.

39. The issue is one that has not been looked at nor addressed for any other advertiser since the Air Services Price Advertising provisions of the ATR have been put in place. This is a much broader issue which requires careful consideration to establish whether or not these "subsequent pages" do, in fact, constitute an advertisement and fall within the scope of the ATR.

40. For this reason, the e-mails requested by Mr. Lukacs, referred to by Mr. Lynch as having been sent in error, are irrelevant in any case. It is also submitted that the exchange is not relevant since they were sent in error, were not intended to be received by Expedia, and were not discussed by Mr. Lynch and Mr. de Blois.

41. Mr. Lynch no longer has this email since, as a transitory document, it was deleted immediately in accordance with government policy and is not retrievable by the Agency's informatics team.

c) Evidence damaging to the Agency's case

42. Mr. Lukacs notes that in an email exchange dated May 14, 26 and 27, 2014, Expedia's representative indicates its Website would be updated to come in compliance with the Agency's March 27, 2014 Notice of Warning on May 23, 2014. Mr. Lukacs argues that these documents are damaging to the Agency's case since this date contradicts the statement made in paragraph 15 of Ms. Sasova's May 20, 2014 affidavit that "Expedia has since rectified the problem."

Applicant's Motion Record, p. 373-374

43. In the September 15, 2014 cross-examinations, in response to Mr. Lukacs' questioning on this issue, Ms. Sasova answered Mr. Lukacs on this point as follows:

> Q. And I put it to you, Ms. Sasova, that there are some serious problems with Exhibit J. The way Expedia's website looked like is not what is shown there and the reason is, I am telling you, because Expedia changed its website only on May 23rd
>
> A. That is not the case. They say 23rd but they do changes before that. It is a ballpark date, Mr. Lukacs. On May 20th the screen shot that I have taken was from Expedia.
>
> Transcript of the September 15, 2014 cross-examination of Simona Sasova on her Affidavit sworn May 20, 2014, p. 123, line 17
> Applicant's Motion Record, P. 282

44. The screen shot referenced in Ms. Sasova's testimony is attachment "K" to her May 20, 2014 affidavit and forms part of Ms. Sasova's sworn testimony.

45. In the Agency's respectful submission, sworn testimony is to be preferred over unsworn statements made in an email, particularly when the explanation provided by the affiant provides a credible response when asked about the discrepancy.

d) Objections to questions related to Exhibit No. A for Identification

46. In the September 15, 2014 cross-examinations, Agency counsel objected, in principle, to Mr. Lukacs' attempt at placing this document on the public record as an exhibit given that it is marked "without prejudice" and is in respect of communications between counsel regarding settlement negotiations.

> Transcript of the September 15, 2014 cross-examination of Simona Sasova on her Affidavit sworn May 20, 2014, p. 150, line 1
> Applicant's Motion Record, P. 309

47. Mr. Lukacs alleges that the Agency waived its settlement privilege to the extent that the content of settlement discussions was shared with Ms. Sasova.

48. As an employee of the Agency, the fact that she was involved in attempting to achieve settlement is appropriate, particularly given the regulatory compliance nature of the

negotiations and her position as Designated Enforcement Officer, and in no way constitutes a waiver of privilege.

49. Furthermore, the proposed line of questioning is not relevant to the application for judicial review since Ms. Sasova's attempts at settling this matter, including whether or not she knew of Mr. Lukacs' specific demands, are unrelated to the application for judicial review. As stated, her testimony does not establish that Expedia's ad became fully compliant with the regulations as a result of her efforts to achieve a resolution to this Application.

Order setting a schedule for the remaining steps in this proceeding.

50. The Agency has no objection to Mr. Lukacs' request that this Honourable Court set a schedule for the remaining steps in this proceeding.

COSTS

2) Whether the Agency should be required to pay the Applicant his costs of the September 15, 2014 continuation of Ms. Sasova's cross-examination;

51. When the Applicant's Direction to Attend was received in regard to the initial cross-examinations, originally scheduled for June 9, 2014 but postponed, Agency counsel objected to the production of documents:

> Mr. Lukacs
>
> In response to your email below, in your application, you seek an order of mandamus requiring the CTA to render a decision in the matter you raised with the Agency.
>
> Please note that any communications that might have occurred between Ms. Sasova and Expedia in the conduct of her investigation, as Designated Enforcement Officer, are irrelevant to the issue you have raised in your application and will not be provided.
>
> Applicant's Motion Record, p. 84

52. At the September 4, 2014 cross-examinations, documents that were in existence before and up to the May 20, 2014 date of Ms. Sasova's affidavit were produced in a good faith attempt to be transparent and demonstrate what had been achieved by the Enforcement Division since Mr. Lukacs' February 24, 2014 letter to the Agency.

> Exhibit No 9 to the transcript of the September 15, 2014 cross-examination of Simona Sasova on her Affidavit sworn May 20, 2014. Applicant's Motion Record, p. 381

53. Documents dated after Ms. Sasova's affidavit that Mr. Lukacs requested were only at issue for disclosure in this Application due to the lengthy delay between the adjournment of the Application and the re-scheduled cross-examination. This delay was caused by an adjournment, on consent of the parties.

54. The Agency respectfully requests that it not be required to pay Mr. Lukacs' costs of the September 15 cross-examination.

3) Whether the Agency should pay the Costs of this Motion

55. The Applicant has only through this motion, for the first time, stated the position that the document production and cross-examinations of Ms. Sasova are for the purpose of establishing a case that mandamus will have "some practical value or effect", as required by the decision in *Apotex Inc. v. Canada* (Attorney General) (C.A.), (1994) 1 F.C. 742.

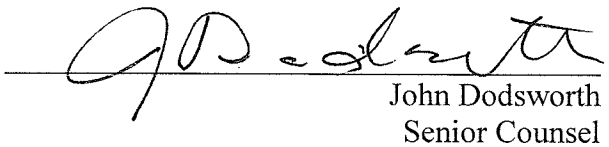
56. Ms. Sasova testified in the September 4, 2014 cross-examinations, in response to the Applicant's questions, clearly what she meant in paragraph 16 of her May 20, 2014 affidavit, when she stated that Expedia's advertisements were acceptable. Notwithstanding this, a second cross-examination was held at Mr. Lukacs' request on September 15, 2014 and this motion then pursued.

57. The parties should therefore bear their own costs in this motion.

PART IV - ORDER SOUGHT

58. The Agency respectfully requests that this Honourable Court deny the Applicant's request for costs of the September 15, 2014 cross-examination and of this motion, as well as the request for additional documents, the request to further cross-examine Ms. Sasova on her affidavit dated May 20, 2014 and Mr. Lukacs' request for further and other relief.

ALL OF WHICH IS RESPECTFULLY SUBMITTED. Dated at the City of Gatineau, in the Province of Quebec, this 24th day of October, 2014.



John Dodsworth
Senior Counsel
Canadian Transportation Agency

PART V – AUTHORITIES

Merck Frosst Canada Inc v. Canada (Minister of Health), [1997] F.C.J. No. 1847

TAB 2

Indexed as:

Merck Frosst Canada Inc. v. Canada (Minister of Health)

Between
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

[1997] F.C.J. No. 1847

[1997] A.C.F. no 1847

146 F.T.R. 249

80 C.P.R. (3d) 550

1997 CarswellNat 2661

79 A.C.W.S. (3d) 609

Court File No. T-1273-97

Federal Court of Canada - Trial Division
Ottawa, Ontario

Hugessen J.

Heard: October 6, 9 and 10, 1997
Oral Judgment: October 10, 1997

(24 paras.)

Practice -- Discovery -- Examination -- Objections to questions.

This was an application by Merck to compel answers to questions asked at a cross-examination on an affidavit. The respondent Minister of Health issued a notice of compliance for a drug manufactured by the respondent, Apotex. There was a dispute as to whether the drug violated a patent held by Merck. Merck brought a breach of patent action against Apotex. It also sought judicial review of the decision to issue the notice of compliance. Merck cross-examined Apotex's chairman and the Minister's director of the bureau of pharmaceutical assessment on their affidavits. Merck sought to compel the chairman and director to answer questions objected to during the cross-examination.

HELD: The application was granted. Apotex's chairman and the director of the bureau of pharmaceutical assessment were ordered to re-attend cross-examination to answer the questions. Merck was not entitled to compel answers in regard to non-compliance by the Minister with acts or regulations in respect of the issuance of the notice of compliance. However, Merck was entitled to enforce compliance by both Apotex and the Minister with regulations in regard to intellectual property rights which did not relate to public health and safety. Apotex and the Minister were directed to answer questions related to Apotex's drug submissions to the Minister, notices of withdrawal, deficiency, the impugned drug manufacturing process and product monographs.

Statutes, Regulations and Rules Cited:

Food and Drug Act.
Food and Drug Regulations, C.R.C., c. 870.
Patented Medicines (Notice of Compliance) Regulations, SOR/ 93-133, s. 7.

Counsel:

R. Charlton and L. Cresthol, for the applicants.
A. Lespérance and F. Couto, for the respondents, Minister of Health and the Attorney General for Canada.
H. Radomski and A. Brodkin, for the respondent, Apotex Inc.
D. McCaffrey, Q.C., and J. Myers, for the respondent, Apotex Fermentation Inc.

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1 **HUGESSEN J.** (Reasons for Order, orally):-- The background to this litigation has been very recently and very thoroughly set out by my brother McKay J. in reasons delivered only a few days ago. Without apology, I set it out again in his words:

> 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[Registered] 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.

2 McKay J. dismissed both Merck's motion to amend its application and Apotex's motion to convert the proceedings to an action.

3 I am now seized of the motions to compel answers to a large number of questions which were objected to during the cross-examinations of Ms. Carmen and Mr. Sherman, as well as for production of documents.

4 It is well to start with some elementary principles. Cross-examination is not examination for discovery and differs from examination for discovery in several important respects. In particular:

a) the person examined is a witness not a party;
b) answers given are evidence not admissions;
c) absence of knowledge is an acceptable answer; the witness cannot be required to inform him or herself;
d) production of documents can only be required on the same basis as for any other witness i.e. if the witness has the custody or control of the document;
e) the rules of relevance are more limited.

5 Since the objections which have given rise to the motions before me are virtually all based upon relevance, I turn, at once, to that subject.

6 For present purposes, I think it is useful to look at relevance as being of two sorts: formal relevance and legal relevance.

7 Formal relevance is determined by reference to the issues of fact which separate the parties. In an action those issues are defined by the pleadings, but in an application for judicial review, where there are no pleadings (the notice of motion itself being required to set out only the legal as opposed to the factual grounds for seeking review), the issues are defined by the affidavits which are filed by the parties. Thus, cross-examination of the deponents of an affidavit is limited to those facts sworn to by the deponent and the deponent of any other affidavits filed in the proceeding.

8 Over and above formal relevance, however, questions on cross-examination must also meet the requirement of legal relevance. Even when a fact has been sworn to in the proceding, it does not have legal relevance unless its existence or non-existence can assist in determining whether or not the remedy sought can be granted. (I leave aside questions aimed at attacking the witness's personal credibility which are in a class by themselves). Thus, to take a simple example, where a deponent sets out his or her name and address, as many do, it would be a very rare case where questions on those matters would have legal relevance, that is to say, have any possible bearing on the outcome of the litigation.

9 I pause at this point to deal with an argument put forward by the applicants which seeks to draw a parallel between the disallowance of questions based on absence of legal relevance and interlocutory motions to strike out parts of affidavits on the same grounds. The case primarily relied on is the decision of the Court of Appeal in Pharmacia Inc. v. Canada (1994), 58 C.P.R. (3d) 209, which held that, with very few exceptions such interlocutory motions could not be allowed in an application for judicial review. The argument is made, if I understand it correctly, that objections based on absence of relevance of questions put in cross-examination on an affidavit fall into the same category as motions to strike the underlying parts of the affidavit itself and should, therefore, also be disallowed. I entirely reject this argument. There is indeed a parallel between motions to strike and objections taken on grounds of legal relevance but it is quite different from what the applicants suggest. The policy consideration underlying the decision in Pharmacia, supra, was based on the statutory admonition that applications for judicial review should be heard expeditiously and in a summary way; allowing interlocutory motions to strike allegations would defeat that policy. Equally, the same considerations militate strongly against allowing parties to waste their own and the Court's time and effort (to say nothing of money) in interminable questioning on matters that can have no conceivable impact on the outcome. I would only add that the fact that the opposite party, in answer to irrelevant allegations in an affidavit, files equally irrelevant allegation to counter them, does not make either set of allegations relevant.

10 Turning now to the specifics of the present case, it is my view that the law is clear that Merck, as a patentee and holder of an NOC for a medicine does not have any right to raise non-compliance by the Minister with the Food and Drug Act or the Regulations made thereunder in respect of the issuance or proposed issuance of an NOC to another drug manufacturer. Specifically, Merck does not have the right to object to the issuance of an NOC to Apotex for the same medicine for which Merck holds an NOC on the grounds of non-compliance with that Act and those Regulations by either Apotex or the Minister. I think that that proposition flows clearly and unequivocally from two decisions of the Court of Appeal confirming two decisions by Trial judges of this Court: Glaxo Canada Inc. v. Canada (1990), 31 C.P.R. (3d) 25, affirming (1987), 18 C.P.R. (3d) 206, and Merck Frost Canada Inc. v. Canada (1994), 55 C.P.R. (3d) 302, affirming (1994), 53 C.P.R. (3d) 368. There are other decisions of the Trial Division of this Court to the same effect. I am not persuaded that any of these decisions were given per incuriam.

11 Some of the cases have used concepts such as absence of standing and non-justiciability as a convenient shorthand to describe this limitation on the patentee's rights. Seizing on this the applicants argue, based on such cases as Canada v. Finlay, [1986] 2 S.C.R. 607, Canada v. Borowski, [1981] 2 S.C.R. 575 and Operation Dismantle v. Canada, [1985] 1 S.C.R. 441, that they do indeed have standing and that the issues that they raise are, in fact, justiciable. The argument mistakes the form for the substance. It is not lack of standing or justiciability in the strict sense of those words which prevents the applicants from raising non-compliance with the health and safety concerns of the Food and Drug Act, and Regulations; it is simply that those matters are of no concern to them and cannot be raised by them in an attack on a decision of the Minister to issue an NOC. It is the Minister himself who is charged with the protection of the public health and safety and no private interest of the applicants arises from his alleged failure to perform his duties with respect to other persons.

12 As an exception to the foregoing, however, the Patented Medicine (Notice of Compliance) Regulations - the "linkage" Regulations - do give the Merck applicants a right, at the very least by implication, to enforce compliance by both Apotex and the Minister with those Regulations and to object to the issuance of an NOC on the grounds of non-compliance therewith. The linkage Regulations, however, do not have the effect of incorporating into themselves the whole of the Food and Drug Act and Regulations so as to create any right for the applicants to enforce the latter. Their clear and evident purpose is to provide an additional patent protection to the patentee in respect of his intellectual property rights and they have absolutely nothing whatever to do with public health and safety.

13 As I understand it, one of Merck's principal contentions in these judicial review proceedings is that there was non-compliance with the linkage Regulations as a result of the non-concordance or lack of sequence in the timing as between Apotex's new drug submissions and its notices of allegation and detailed statements made pursuant to the linkage Regulations. I make no comment as to the merit of that contention as a matter of law and it will fall to be determined by the judge who hears the application for judicial review. I do, however, for the reasons previously stated, think that Merck has the right to raise the point and that, accordingly, questions which go to establish the factual foundation for the argument have legal relevance.

14 This brings me to the particular subject matter of these motions. The questions objected to and now sought to be answered are listed in Annexes 1 and 2 to the applicants' memorandum of fact and law. They are very numerous and many, if not most of them, are cast in too general terms and are too unfocused to be admissible as such. That is not, however, the basis on which they have been objected to and it would be unfair, in the circumstances, to simply disallow them on that ground. Indeed, on the basis of the categories under which the questions have been grouped and the very thorough argument which the parties have presented to me over the last three days, I think it is possible for me to give a ruling which will not only allow these cross-examinations (and any others which may be outstanding) to be completed in very short order, but also permit the establishment of a realistic timetable for the filing of application records well prior to the hearing date fixed for January 26, 1998.

15 I take the categories as they are listed at pages 18 and following of the applicants' memorandum:

16 1) Apotex's first new drug submissions (1993)

> Questions relating to and production only of those parts of Apotex's 1993 new drug submission (including any refiling or amendment thereof) for Apo-lovostatin which permit the identification of the micro-organism(s) intended to be used in the production process are allowed; likewise,

witnesses must produce any notices of allegation and detailed statements filed or served by Apotex in respect of lovostatin and give the date of such filing and/or service;

17 2) Apotex's refiled new drug submission (1995)

The same question and productions are allowed with respect to the 1995 new drug submission save to the extent that such questions and documents have already been answered or produced under category 1) above;

18 3) Notices of Withdrawal, Deficiency or Non-compliance

While I fail to see the relevance of notices of deficiency or non-compliance, questions relating to the withdrawal of any new drug submission by Apotex respecting lovostatin or any part of such new drug submission and production of any documents giving effect to such withdrawal are allowed.

19 4) The micro organism Aspergillus obcurus

The micro organism Aspergillus obcurus not being part of the process for production of the drug for which an NOC was issued by the Minister to Apotex in March 1997, questions relating thereto are irrelevant. However, since Mr. Radomski has agreed to produce items 52 and 77 relating to the withdrawal of the process using obscurus that concession should be given effect to and those items answered;

20 5) Notifiable change

Questions relating to any "notifiable change" submitted regarding Apo-lovostatin and production of relevant documents only insofar as they pertain to the identification of the micro-organism intended to be used in the process are allowed. This will include Mr. Radomski's concession with respect to items 114 and 116;

21 6) Product Monographs for Apo-lovostatin

Questions relating to the product monograph(s) are irrelevant and are disallowed save insofar as such product monograph(s) may form part of the answers or productions previously ordered. In addition items 140 and 144 have been conceded by Mr. Radomski and are allowed;

22 8) Minister's Involvement and Activities under the Act[1]

Most of the questions in this category are repetitive of matters already dealt with. To the extent that they are not, they seem to be based on an attempt either to show an apprehension of bias, a ground of review not invoked in these proceedings, or to demonstrate Apotex's bad character and general disregard for what Merck views as the spirit and letter of the Linkage Regulations. They are irrelevant and are disallowed;

23 11) Additional Indications

These questions are irrelevant to the decision to issue the notice of compliance which is under attack in these proceedings. They are disallowed.

24 Before closing, I may say that I have the distinct impression that virtually all of the matters for which I have ordered answers or productions are already available to Merck and are in fact largely non contentious. That may have some bearing on the question of costs on which I invite submissions.

ORDER

Ms. Carmen and Mr. Sherman are ordered to re-attend and to answer the questions and make the productions detailed hereinabove.

The respondents having enjoyed a substantial measure of success and the applicants having sought costs on a solicitor and client basis, costs in the amount of $3,000.00 are awarded to the respondent Apotex payable in any event of the cause.

HUGESSEN J.

1 It will be noted that some of the categories have been dropped and accordingly the numeral sequence is incomplete.

Court File No.: A-167-14

FEDERAL COURT OF APPEAL

BETWEEN:

DR. GABOR LUKACS

Applicant

and

CANADIAN TRANSPORTATION AGENCY

Respondent

RECORD OF THE RESPONDENT CANADIAN TRANSPORTATION AGENCY

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