Federal Court of Appeal | Cour d'appel fédérale

Date: 20200408

Docket: A-16-20

Citation: 2020 FCA 71

CORAM: **DE MONTIGNY J.A.**
WOODS J.A.
LASKIN J.A.

BETWEEN:

APOTEX INC.

Appellant

and

BAYER INC. and BAYER INTELLECTUAL PROPERTY GMBH, TEVA CANADA LIMITED, TARO PHARMACEUTICALS INC. and SANDOZ CANADA INC.

Respondents

Heard by teleconference at Ottawa, Ontario, and Toronto, Ontario, on April 1, 2020.

Judgment delivered at Ottawa, Ontario, on April 8, 2020.

REASONS FOR JUDGMENT BY: LASKIN J.A.

CONCURRED IN BY: DE MONTIGNY J.A.
WOODS J.A.

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REASONS FOR JUDGMENT

LASKIN J.A.

[1] This appeal by Apotex Inc., and the appeal by Teva Canada Limited in file A-15-20 with which it was heard together, challenge a decision of the Federal Court (2019 FC 1370, Pentney J.) on motions by the Bayer companies under rule 220(1)(b) of the *Federal Courts Rules*,

SOR/98-106. Rule 220(1)(b) authorizes a party to bring a motion before trial to request that the Court determine a question as to the admissibility of evidence.

[2] Apotex and Teva are defendants in patent infringement actions brought by Bayer under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133. The questions put to the Federal Court in the motions were (1) whether, under the Notice to the Profession re Experimental Testing issued by the Chief Justice of the Federal Court, Bayer requires leave of the Court to lead evidence of experimental testing of the drug in issue conducted by Bayer before it commenced the actions, and (2) if so, whether leave should be granted.

[3] The Notice was issued in May 2016, replacing an earlier version issued in 2014. It is reproduced (in English and French) in an appendix to these reasons.

[4] The Notice sets out a requirement to give notice to "the other parties" where a party to a patent infringement or validity action intends to rely on evidence of "experimental testing conducted for the purpose of litigation." It states that unless the required notice is given, "the party shall not, without leave of the Court, lead evidence at the trial or hearing as to any experiments conducted by or for it for the purpose of the litigation." The party is to give notice at least two months before "the scheduled service of its expert report(s) to which the testing relates," though this timing may be abridged by the case management judge where it is not workable. The notice to be given is reasonable notice of

- the facts to be proven by such testing;
- the nature of the experimental procedure to be performed;
- when and where the adverse parties' counsel and representative(s) can attend to watch the experiment(s); and
- when and in what format the data and test results from such experiment(s) will be shared with the adverse parties.

[5] Here, Bayer conducted testing in September and October 2017. At the time, no infringement or validity litigation was pending in relation to the patent now in question in the actions. Bayer acknowledges that the testing was carried out for the purposes of potential future litigation. Teva and Apotex served notices of allegation under the *PM (NOC) Regulations* in September and October 2018, respectively. Bayer commenced the actions against Teva and Apotex in November and December 2018, respectively, more than a year after the testing took place.

[6] After the actions were commenced, Bayer advised Apotex and Teva of its intention to rely on the testing at trial. Apotex and Teva took the position that the Notice precluded Bayer from doing so without leave of the Court, because the requisite notice of the testing had not been given. The parties agreed, and the motion judge (who will also be the trial judge) accepted, that a motion under rule 220(1)(b) would be an efficient means of resolving the questions whether the Notice applies and, if so, whether leave should be granted.

[7] The motion judge answered no to the first question, and in light of that answer concluded that he did not have to decide the second. He found (at paragraph 47 of his reasons) that "the wording of the Notice, interpreted in light of its underlying purposes and considered in the

specific context of the current PM (NOC) Regulations scheme, leads inexorably to the conclusion that the Notice does not apply to the Bayer 2017 […] testing evidence." This conclusion was in his view "further reinforced by the fact that the Notice itself does not have the force of law."

[8] The motion judge gave three main reasons in support of his conclusion. First, he relied (at paragraph 48) on the specific wording of the Notice, which, he stated "speaks to the litigation context." He pointed in this connection to both the opening paragraph of the Notice, which refers to an infringement or validity action and the purposes of litigation, and the concluding paragraph, with its reference to experiments "conducted by or for it for the purposes of the litigation" (his emphasis). It was difficult, he went on (at paragraph 49), "to envisage how this Notice can be complied with outside of a litigation context," and also difficult "to understand how the Court might have jurisdiction to supervise the conduct of testing by a patent owner outside of the context of litigation before the Court."

[9] Second, the motion judge stated (at paragraph 51) that "[i]n the context of the current PM (NOC) Regulations scheme, [he was] unable to accept the argument that the mere listing of a patent on the Patent Register is sufficient to trigger the application of the Notice." He observed that the listing of a patent does not either give the patent owner notice of any specific company that might later seek approval to sell a generic version of the drug, or trigger a timeline for litigation. He found it unnecessary to decide whether the Notice applies to testing conducted after a notice of allegation is served, because in the case before him the testing was done before that date.

[10] Third, the motion judge added (at paragraphs 52 to 54) that the finding that the Notice does not apply to the testing by Bayer "does not undermine the underlying rationale of the Notice." This was so, he stated, for several reasons. The Notice will continue to apply to any testing conducted after commencement of the litigation. Arguments about fairness, ensuring effective discovery, and ensuring the completeness of the record at trial can still be made: Apotex and Teva remain free to argue at trial that the Notice has not supplanted the long-standing general practice of the Court (the leading authority for which is *Omark Industries (1960) Ltd. v. Gouger Saw Chain Co. et al.* (1964), [1965] 1 Ex. C.R. 457 at 516, 45 C.P.R. 169) to exclude evidence of testing conducted during litigation without giving adverse parties notice and an opportunity to attend. Apotex and Teva also remain free to pursue arguments at trial as to the reliability and weight of the evidence.

[11] Apotex and Teva now appeal from the order of the motion judge, with leave of the Court granted under subsection 6.11(1) of the *PM (NOC) Regulations*. Because of the urgency of the matter – the trial of the common invalidity issues is scheduled for September 2020 – and the impact of the COVID-19 pandemic on this Court's operations, arrangements were made, with the parties' agreement, to have the appeals heard by teleconference. The Court appreciates the parties' cooperation in this endeavour.

[12] For the reasons I now set out, I would dismiss the appeals. These reasons for judgment apply equally to the appeal by Apotex in file A-16-20 and the appeal by Teva in file A-15-20. The original of these reasons for judgment will be filed in file A-16-20. A copy will be filed in, and serve as the reasons for judgment in, file A-15-20.

[13] I first address the standard of review. The parties agree that the standard of review is governed by *Housen v. Nikolaisen*, 2002 SCC 33. They disagree on what standard it requires. Apotex and Teva characterize the question decided by the motion judge as a question of law, or at a minimum as one giving rise to an extricable question of law. Therefore, they submit, the correctness standard applies. Bayer submits that the decision is situation-specific, limited to the testing conducted by Bayer and to the context of an action under the *PM (NOC) Regulations*, and is properly regarded as one of fact or mixed fact and law, to which the deferential palpable and overriding error standard applies.

[14] I agree with Apotex and Teva on this issue. While the first question put to the motion judge refers specifically to the testing conducted by Bayer in 2017, to reach his conclusion, the motion judge considered and decided whether the Notice applies to testing conducted before the commencement of litigation. I see this as an extricable question of law, to which the correctness standard applies. But in the end the standard of review here is of no real moment, because in my view the decision of the motion judge was correct.

[15] I turn then to the substance of the motion judge's decision. In considering the reach of the Notice, he applied, appropriately in my view, a textual, contextual, and purposive approach, similar to that applied in the interpretation of legislation and subordinate instruments. It is evident that he gave considerable weight to the ordinary meaning of the text, in concluding that it "speaks to the litigation context."

[16] In my view he was right to do so. The text of the Notice includes a number of expressions that contemplate ongoing litigation. For example, the Notice refers in its first line to the use of testing to establish "any fact in issue." What facts are in issue will not be known until pleadings are exchanged in litigation. The first paragraph goes on to specify that the time by which the party seeking to rely on testing is to give notice is determined by reference to the time for the service of expert reports. This too will not be known before litigation is commenced. Similarly, there are no "other parties" or "adverse parties" before a statement of claim naming the parties is issued. Nor can there be a case management judge to perform the scheduling and dispute-resolution functions contemplated by the Notice if no litigation has yet been launched. And as the motion judge pointed out, the concluding paragraph of the Notice refers to testing conducted "by or for it for the purpose of the litigation" – a phrase that also contemplates litigation already commenced.

[17] There is nothing in the French version of the Notice that calls for a different conclusion. The expressions in the French version corresponding to the English expressions referred to above similarly contemplate that litigation has been commenced. If anything, the French version is even more explicit: it refers twice to "les besoins du litige" (equivalent to "the purpose of the litigation").

[18] The motion judge aptly observed that "[i]t is difficult to envisage how this Notice can be complied with outside of a litigation context." A party cannot, for instance, serve notice on "other parties" when those parties have not yet been identified.

[19] I also substantially agree with the motion judge's treatment of the contextual and purposive factors that he considered. None of these factors detract in my view from the conclusion that flows from the ordinary meaning of the words of the Notice.

[20] I would add that the context provided by the long-standing general practice of the Court described in *Omark Industries* provides further support for the motion judge's conclusion. The Court's practice is described in the case law as applicable to testing conducted "*pendente lite*," a term that appears to be used to mean either during litigation or during the trial: see, in addition to *Omark Industries*, *Halford v. Seed Hawk Inc*., 2001 FCT 1154 at paras. 32-35; *Merck & Co. Inc. v. Canada (Minister of Health)*, 2003 FC 1242 at paras. 7-13; *Apotex Inc. v. Pfizer Canada Inc.*, 2013 FC 493 at para. 37. It is common ground that there are no reported instances of the application of this practice to testing conducted before the commencement of litigation.

[21] The Notice appears to be an attempt to codify this practice and to provide a framework for its application. If the Notice is intended to apply to pre-litigation testing – to testing beyond that to which the practice of the Court has to date been applied – it seems very likely that it would say so expressly.

[22] During argument, the question was raised whether a notice to the profession like the Notice in issue here is as a matter of law capable, even if by its terms it did apply, of modifying the rules governing the admissibility of evidence. Given the disposition that I propose, it is not necessary for the Court to decide this question.

[23] I would dismiss the appeals with costs.

"J.B. Laskin"
J.A.

"I agree.
Yves de Montigny J.A."

"I agree.
Judith Woods J.A."

APPENDIX

Federal Court **Cour fédérale**

NOTICE TO THE PROFESSION

TO: Parties and Members of the Legal Profession

FROM: The Honourable Paul Crampton
Chief Justice

DATE: May 12, 2016

RE: Experimental Testing

In an action for infringement or validity of a patent, where a party intends to establish any fact in issue by experimental testing conducted for the purpose of litigation, it shall, no later than two months before the scheduled service of its expert report(s) to which the testing relates, provide reasonable notice to the other parties as to:

- the facts to be proven by such testing;
- the nature of the experimental procedure to be performed;
- when and where the adverse parties' counsel and representative(s) can attend to watch the experiments(s); and
- when and in what format the data and test results from such experiment(s) will be shared with the adverse parties.

In circumstances where the minimum two month notice requirement is not workable (for example, with regard to responding reports), the time period may be abridged by the Case Management Judge.

Where the parties cannot agree as to these matters, the Case Management Judge may resolve them at a case management conference.

Unless a party intending to rely on such experiments has so advised the other parties, the party shall not, without leave of the Court, lead evidence at the trial or hearing as to any experiments conducted by or for it for the purpose of the litigation.

"Paul Crampton"
Chief Justice

Cour fédérale **Federal Court**

AVIS À LA COMMUNAUTÉ JURIDIQUE

AUX: Parties et Membres de la communauté juridique

FROM: L'honorable Paul Crampton
juge en chef

DATE: le 12 mai 2016

RE: Tests expérimentaux

Dans le cadre d'une action en matière de contrefaçon ou de validité d'un brevet, lorsqu'une partie a l'intention d'établir un fait en litige par des tests expérimentaux effectués pour les besoins du litige, elle doit, au plus tard deux mois avant la signification prévue du (des) rapport(s) de ses experts, sur lequel (lesquels) portent les tests, donner un préavis raisonnable aux autres parties :

- quant aux faits à prouver par ces tests;
- quant à la nature de la procédure expérimentale qui sera effectuée;
- quant au moment et quant à l'endroit où les avocats et le(s) représentants(s) des parties adverses peuvent assister à (aux) expérience(s);
- quant au moment où les données et les résultats de ces tests seront transmis aux parties adverses et quant à la forme sous laquelle ils seront transmis.

Dans le cas où la période de préavis minimale de deux mois n'est pas pratique (par exemple, en ce qui concerne des rapports en réponse), le délai peut être abrégé par le juge responsable de la gestion de l'instance.

Lorsque les parties ne s'entendent pas sur ces questions, le juge responsable de la gestion de l'instance peut régler ce problème lors d'une conférence de gestion de l'instance.

Une partie ne peut pas, sans l'autorisation de la Cour, soumettre au procès ou à l'audience de la preuve relative à des tests effectués par elle ou pour son compte pour les besoins du litige, sauf si elle a avisé les autres parties qu'elle avait l'intention de le faire.

«Paul Crampton»
Juge en chef

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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REASONS FOR JUDGMENT BY:	LASKIN J.A.
CONCURRED IN BY:	DE MONTIGNY J.A. WOODS J.A.
DATED:	APRIL 8, 2020

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