Federal Court  Cour fédérale

Date: 20191031

Dockets: T-1960-18
T-2093-18
T-435-19
T-806-19

Citation: 2019 FC 1370

Winnipeg, Manitoba, October 31, 2019

PRESENT: Mr. Justice Pentney

Docket: T-1960-18

BETWEEN:

BAYER INC. and
BAYER INTELLECTUAL PROPERTY GMBH

Plaintiffs

and

TEVA CANADA LIMITED

Defendant

Docket: T-2093-18

AND BETWEEN:

BAYER INC. and
BAYER INTELLECTUAL PROPERTY GMBH

Plaintiffs

and

APOTEX INC.

Defendant

Docket: T-435-19

AND BETWEEN:

**BAYER INC. and
BAYER INTELLECTUAL PROPERTY
GMBH**

Plaintiffs

and

TARO PHARMACEUTICALS INC.

Defendant

Docket: T-806-19

AND BETWEEN:

**BAYER INC. and
BAYER INTELLECTUAL PROPERTY
GMBH**

Plaintiffs

and

SANDOZ CANADA INC.

Defendant

ORDER AND REASONS

I. Introduction

[1] The Plaintiffs, Bayer Inc. and Bayer Intellectual Property GmbH (Bayer) brought a motion pursuant to Rule 220(1)(b) of the *Federal Courts Rules*, SOR/98-106 to determine whether they require leave of the Court to rely on certain evidence of studies of their patented drug, rivaroxaban, at the trial of the patent infringement actions they have launched against the various Defendants, and, if so, whether leave should be granted. The evidence, as will be explained below, relates to certain tests that were done by Bayer in preparation for potential litigation but before it commenced these actions.

[2] The Defendants take the position that the Notice to the Profession on Experimental Testing (Notice) issued by the Chief Justice on behalf of the Court applies to this testing, and therefore Bayer required leave of the Court in order to rely on the test results at trial. The Defendants argue that Bayer has deliberately tried to do an "end run" around the Notice, by conducting its testing before it launched its actions. They contend that Bayer should not be rewarded for its conduct.

[3] For the reasons set out below, I am not persuaded that the Notice applies in these circumstances. However, the question of whether Bayer can rely on the test results at trial is not closed, since the issue may be argued by the parties at trial. This result will likely disappoint the parties, who were seeking clarity on this question prior to the trial, but it is an inevitable result of my determination within the confines of a Rule 220 motion.

II. Background

[4] The background to these cases has been set out in several previous orders (reported at 2019 FC 191 and 2019 FC 1039). Briefly, Bayer launched actions under the *Patented Medicine (Notice of Compliance) Regulations*, SOR/93-133 [the *PM (NOC) Regulations*] against the Defendants arising from their applications for approval to produce and market generic versions of the drug rivaroxaban. Bayer claims that these products will infringe several of its patents.

[5] In February 2019, the Case Management Judge directed that there be a hearing on the common issues of claims construction and invalidity in the Teva and Apotex actions (2019 FC 191). In August 2019, I issued an order adding Taro and Sandoz to the hearing of common issues (2019 FC 1039); this order is currently under appeal to the Federal Court of Appeal. In addition, there will be separate hearings for each Defendant concerning the infringement allegations.

[6] This Motion concerns testing that Bayer conducted in relation to one of the relevant patents, Canadian Patent No. 2,547,113 (the "113 Patent"). The sole inventor listed on the 113 Patent is Dr. Benke. The subject matter of the 113 Patent and its claims are pharmaceutical compositions comprising rivaroxaban in hydrophilized form, prepared using process(es) that improve its bioavailability compared to products prepared in other ways. In 2013, during the prosecution of a corresponding patent application before the United States Patent & Trademark Office, Dr. Benke provided a declaration making certain statements about the bioavailability of the drug when prepared using different methods. It appears that these statements were based on the results of dog studies, which Bayer had conducted at that time.

[7] The Defendants have argued, in their respective Statements of Defence (and, in the case of Teva, in the counterclaim it had filed, but which it has since discontinued) that the 113 Patent is invalid. They rely, in part, on the declaration made by Dr. Benke in 2013.

[8] During the course of trial preparation, Bayer disclosed that it intended to rely on more recent dog studies it had conducted in late 2017, before the commencement of any of these proceedings. It acknowledges that this testing was done for the purposes of potential future litigation that may arise prior to the expiry of the 113 Patent; there is no evidence of any clinical or regulatory reason to have conducted the tests.

[9] The Defendants say that Bayer's evidence about the more recent dog trials should not be admissible, because the testing was done without notice to them. They claim that this contravenes the Notice which itself simply reflects and reinforces the long-standing practice of this Court not to admit testing done in patent cases without notice to the other side.

[10] During several Case Management Conferences, the question of how to address the issue of admissibility was discussed. It was agreed between the parties and the Court that a motion pursuant to Rule 220(1)(b) was an efficient means of resolving the issue of whether this testing fell within the Notice, and if so, whether leave of the Court should be granted to admit it.

[11] A Rule 220 motion proceeds in two stages: first, the Court determines whether to order that the proposed questions be determined before trial; and second, if it makes such an order, then the Court must, after a new hearing, render a second decision answering the questions.

(*Perera v Canada*, [1998] 3 FC 381 (CA) [*Perera*]). In this case, the first stage was completed during several Case Management Conferences, during which the parties agreed that this was an expedient manner of resolving this question before trial.

[12] Two questions were set, on consent of the parties:

A. Do the Plaintiffs require leave of the Court pursuant to the Notice in order to lead evidence at trial of testing conducted by the Plaintiffs in September and October 2017 without notice to the Defendants (the Testing); and

B. If the answer [to the first question] is "yes", should the Plaintiffs be granted leave pursuant to the Notice to lead evidence at trial of the Testing?

III. Analysis

[13] This motion is framed by Rule 220, as well as the Notice. The first sets the parameters of my consideration of the matter, while the latter establishes the terms for the parties' arguments. In order to analyze the issues raised in this matter, it is necessary to begin with some background on both the Rule and the Notice before turning to the parties' arguments on the two questions set out above.

A. *Rule 220(1)(b)*

[14] As noted above, the Court has established that the procedure to follow under Rule 220 involves two stages. As stated in *Perera*, in relation to Rule 474 (the predecessor to Rule 220): "[r]ule 474 contemplates a two-stage procedure: first, the court decides whether to order that the proposed questions be determined before trial; second, if it makes such an order, then the Court

must, after a new hearing, render a second decision answering the questions of law" (at para 11). The Court observed that "the procedure contemplated by Rule 474 is exceptional and should be resorted to only when the Court is of the view that the adoption of that exceptional course will save time and expense" (at para 15).

[15] In relation to motions brought under Rule 220(1)(b) regarding admissibility of evidence before trial, the Court has ruled that this discretion "should be used with great restraint" (*Cantwell v Canada (Environment)*, [1990] FCJ No 1087 (QL) (TD), cited with approval in *Kirkbi AG v Ritvik Holdings Inc* (1998), 142 FTR 308, [1998] FCJ No 254 (QL) (TD) at para 14 [*Kirkbi*]). In *Kirkbi*, Justice Muldoon noted the general reluctance on the part of the Court to determine questions of admissibility prior to trial, and stated:

> [18] Faced with the general reluctance on the part of the Court to determine questions of the admissibility of evidence prior to trial, it appears that rule 474(1)(b) ought simply to be confined to general questions of admissibility, rather than the admissibility of evidence where the context of the evidence is required to be assessed. For the latter type of evidence, it appears that these matters are best left to the trial judge or the summary motions judge to determine, where the context and scope of the evidence can also be assessed.
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> [19] The motion before this Court does not pertain to the admissibility of evidence in a general sense…. The summary judgment judge is in the best position to hear the entire scope of the case and can best determine the evidence in its proper setting. The admissibility of this evidence ought not to be determined in a vacuum, as the effect of ruling this evidence inadmissible means that it cannot be adduced at trial. It should be noted that the summary judgment judge has the power to dismiss the action, in whole or in part and therefore the plaintiffs are also able to achieve the same effect as a motion under rule 474 by asking that the issue of the admissibility of evidence be determined by the summary motions judge.

[16] With this as the framework, I will now turn to the Court's approach to *ex parte* testing in patent litigation.

B. *Ex parte testing*

(1) The previous practice

[17] The long-standing practice of this Court and its predecessor, the Exchequer Court of Canada, in patent actions is not to accept a party's evidence of tests and experiments where notice and an opportunity to attend is not granted to the opposing party. This practice is described in various ways in the jurisprudence. Most of the cases refer to *Omark Industries (1960) Ltd v Gouger Saw Chain Co*, [1965] 1 Ex CR 457, 45 CPR 169 [*Omark Industries*] as the leading authority. In that case, Justice Noel said, at page 228:

> There is no question that the practice in this Court seems to have been that evidence of tests and experiments conducted *pendente lite* without notice being given to the other side and an opportunity to attend should not be considered and I believe that this is a salutary rule. I might also add that in any event tests and experiments conducted even before the trial in the presence of the other party is much more probative than if conducted *ex parte*.

[18] In *Merck & Co v Apotex Inc* (1994), 88 FTR 260, [1994] FCJ No 1898 (QL) (TD) [*Merck (1994)*], Justice MacKay explained his decision to exclude evidence of certain tests conducted during the trial and in the absence of the other party, at paragraph 127: "I did so on the general principles evolved in the practice of this court in relation to testing, whether before or during trial, which are intended to ensure fairness as between the parties and to ensure that the court has evidence from both sides about tests conducted" (citing *Omark Industries*. See also *Halford v Seed Hawk Inc*, 2001 FCT 1154 at para 37 [*Halford*]).

[19] In several decisions, it was noted that this is a rule of practice, not an inflexible rule of evidence, and therefore the circumstances of the case will determine the result. In *Apotex Inc v Pfizer Canada Inc*, 2013 FC 493 [*Apotex (2013)*], Justice James O'Reilly found that a party that had provided samples of its product to the other side for the purposes of testing, but then did not request to attend the testing that it knew was going on, could not later argue that the results of those tests should be inadmissible (see para 40). Similarly, in *AbbVie Corp v Janssen Inc*, 2014 FC 55, Justice Roger Hughes found that the defendant could not complain about testing done on its own product by the plaintiff, when the defendant chose not to conduct any testing of its own (see paras 62-70).

[20] Furthermore, the practice relates to experiments or testing, not to other types of evaluation of the patented product. In *Omark Industries*, the evidence was found to be in the nature of measurements rather than experiments or testing, and so fell outside of the general prohibition (see, to a similar effect: *Apotex (2013)* at para 34; *Bombardier Recreational Products Inc v Arctic Cat Inc*, 2017 FC 207 at para 599 [*Bombardier*]).

[21] Finally, this practice was found not to apply to the summary procedures that previously existed in relation to patented medicines. In *Merck & Co v Canada (Health)*, 2003 FC 1242, Prothonotary Mireille Tabib found that the practice of excluding *ex parte* testing evidence should not apply to the summary procedures under the former *PM (NOC) Regulations*, SOR/93-133, because of the "fundamental difference between actions, where full discovery is available, and the summary procedure contemplated in the Regulations" (at para 8). She continued:

> [9] Where full discovery is available, it is designed to allow the parties to fully explore each other's case, to ensure that neither is taken by surprise at trial and that they have an opportunity to present complete evidence at trial. A practice of conducting tests *in*

> *camera* for presentation at trial is indeed to be discouraged as defeating the purposes of discovery. Moreover, the discovery process and the rules governing the conduct of actions provides appropriate time, procedures and opportunity for parties to conduct supervised experimentations on notice. This would include the understandable need for a party to conduct private testing in advance of a decision to rely upon it at trial or to re-orient its evidence in the event a supervised experiment proves unsatisfactory.
>
> [10] In contrast, summary proceedings are designed to be expeditious. Allowing the parties to gain advance knowledge of the facts and evidence available to the other side and ensuring that a full evidentiary record be presented for determination by the Court is neither a paramount concern of this type of proceeding nor particularly conducive to achieving its aim. Neither do the rules governing the prosecution of these summary proceedings lend themselves to a practice of conducting joint or supervised experimentations. As it is, there is in *Regulations* proceedings often barely enough time for parties to conduct experiments that may (or may not) be probative or useful to their case. I suspect that as often as not, experiments are conducted as an integral part of the elaboration of the litigation strategy. To require notice and an opportunity to attend to the opposing party would both add an unbearable pressure on scheduling constraints and expose parties to choosing between opening up their defence brief to the opposing side or foregoing presenting potentially crucial evidence.
>
> [11] Fairness and preventing the introduction of evidence without the opportunity of meaningful cross-examination must, however, remain a consideration, and it may be that in appropriate cases rulings on admissibility or exclusion would need to be made. I conclude however, that there is no general rule of inadmissibility of test results conducted *ex parte* and *pendente lite* in summary proceedings.

[22] Of course, the current *PM (NOC) Regulations* now provide for an action on an accelerated timeline, and so a question may arise as to whether the procedures established in the Notice may need to be adjusted in light of this change. I do not need to resolve this question here, and so simply mention it in passing.

[23] Other limitations have been discussed in more recent decisions which involve the Notice, to which I will now turn.

(2) The Notice to the Profession

[24] On February 27, 2014, the Chief Justice, on behalf of the Court, issued a Notice to the Profession on "Experimental Testing", which largely reflected the practice described above. A slightly updated version was issued on May 12, 2016, and this is the Notice that is in issue in this Motion. For ease of reference, the 2016 Notice is set out in the Appendix.

[25] As this Notice is the basis for the parties' arguments, it is explored in more detail below. In brief, the Notice broadly reflects the previous practice of the Court, in that it states "[u]nless 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 purposes of the litigation." The Notice specifies certain details regarding the timing and contents of the required notice, and provides that the timeline can be abridged, and that the Case Management Judge may address other matters arising from the Notice.

[26] The Notice has been commented on in several cases, and two main points emerge. First, "the jurisprudence and notice to the parties and to the profession speak to the general practice of the Court and not to a rule of the Court or to a rule of evidence that mandates the automatic exclusion of testing evidence" (*Bombardier* at para 602).

[27] Second, as with the prior practice of the Court, the circumstances may warrant refusing or granting a request to rely on *ex parte* testing. Thus, where a party declined an offer to participate,

or could have undertaken testing of its own product, the Court has been prepared to admit the test results over the objections of the opposing party: see, for example *Bombardier* at para 602:

> [602] Finally, the jurisprudence and notice to the parties and to the profession speak to the general practice of the Court and not to a rule of the Court or to a rule of evidence that mandates the automatic exclusion of the testing evidence. As noted by Justice Hughes in *Abbvie Corporation v Janssen Inc.*, 2014 FC 55 at para 64 [*Abbvie*], there is no rule in the *Federal Courts Rules*, S.O.R./98-106 specifically directed to the admissibility of experimental testing. The common law rules of evidence do require the exclusion of evidence where the prejudicial effect of that evidence surpasses its probative value: see, for example, *R. v Ferris*, [1994] 3 SCR 756; *Harmony Consulting Ltd. v G A Foss Transport Ltd.*, 2012 FCA 226 at para 101.

[28] With this background, I will now turn to the arguments of the parties on the two questions.

(a) *The arguments of the parties*

[29] Bayer argues that the Notice does not apply to the evidence it intends to introduce because the testing was done before the commencement of the litigation. It submits that it could not comply with the Notice when it did the testing because there was no litigation underway at that time. Bayer points to the wording of the Notice, which states that it applies in the context of an "action for infringement or validity of a patent." When it did this testing, there were no adverse parties, adverse counsel, or adverse representatives to advise of the time and location of the testing, no litigation timetable to fix the two-month notice period, and no Case Management Judge to resolve any matters arising from the Notice.

[30] Bayer submits that the Notice is silent on pre-litigation testing, because in that context the Notice could not fulfil "its foremost and basic function, *i.e.* to provide notice." In this case,

Bayer conducted the testing before any party served a Notice of Allegation in regard to a generic version of rivaroxaban. Bayer submits that the Notice should not be interpreted in such a manner that it would impose an impossible burden on a party. That is what the Defendants are proposing here, by suggesting that Bayer should have given notice to unknown potential future defendants before it conducted its testing. As Bayer puts it in its factum: "[t]he Notice cannot apply in circumstances where it cannot be complied with."

[31] If the Notice applies, Bayer submits that it should be granted leave to introduce its evidence. It disclosed information regarding the dog studies which allowed experts retained by the Defendants to assess the studies and to offer their critiques of the information provided about the testing protocols, practices, and conditions. All of the Defendants will have a further opportunity to test this evidence through further cross-examination and at the trial.

[32] In addition, Bayer provided evidence that there may be ethical concerns about re-doing the dog testing for the purpose of litigation rather than for some scientifically-based reason. A further difficulty would arise if Bayer had to re-do the testing, in that it may not be possible to find testing facilities that would be able to do the testing in the limited time available, and coordinating the invitations to all four Defendants would be a significant task.

[33] Bayer contends that the Court should be guided by proportionality and Rule 6.09 of the *PM (NOC) Regulations* which require all parties to these proceedings to cooperate in expediting the matter. Bayer spent considerable time and money in doing these studies, and it should be entitled to rely on them at trial. No prejudice to the Defendants has been established.

[34] The essence of Bayer's argument is that it only makes sense for the Notice to apply in regard to testing done during the course of the litigation. Only then can the parties comply with the requirements of the Notice. The Defendants' concerns about the testing go to its evidentiary weight rather than to its admissibility.

[35] The Defendants submit that Bayer has misconstrued the Notice – they argue that it applies to any testing done for the purpose of litigation. It is the purpose, not the timing, of the testing which is the primary consideration. The Defendants quote the Notice, which requires notice to the other side "[w]here a party intends to establish any fact in issue by experimental testing conducted for the purposes of litigation…" In this case, there is no doubt that Bayer intends to establish a fact in issue and that the testing was conducted for the purposes of litigation. Therefore the Notice should apply to it.

[36] The Defendants contend that the underlying rationale for the Notice, which continues and reinforces the prior practice of the Court, is to ensure that there is fairness between the parties and that the Court has complete and meaningful evidence from all parties. *Ex parte* testing defeats these purposes by shielding one side's evidence from effective scrutiny, and preventing effective discovery. If Bayer is permitted to do this "end run" around the Notice, other parties will be encouraged to mimic this behaviour, and the advantages of notice of such testing will be lost.

[37] Teva submits that it is not putting Bayer in an impossible position by arguing that it must comply with the Notice. As Teva put it in its factum "if Bayer intends to rely on the 2017 Dog Testing, it must be repeated." The other Defendants essentially adopted the same position.

[38] The Defendants note that Bayer has produced no evidence to explain why it chose to conduct the dog testing when it did, rather than waiting for the commencement of litigation. They argue that it was a deliberate strategy. This is reinforced by the manner in which the testing was conducted. The documents produced by Bayer confirm that the "study sponsor" of the dog studies was not Bayer, but rather Gowling WLG, Bayer's external Canadian counsel. In addition, each of the third-party testers involved in the study were asked to execute the Federal Court's *Certificate Concerning the Code of Conduct for Expert Witnesses* prior to commencing their work.

[39] The Defendant Taro advances an additional argument, which relates to the scheme of the *PM (NOC) Regulations* as a whole. They argue that once a first person lists a patent on the Patent Register they must be taken to be necessarily contemplating litigation, since the listing is the initial trigger to the requirement for a generic to provide a Notice of Allegation, which in turn can lead the first person to launch a patent infringement action. Once Bayer listed rivaroxaban on the Register, it must be taken to have been contemplating litigation. Any testing done after that by Bayer must fall within the Notice.

[40] In a further alternative, Sandoz argues that Bayer has failed to produce sufficient evidence as to the relevance to particular facts in issue, and therefore the Court should defer any ruling on admissibility until the trial, when the matter can be considered in the context of the evidence as a whole.

[41] In essence, the Defendants' main argument is that ex parte testing for the purpose of litigation is presumptively inadmissible in a patent action. The Notice should apply to the testing done by Bayer regardless of when it was done, because otherwise it is being allowed to

circumvent the requirements imposed on all parties by the Court. The Notice must be interpreted to prevent the reliance on *ex parte* testing done for the purposes of litigation, regardless of when the testing was actually done, because that is the only way to prevent parties from simply accelerating their testing in order to avoid the notice requirements. If that is allowed, the purposes of fairness and ensuring a complete record is before the Court will be defeated, and trials will be needlessly extended by arguments about the admissibility and weight of the evidence of the pre-litigation testing. In this case, applying the Notice will simply require Bayer to re-do the testing if it wishes to rely on this evidence at trial.

[42] The Defendants also argue that if the Notice applies, Bayer should be denied leave to introduce this evidence. They made submissions on the test that should be applied to the leave stage, as well as to the reasons that Bayer should not be allowed to rely on this evidence. In view of my disposition of this matter, however, it is not necessary to explore these in detail.

(b) *Discussion*

[43] At the outset, it is important to recall that this is a motion under Rule 220(1)(b), seeking a ruling before trial on whether the Notice applies to the evidence Bayer wants to lead about its 2017 dog testing of rivaroxaban. It is not a free-standing motion on the admissibility of this evidence, either in light of the practice of the Court regarding *ex parte* testing in patent actions, or the more general rules of evidence regarding admissibility. What is clear, however, is that at this stage I am limited to addressing the questions set pursuant to Rule 220.

[44] There is force in the arguments of both sides on the specific question that was stated: does the Notice apply to Bayer's 2017 dog testing evidence? On the one hand, Bayer is

undoubtedly correct that the Notice can only be applied when it can be complied with, and this requires that there be other "parties" to the litigation to whom notice of the testing can be given.

[45] On the other hand, the Defendants are also correct in arguing that the purpose of the Notice is not simply to provide notice. Rather, it seeks to ensure fairness in the proceeding and that the Court has the best and most comprehensive evidence on the testing, and this speaks to a focus on the purposes of the testing. Achieving these purposes is not possible where one party deliberately undertakes *ex parte* testing, and this practice should not be encouraged.

[46] I would underline here that the situation may be different where there was some other legitimate reason for the testing to be done at a particular time prior to the trial. Bayer offered no such reason here.

[47] I find that the wording of the Notice, interpreted in light of its underling 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 dog testing evidence. This is further reinforced by the fact that the Notice itself does not have the force of law. It is an important indication of the practice of the Court, and I agree with the Defendants that it is to be given due weight, but as has been noted in several prior cases, it states a guiding principle which is to be considered and applied in the circumstances of each case.

[48] First, the specific wording of the Notice speaks to the litigation context. Its opening phrase make the point: "[i]n 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… provide reasonable notice to the other parties…" The point is also confirmed

in the closing paragraph of the Notice, which provides "[u]nless 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 purposes of the litigation." (emphasis added)

[49] It is difficult to envisage how this Notice can be complied with outside of a litigation context. It is 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.

[50] In this case, it is not disputed that Bayer conducted the testing prior to the launch of litigation, and prior to the receipt by Bayer of any Notice of Allegation from any of the Defendants. In this respect, Bayer is correct to argue that the testing was not done "for the purposes of the litigation" in the sense of the actions it has launched against these defendants.

[51] In the context of the current *PM (NOC) Regulations* scheme, I am 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. As a practical matter, such a listing does not give a patent owner any notice of any specific company that may in future seek approval to sell a generic version of the drug. Nor does it trigger a timeline for litigation. Those steps come later on in the process, and it is not necessary for the purposes of these proceedings to determine whether either the Notice or the more general practice of the Court apply to any testing done after a NOA is provided, because in this case the testing was done prior to that date.

[52] Finding that the Notice does not apply to the Bayer testing does not undermine the underlying rationale of the Notice, for several reasons. First, the Notice will continue to apply to

any testing conducted once litigation is commenced – and here I would observe that some previous decisions refer to testing conducted prior to trial, but surely the relevant period is not when the trial starts, but rather when the litigation is commenced by the service and filing of some originating process.

[53] Second, finding that the Notice does not apply to testing conducted prior to the launch of the litigation does not put an end to the argument about the importance of fairness, ensuring effective discovery, and that the Court has a complete record before it. The Defendants remain free to argue that the adoption of the Notice has not extinguished the prior practice of the Court to exclude such evidence, particularly where the Notice is found not to apply. On this point I would simply note in passing that some of the prior cases find that testing conducted prior to trial is included within the scope of the practice (see, for example: *Merck (1994)*, at para 127; *Halford*; *Apotex (2013)*, at paras 39 and 42). Whether this extends to testing conducted prior to the launch of litigation appears not to have been specifically determined in prior cases.

[54] Finally, even if the evidence is admitted at trial, the Defendants remain free to pursue their arguments regarding the reliability of the evidence and the weight that should be attributed to it, including through cross-examination and the introduction of further evidence.

[55] I would also note in passing that this ruling does not preclude any of the parties from seeking to reproduce the 2017 dog testing study, with notice to the other parties, if they so choose. This would obviously negate many of the concerns that have animated the arguments on all sides, but it is entirely up to the parties to determine whether they may wish to do so.

IV. Conclusion

[56] The questions stated in this motion are:

A. Do the Plaintiffs require leave of the Court pursuant to the Notice in order to lead evidence at trial of testing conducted by the Plaintiffs in September and October 2017 without notice to the Defendants (the Testing);

B. If the answer [to the first question] is "yes", should the Plaintiffs be granted leave pursuant to the Notice to lead evidence at trial of the Testing?

[57] For the reasons set out above, I find that the first question should be answered in the negative. The Plaintiffs do not require leave of the Court pursuant to the Notice in order to lead evidence at trial about the Testing.

[58] In light of my conclusion on the first question, it is not necessary to answer the second question.

[59] The parties sought costs in this motion, but in view of the manner in which it proceeded, and the result, and in exercise of my discretion pursuant to Rule 400, I am not awarding any costs. Each party shall bear its own costs in relation to this motion.

ORDER in T-1960-18, T-2093-18, T-435-19 and T-806-19

THIS COURT ORDERS that:

1. The Plaintiffs do not require leave of the Court pursuant to the 2016 Notice to the Profession re Experimental Testing in order to lead evidence at trial about the 2017 dog testing.

2. In light of my conclusion on the first question, it is not necessary to answer the second question.

3. No costs are awarded.

"William F. Pentney"
Judge

APPENDIX

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 experiment(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

FEDERAL COURT

SOLICITORS OF RECORD

DOCKETS:	T-1960-18, T-2093-18, T-435-19, T-806-19
DOCKET:	T-1960-18
STYLE OF CAUSE:	BAYER INC. AND BAYER INTELLECTUAL PROPERTY GMBH v TEVA CANADA LIMITED
DOCKET:	T-2093-18
STYLE OF CAUSE:	BAYER INC. AND BAYER INTELLECTUAL PROPERTY GMBH v APOTEX INC.
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DOCKET:	T-806-19
STYLE OF CAUSE:	BAYER INC. AND BAYER INTELLECTUAL PROPERTY GMBH v SANDOZ CANADA INC.
PLACE OF HEARING:	OTTAWA, ONTARIO
DATE OF HEARING:	SEPTEMBER 5, 2019
ORDER AND REASONS:	PENTNEY J.
DATED:	OCTOBER 31, 2019

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Kavita Ramamoorthy	FOR THE DEFENDANT TARO PHARMACEUTICALS INC.
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