Federal Court  Cour fédérale

Date: 20210607

Docket: T-1660-11

Citation: 2021 FC 554

Ottawa, Ontario, June 7, 2021

PRESENT: The Honourable Mr. Justice Southcott

BETWEEN:

BERNARD CHARLES SHERMAN
AND APOTEX INC.

Plaintiffs/
Defendants by Counterclaim

and

PFIZER CANADA INC., PFIZER INC. AND
DOE CO. AND ALL OTHER ENTITIES UNKNOWN
TO THE PLAINTIFFS WHICH ARE PART OF
THE PFIZER GROUP OF COMPANIES

Defendants/
Plaintiffs by Counterclaim

ORDER AND REASONS

I. Overview

[1] In this motion, the Plaintiffs/Defendants by Counterclaim [collectively, Apotex] appeal, pursuant to Rule 51 of the Federal Court Rules, SOR/98-106 [the Rules], an Order of Madam

Prothonotary Milczynski [the Prothonotary] dated May 4, 2021 [the Order]. The Order dismissed Apotex's motion under Rule 249 for an order directing the Defendants/Plaintiffs by Counterclaim [collectively, Pfizer] to provide Apotex with samples of ACCUPRIL finished tablets made on or after September 1, 2018 through to December 6, 2019, as well as samples of the quinapril active pharmaceutical ingredient [API] and each excipient used in the manufacture of the ACCUPRIL tablets.

[2] As explained in more detail below, this motion and Apotex's appeal are dismissed, because, applying the relevant standard of review, I have found no reviewable error on the part of the Prothonotary.

II. **Background**

[3] On June 21, 2011, Apotex was issued Canadian Patent No. 2,355,347 [the 347 Patent]. The 347 Patent is titled "Pharmaceutical compositions comprising quinapril magnesium". The claims of the 347 Patent include a process for making a pharmaceutical composition comprising quinapril magnesium through a process that reacts quinapril or an acid addition salt of quinapril (e.g. quinapril hydrochloride) with an alkaline magnesium compound (e.g. magnesium carbonate) in a solvent to convert at least 80% of the quinapril or acid addition salt of quinapril into quinapril magnesium.

[4] Apotex brought the action underlying this motion on October 11, 2011, alleging that the 347 Patent was infringed by Pfizer's manufacture and sale of two quinapril tablets called ACCUPRIL and ACCURETIC [the Action]. Pfizer has marketed and sold ACCUPRIL and

ACCURETIC for treating high blood pressure since 1992. In the Action, Apotex claims that the manufacture and sale of ACCUPRIL and ACCURETIC tablets for the period of June 15, 2000 (when the 347 Patent application was published) to December 7, 2019 (when the 347 Patent expired) have infringed the 347 Patent.

[5] Pfizer denies that the manufacture and sale of ACCUPRIL and ACCURETIC tablets infringe the 347 Patent and raises defences, including that the 347 Patent is invalid. Pfizer also alleges that its process for manufacturing ACCUPRIL and ACCCURETIC tablets has been in accordance with prior art processes as it has been manufacturing the tablets since 1992.

[6] Pfizer's documentation produced in the Action does not provide any measurement of whether ACCUPRIL and ACCURETIC contain quinapril magnesium or, if so, in what proportions. In 2014, Apotex examined Pfizer's discovery representative for six days. Apotex was advised that Pfizer did not retain any in-process samples but kept final retention samples for the expiry period of the applicable lot. No requests for samples or to attend or observe Pfizer's manufacturing process were made at that time. The trial of the liability phase of the Action has been scheduled to commence on January 17, 2022.

[7] In February 2021, Apotex asked Pfizer to provide it with samples from batches of its tablets from June 15, 2000 to December 7, 2019. Pfizer refused, and Apotex brought a Rule 249 motion seeking, for each batch of ACCUPRIL and ACCURETIC for the relevant period, or representative samples thereof, the following:

A. 500 finished tablets;

B. 500 uncoated tablets;

C. 100 grams of dry granulate; and

D. 100 grams each of the quinapril API lots and 500 grams each of the excipient lots used in the manufacture of their respective batches.

[8] Following communications between the parties surrounding Pfizer's retention practices, on April 23, 2021, prior to the hearing of the Rule 249 motion, Apotex filed an Amended Notice of Motion that instead sought the following samples:

A. 500 finished tablets of ACCUPRIL 5 or 10 mg tablets made on or after September 1, 2018 through to December 6, 2019;

B. 500 finished tablets of ACCUPRIL 20 or 40 mg tablets made on or after September 1, 2018 through to December 6, 2019; and

C. 10 grams of the quinapril API and each excipient used in the manufacture of the ACCUPRIL tablets referenced above in the Amended Notice of Motion.

[9] The Prothonotary heard submissions from the parties' counsel on April 23, 2021, and issued the Order dismissing the motion on May 4, 2021.

III. **The Prothonotary's Order**

[10] The Prothonotary indicated that she understood Apotex's Rule 249 motion to raise three issues for determination: first, what is available by way of samples; second, what reliable test(s) might be performed that would have a reasonable possibility or prospect of yielding helpful and relevant results; and third, whether Apotex waiting to make its request for samples until under a year before the scheduled trial date should be a factor in considering whether to grant Apotex's sample request.

[11] The Prothonotary then set out Rule 249(1) and explained that *Apotex Inc v Eli Lilly Canada Inc*, 2013 FCA 45 [*Eli Lilly*] established that Rule 249 should be interpreted to facilitate fair and expeditious determination of the issues and balance the competing interests between the party making the request and the party in possession of the sample. There must also be consideration of what evidence will assist the Court in the trial of the action.

[12] Apotex adduced evidence in support of the Rule 249 motion through an affidavit from its expert, Dr. Michael Cima, a Professor of Material Science and Engineering at the Massachusetts Institute of Technology. The Prothonotary considered Dr. Cima's affidavit and found that Dr. Cima provided evidence that testing techniques are available that can detect the presence of quinapril magnesium in the Pfizer tablets. Dr. Cima also referenced quantification of the amount of quinapril magnesium, but the Prothonotary found that this evidence was vague and indeterminate.

[13] Pfizer filed an affidavit from its own expert, Dr. Phil Williams, Professor of Biophysics and the Director of Research and Knowledge Exchange at the School of Pharmacy at the

University of Nottingham. The Prothonotary noted that Dr. Williams' evidence was that establishing a quantitative test is generally more difficult than establishing a qualitative test that measures only the presence of a particular compound. Dr. Williams stated that he was unaware of any analytical test that could be applied to the Pfizer tablets to determine whether at least 80% of the quinapril chloride API in the tablets is converted into quinapril magnesium. He further stated that it might not be possible to develop an 80% conversion test and that, even if it was possible, it would likely require many months.

[14] Based on the two expert affidavits, the Prothonotary found that Apotex had not established that a test has been designed or exists that can determine whether at least 80% of the quinapril hydrochloride API converts into quinapril magnesium or that there is some reasonable degree of likelihood that such testing can be designed and conducted. The Prothonotary held that the motion must fail for that reason alone. There was no useful purpose for requiring Pfizer to provide samples in any amount if there is no identified testing process. The Prothonotary stated that whether such testing process can or might be designed and implemented was speculative or, as described by Pfizer's counsel, at best aspirational.

[15] However, the Prothonotary went on to also find that at this stage of the litigation, with only eight months or so before trial, advancing the request for samples was late. The Prothonotary was not satisfied that compelling Pfizer to produce samples would facilitate or expedite the trial process. Rather, it may derail it and ultimately serve no useful purpose. The Prothonotary explained that, to the extent that testing protocols or processes could have been designed to measure the quantity of quinapril magnesium salt in a finished tablet and that

disclosed the minimum 80% conversion as claimed by the 347 Patent, it and the request for samples to subject to such test ought to have been made well before February 2021.

[16] The Prothonotary concluded by reciting the standard set out in *Eli Lilly* of "a reasonable possibility that the proposed test will reveal something useful for the trier of fact". Taking into account the questions surrounding the testing process itself and the timing of the request, the Prothonotary was not satisfied that there is a reasonable possibility that reliable testing can be conducted that could/may reveal something useful in time of trial, or at all. Accordingly, the Prothonotary dismissed the motion.

IV. **Issues**

[17] Based on the parties' arguments, I would characterize the issues in this appeal as follows:

A. Did the Prothonotary err in law by applying an incorrect test under Rule 249?

B. Did the Prothonotary make palpable and overriding errors of fact or mixed fact and law?

V. **Standard of Review**

[18] The Federal Court of Appeal in *Hospira Healthcare Corp v Kennedy Institute of Rheumatology*, 2016 FCA 215 at paras 64-65, established that a decision of a prothonotary under appeal to a judge is subject to the standard of review from *Housen v Nikolaisen,* 2002 SCC 33 [*Housen*]. Based on this standard, issues of law in a prothonotary's order are reviewable on a standard of correctness, and findings of fact or mixed fact and law are reviewable on the standard

of palpable and overriding error. The parties agree that these standards of review apply in the present appeal.

VI. **Analysis**

A. *Did the Prothonotary err in law by applying an incorrect test under Rule 249?*

[19] The motion for production of samples now under appeal was brought under Rule 249(1), which provides as follows:

Inspection of Property	**Examen de biens**
Order for inspection	**Ordonnance d'examen**
249 (1) On motion, where the Court is satisfied that it is necessary or expedient for the purpose of obtaining information or evidence in full, the Court may order, in respect of any property that is the subject-matter of an action or as to which a question may arise therein, that	**249 (1)** La Cour peut, sur requête, si elle l'estime nécessaire ou opportun pour obtenir des renseignements complets ou une preuve complète, ordonner à l'égard des biens qui font l'objet de l'action ou au sujet desquels une question peut y être soulevée :
(a) a sample be taken of the property;	**a)** que des échantillons de ces biens soient prélevés;
(b) an inspection be made of the property; or	**b)** que l'examen de ces biens soit effectué;
(c) an experiment be tried on or with the property.	**c)** que des expériences soient effectuées sur ces biens ou à l'aide de ceux-ci.

[20] The parties agree that *Eli Lilly* is the leading authority prescribing the test to be applied in a Rule 249 motion. The Federal Court of Appeal, at paragraph 8, endorsed the interpretation of the Rule as requiring "a reasonable possibility that the proposed test will reveal something useful for the trier of fact (that is something which will assist the trier of fact in determining an issue in the proceeding)". *Eli Lilly* also provided the following additional guidance (at para 10):

> 10. Read in the context of Rule 3, which was added in the 1998 revision of the Rules, the test set out in Rule 249 is clear and does not require that this Court provide more detailed and strict guidelines in respect of its application. In fact, it would be unwise to try to do so as it is evident that the use of the words "necessary *or* expedient" was intended to give a broad discretion to the Court. As always, facts do matter and they are particularly important when dealing with motions such as those under Rule 249 which require the Court to balance any number of factors relevant to the three main interests at play: those of the party requesting the inspection or samples, those of the party in possession of the property concerned and those of the trier of fact. It is because of this need to balance all the relevant factors that a party must move to get an order under Rule 249, contrary to other discovery Rules. In our view, this is exactly how the Prothonotary approached her task when she set out to determine the motions before her.

[21] I note that Apotex makes submissions, relying on older authorities, that the courts have also phrased the question as whether, if the decision-maker on the motion was presiding at the trial, he or she would view an inspection as beneficial (see *Poly Foam Products Ltd v Cascades Sentinel Ltd*, 31 CPR (3d) 11, [1990] FCJ No 453 (FCTD) at paras 9, 12-13; *Richter Gedeon Vegyészeti Gyar Rt v Apotex Inc*, 2002 FCT 1284, [2002] FCJ No 1740 (FCTD) at paras 7, 29-31, aff'd 2003 FCA 221). Of course, the question of whether I would view the proposed testing as beneficial is immaterial, given that my role is one of appellate review of the Prothonotary as the decision-maker, in which I must be governed by the applicable standard of review. The Prothonotary framed her analysis as an application of the *Eli Lilly* test and did not reference these

older authorities. However, I do not understand Apotex to be arguing that she erred in that regard and, in any event, I would find no such error.

[22] Indeed, Apotex acknowledges that the Prothonotary cited *Eli Lilly* and correctly recited the test set out in paragraph 8 thereof. Consistent with the further guidance in paragraph 10 of *Eli Lilly*, the Prothonotary also referenced the need to balance the competing interests between the party making the request and the party in possession of the sample, as well as considering what evidence would assist the Court in the trial of the action. However, Apotex submits that the Prothonotary's analysis in the Order demonstrates that she applied a test that departs from *Eli Lilly* and that this represents an error of law, reviewable on the standard of correctness.

[23] I accept that, if the record demonstrated that the Prothonotary applied a test different from the one she articulated in the Order, this could potentially represent an error of law reviewable on the correctness standard. However, a court exercising an appellate function must be cautious in finding an error of law in such circumstances, where it is difficult to extricate legal questions from factual ones (see *Housen* at para 36).

[24] In arguing that the wrong test was applied, Apotex relies on what it considers to be the key paragraph in the Prothonotary's analysis, which reads as follows:

> Apotex has not established that a test has been designed or exists that can determine whether at least 80% of the quinapril hydrochloride API converts into quinapril magnesium. It has also not established through Dr. Cima's evidence that there is some reasonable degree of likelihood that such testing can be designed and conducted.

[25] Apotex submits that this paragraph demonstrates that the Prothonotary applied a legal test, which required either that the testing proposed by Apotex had previously been carried out or that it be demonstrated that the proposed testing would work. While the test prescribed by *Eli Lilly* clearly does not impose such a requirement, I do not read the Order as demonstrating that the Prothonotary treated such a requirement as the test guiding her decision. Rather, as Pfizer submits, the above paragraph of the Order represents the Prothonotary arriving at factual conclusions based on the expert evidence, to which she applied the test identified elsewhere in the Order.

[26] Immediately following this paragraph, the Prothonotary states that, for this reason alone, the motion must fail, and further explains this reason by stating that there is no useful purpose in requiring Pfizer to provide samples in any amount if there is no identified testing process. She also states her conclusion that the design and implementation of such testing is speculative or, as described by counsel for Pfizer, aspirational. Again, I interpret this portion of the analysis as arriving at factual conclusions, which, upon application of the *Eli Lilly* test, resulted in dismissal of the motion. That is, evidence that is speculative does not establish a reasonable possibility that the proposed test will reveal something useful for the trier of fact. I do not regard this analysis as demonstrating the application of a legal test departing from *Eli Lilly*.

[27] Finally, Apotex notes that the last paragraph of the reasons in the Order states the following conclusion:

> As set out in *Apotex Inc v Eli Lilly Canada* at paragraph 8, the consideration is whether "there is a reasonable possibility that the proposed test will reveal something useful for the trier of fact". Taking into account the questions surrounding the testing process

> itself and the timing of the request, I am not satisfied that there is a reasonable possibility that reliable testing can be conducted that could/may reveal something useful in time for trial, or at all. Accordingly, the motion must be dismissed.

[28] While the Prothonotary states the applicable test from *Eli Lilly* in the first sentence of this paragraph, Pfizer submits that the second sentence imposes a requirement for "reliable" testing, which is inconsistent with the jurisprudence. I agree that the applicable test does not impose such a requirement. However, I again do not read this portion of the Order as stating a test that the Prothonotary thought must be met in order to grant the motion. In this final paragraph of the Prothonotary's reasons, she is summarizing the findings of fact at which she arrived in the Order. I read the reference to reliable testing as related to her analysis of the shortcomings of Dr. Cima's evidence surrounding quantitative testing.

[29] Having considered the parties' arguments under this issue, I find no error of law on the part of the Prothonotary. However, I must also consider whether the Prothonotary's analysis demonstrates errors of fact or mixed fact and law, which, applying the palpable and overriding error standard, would warrant interfering with the Order.

B. *Did the Prothonotary make palpable and overriding errors of fact or mixed fact and law?*

[30] Again referencing the above-quoted paragraph from the Order, which Apotex submits is key to the Prothonotary's analysis, it argues that the Prothonotary made a palpable and overriding error in finding that Apotex did not establish that a test has been designed or exists that can determine whether at least 80% of the quinapril hydrochloride API converts into

quinapril magnesium. Apotex submits that Dr. Cima's evidence established both that such a test existed and that there was a reasonable likelihood that such testing could be designed and conducted.

[31] In advancing this argument, Apotex refers to paragraphs 29 and 47 to 55 of Dr. Cima's affidavit. In paragraph 29, Dr. Cima opines that testing for the presence and quantification of magnesium quinapril can be performed on each batch of tablets in order to assess whether they contain quinapril magnesium and, if so, in what quantity. To similar effect, paragraph 47 states that determining whether Pfizer's tablets contain quinapril hydrochloride and/or quinapril magnesium, and in what proportions, can be accomplished by testing. Paragraph 49 then states that several tests are routinely used for solid state analyses of pharmaceutical ingredients and products that can be used to distinguish, characterize, and quantify an API as well as excipients.

[32] Apotex relies on these paragraphs, because they explicitly refer to the availability of quantitative testing that could be applied to Pfizer's tablets.

[33] Paragraph 49 also provides examples of common methods used for solid state analyses of pharmaceutical ingredients and products and, after several paragraphs that describe such methods, Dr. Cima states the following conclusions in paragraphs 54 and 55:

> 54. One or more of the methods described above may also be used to seek to assess the amount of a specific solid present in a sample by use of appropriate standards.
>
> 55. Thus, testing is very appropriate to determines if Pfizer's tablets contain quinapril hydrochloride and/or quinapril magnesium, and in what proportions.

[34] Following her review of Dr. Cima's evidence, including what the Prothonotary considered to be detailed descriptions of qualitative testing methods, the Prothonotary characterized his evidence as to the availability of quantitative testing as less certain, vague and indeterminate. In arriving at this conclusion, the Prothonotary referred in particular to Dr. Cima's paragraph 54.

[35] Apotex argues that this conclusion is unsupported by the evidence and, in focusing on paragraph 54, overlooks the other paragraphs (cited above) in which Dr. Cima (who was not cross-examined by Pfizer) opined that the quantification of conversion could be determined by the tests proposed. The Prothonotary referred to the evidence of Pfizer's expert, Dr. Williams, that establishing a quantitative test is generally more difficult than establishing a qualitative test, that he was unaware of any such test that could be applied to the Pfizer tablets, and that it may not be possible to develop an 80% conversion test. However, Apotex notes that Pfizer's expert, Dr. Williams, did not opine that a quantitative test could not be developed or performed.

[36] Apotex therefore submits that, given Dr. Cima's evidence that quantitative testing is available, and the absence of a more definitive opinion from Dr. Williams that it is not, the Prothonotary's conclusion (that Apotex has not established that such a test has been designed or exists) cannot be supported by the evidence and represents a palpable (meaning plainly wrong) error. Given the Prothonotary's statement that, for this reason alone, the motion must fail, Apotex argues that this error is also overriding (meaning determinative of the result).

[37] Having considered Apotex's arguments, and applying the relevant standard of review, I cannot conclude that the Prothonotary has erred as alleged. The analysis in the Order does not support a conclusion that the Prothonotary overlooked the paragraphs of Dr. Cima's affidavit that refer to the availability of quantitative testing. The Prothonotary expressly refers to all of the paragraphs on which Apotex relies, including the fact that they reference testing for quantification, with the exception of paragraph 55. However, paragraph 55 merely states a conclusion that is not materially different from the other paragraphs that are expressly cited. I find no error resulting from the absence of an express reference to paragraph 55.

[38] I appreciate Apotex's point that Dr. Williams does not opine that a quantitative test cannot be developed. However, he does express doubt in this regard in several places in his affidavit, including opining that it would be a "formidable technical challenge" to develop an 80% conversion test. Moreover, while it is clear that the Prothonotary takes Dr. William's doubts into account in her assessment of the evidence, I do not read the Order as turning on Dr. William's opinions.

[39] Rather, as I interpret the Order, it turned on what the Prothonotary considered to be the insufficiency of Dr. Cima's evidence. The Prothonotary recognized Dr. Cima's opinion that quantitative testing was available but did not find that opinion to be well supported. This interpretation is apparent from the distinction the Prothonotary draws between the evidence in Dr. Cima's affidavit related to qualitative testing and that related to quantitative testing. The Prothonotary notes the level of detail with which Dr. Cima describes how several testing methods can be used to perform qualitative testing. While Dr. Cima then refers (in paragraph 54)

to these methods also being used for quantitative testing, he does not provide a similar level of detail as to how each method can be used in that manner. When this distinction is combined with Dr. Cima's choice of language, in stating that one or more of these methods "may also be used to seek to assess" the quantity of a substance, I find no error in the Prothonotary's conclusion that his evidence on the availability of quantitative testing is vague and indeterminate.

[40] Apotex also argues that the Prothonotary erred in concluding that Apotex's motion was brought too late and that, as a result, Pfizer would be unjustly tasked with matters related to delivery of samples. Apotex submits that this conclusion is unsupported by any evidence that Pfizer would face difficulty in providing samples or attending testing within the time frames necessitated by the timing of the motion. Apotex acknowledges the late timing of the motion. However, it argues that any prejudice that might be occasioned by this timing will be experienced by Apotex, as a result of being unable to marshal evidence in accordance with the guidelines on experimental testing, prescribed by the Court's Case and Trial Management Guidelines for Complex Proceedings and Proceedings under the PM(NOC) Regulations [the Guidelines], or otherwise in time for trial.

[41] As an initial point, I note that, as identified earlier in these Reasons, the Prothonotary found that Apotex's evidence was insufficient to satisfy the *Eli Lilly* test and that, for that reason alone, the Rule 249 motion must fail. As such, any error in the Prothonotary's subsequent analysis of the timing of the motion would not be determinative, i.e. not an "overriding" error. I have nevertheless considered Apotex's argument that this portion of the Prothonotary's analysis is in error.

[42] Pfizer submits that, in assessing the Prothonotary's analysis, it is important to recognize her role as the case management judge of this 10-year-old action that will be proceeding to trial in January 2022. Pfizer argues that significant deference must be accorded to this type of case management decision, noting the conclusion of the Federal Court of Appeal in *Apotex Inc v Bristol-Myers Squibb Canada Co*, 2019 FCA 194 [*Bristol-Myers*] at para 8, that the prothonotary who was case managing that matter was entitled to arrive at a view of what was best for the progress of that particular proceeding. On this point, I agree with Apotex's submission that the standard of review does not change just because a case manager's decision is under review. Indeed, *Bristol-Myers* confirms at paragraph 4 that the standard of review prescribed by *Hospira Heathcare* applies. However, I also agree with Pfizer that the context in which a Prothonotary is making a case management decision is part of the factual matrix that can be taken into account in applying the standard of review.

[43] Taking into account that context, I also agree with Pfizer that the absence of evidence as to precisely how long it would take Apotex to develop the necessary quantitative test and then to perform the resulting testing does not support a conclusion that the Prothonotary erred. Dr. Williams opined that, even if an 80% conversion test could be developed, it would likely take several months of experimentation to achieve such a test. He also opined that it could then take many months to employ that test. I appreciate that, as Apotex submits, the time frames represented by these opinions are not particularly precise. However, against the backdrop of that evidence, the time frames contemplated by the Guidelines, and the fact that the Prothonotary was ruling on this motion approximately eight months before trial, I find no error in her analysis. That analysis did not turn on prejudice related to the degree of effort that the production of

samples might impose on Pfizer, but rather on the risk that it posed to the efficient progress of this matter towards trial. The consideration of such factors is consistent with the guidance in *Eli Lilly* that a Court considering a Rule 249 motion must consider the facts and balance factors relevant to the interests of the parties as well as the trier of fact (at para 10).

[44] Finally, I turn to Apotex's argument, with recourse to the express language of Rule 249, that provision of the requested samples is both necessary and expedient for the purpose of obtaining evidence relevant to this proceeding. It is undisputed that the documents produced by Pfizer do not directly address the question whether its products result from a process in which there is conversion to quinapril magnesium in a percentage claimed in the 347 Patent. Apotex submits that there is at least a possibility that the tests Dr. Cima proposes will reveal something useful for the trier of fact. It therefore argues that it should at least be permitted to try to obtain that evidence, both to allow it to present its case and to assist the trier of fact in better adjudicating the issues in this trial.

[45] In advancing that submission, Apotex raises for the Court's consideration what it describes as a "judicial cry for help" in *AB Hassle v Apotex Inc*, 2002 FCT 931, [2002] FCJ No 1221 (FCTD) [*AB Hassle*]. In deciding an application under the *Patented Medicines (Notice of Compliance Regulations)*, SOR/93-133, as in force at the relevant time, Justice Kelen was required to address patent claims concerned with a tablet composition or structure and the process for manufacturing the tablet (see para 10). After reviewing the parties' expert evidence, Justice Kelen expressed several conclusions, including the following paragraphs now emphasized by Apotex (at para 51):

> 51. Based upon the evidence, I conclude:
>
> ….
>
> 6. It is not possible to determine whether the allegation of non-infringement is justified based on speculation and conjecture by the experts. This is particularly frustrating when the best evidence, and probably the conclusive evidence, would be the results of analytical testing of the Apotex tablets themselves;
>
> 7. The overwhelming conclusion of the Court from the expert evidence is that the Apo-omeprazol tablets could have been analytically tested to identify the existence of the reactive layer or reactive material or spontaneous subcoating, and to obtain key technical information about its characteristics. Without this information, the experts are speculating, guessing, and "shadow-boxing"; and,
>
> 8. In a case of patent infringement it is highly discomforting for the Court to rely upon expert witnesses who are "shadow-boxing", and determine which expert witness won the "shadow-boxing" match.

[46] In response to Apotex's "shadow-boxing" argument, Pfizer submits that, if Apotex truly believed that samples were necessary to prove infringement, then it would not have waited 10 years before making its request. In support of this position, Pfizer notes that, in Apotex's Third Amended Reply and Defence to Counterclaim, it asserts that a skilled person can determine "whether a process falls within the claims of the 347 Patent before performing the process" and "without reference to the results of that process". In other words, in Pfizer's submission, Apotex has pleaded that the samples it seeks are not necessary to show infringement.

[47] In deciding this Rule 51 appeal of the Prothonotary's decision, the Court cannot know whether the Court at trial will face an evidentiary lacuna of the sort about which Justice Kelen expressed his frustration in *AB Hassle.* Rather, the Court must be guided by the standard of

review, applied to the Prothonotary's decision in the context of the record before her. As I have applied that standard and found no reviewable error, Apotex's appeal must be dismissed.

VII. **Costs**

[48] Apotex requests that, in the event it is successful on this Rule 51 motion, it be awarded costs of this motion and the motion below. Pfizer requests that this motion be dismissed with cost in its favour. As Pfizer has prevailed, my order will award it costs of this motion.

ORDER IN T-1660-11

THIS COURT'S ORDER is that:

1. The motion by the Plaintiffs/Defendants by Counterclaim for an order pursuant to Rule 51, appealing and setting aside the Order of Prothonotary Milczynski dated May 4, 2021, is dismissed.

2. The Defendants/Plaintiffs by Counterclaim shall have their costs of this motion.

"Richard F. Southcott"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1660-11
STYLE OF CAUSE:	BERNARD CHARLES SHERMAN AND APOTEX INC. v PFIZER CANADA INC., PFIZER INC. AND DOE CO. AND ALL OTHER ENTITIES UNKNOWN TO THE PLAINTIFFS WHICH ARE PART OF THE PFIZER GROUP OF COMPANIES
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