Federal Court  Cour fédérale

Date: 20160705

Docket: T-1440-14

Citation: 2016 FC 581

Ottawa, Ontario, July 5, 2016

PRESENT: The Honourable Mr. Justice Brown

BETWEEN:

BAYER INC. and
BAYER INTELLECTUAL PROPERTY GmbH

Applicants

and

FRESENIUS KABI CANADA LTD. and
THE MINISTER OF HEALTH

Respondents

PUBLIC JUDGMENT AND REASONS
(Confidential Judgment and Reasons Released May 27, 2016)

I. Nature of the Matter and Summary of Disposition

[1] This is an application by Bayer Inc. [Bayer] for an order pursuant to paragraph 6(5)(b) of the *Patented Medicine (Notice of Compliance) Regulations* [*PM (NOC) Regulations*] prohibiting the Minister of Health from issuing a notice of compliance [NOC] to Fresenius Kabi Canada Ltd. [Fresenius] for its proposed new drug for injection moxifloxacin hydrochloride [Fresenius-

moxifloxacin]. Prohibition is sought on the basis of infringement of Bayer's Canadian Patent No. 2,192,418 [the 418 Patent]. Bayer alleges that the Notice of Allegation [NOA] delivered by Fresenius dated May 5, 2014, is defective because it does not contain the "detailed statement" required by subparagraph 5(3)(b)(ii) of the *PM (NOC) Regulations*, and in any event, that the allegations in the NOA are not justified.

[2] Bayer's original application sought prohibition until the expiry of three Bayer patents, namely, Canadian Patent Nos. 1,340,114 [the 114 Patent], the 418 Patent, and 2,378,424 [the 424 Patent]. However, portions of Bayer's application concerning the 424 Patent were struck: *Bayer Inc v Pharmaceutical Partners of Canada Inc*, 2015 FC 388, which decision was upheld on appeal to this Court: *Bayer Inc v Pharmaceutical Partners of Canada Inc*, 2015 FC 797, and by the Federal Court of Appeal: *Bayer Inc v Fresenius Kabi Canada Ltd*, 2016 FCA 13.

[3] The 114 Patent expired on November 3, 2015. Infringement of the 114 Patent was not in issue.

[4] Therefore, the remaining issue is Fresenius' allegation that its new drug does not infringe the 418 Patent. Fresenius seeks regulatory approval for its proposed new drug by comparison with Bayer's AVELOX I.V.™, an antibacterial for use by adults to treat certain bacterial infections including those relative to community acquired pneumonia. Currently, Bayer's AVELOX I.V. ™ is the only moxifloxacin hydrochloride injection product approved for sale in Canada. The 418 Patent is listed on the Patent Register in respect of Bayer's AVELOX I.V. ™.

[5] Bayer alleges that infringement by Fresenius occurs during the manufacturing process of Fresenius-moxifloxacin, i.e., at an intermediate step or stage in the manufacturing process.

[6] The 418 Patent is presumed to be valid absent any proof to the contrary, of which there is none. Fresenius does not challenge the validity of the 418 Patent.

[7] For the reasons that follow, an order will issue prohibiting the Minister of Health from issuing a NOC to Fresenius for its proposed moxifloxacin hydrochloride product for injection until the expiry of the 418 Patent. The determinative issue is the sufficiency of the NOA; I have found the NOA defective, because it does not contain the "detailed statement of legal and factual basis" for the alleged non-infringement which is required by law, namely subparagraph 5(3)(b)(ii) of the *PM (NOC) Regulations*. Had I not found the NOA defective, I would have dismissed this application because Bayer failed to establish on a balance of probabilities that the allegations of non-infringement are not justified.

II. Facts

The Patent

[8] The relevant 418 Patent claims the monohydrate form of moxifloxacin hydrochloride, or 1-cyclopropyl-7-[(S,S)-2,8-diaza-bicyclo[4,3,0]non-8-yl]-6-fluoro-8-methoxy-1,4-dihydro-4-oxo-3-quinolinecarboxylic acid hydrochloride [CDCH], in the following terms:

CLAIMS:

1. A monohydrate of CDCH, of the formula […] which has a characteristic peak at 168.1 ppm in the 13C-NMR spectrum and a band at 2[θ]=26.7 in the X-ray diffractogram.

2. A monohydrate of CDCH according to claim 1 in the prismatic crystal form.

3. A process for the preparation of the CDCH monohydrate according to claim 1 or 2, wherein anhydrous CDCH is treated with an amount of water, which is at least sufficient for thorough mixing and hydration, until the stoichiometric content of water of crystallization has been absorbed and conversion of the crystals is complete, after which the crystals of the monohydrate thus obtained are separated off and the adsorbed water present is removed.

4. A process according to claim 3, wherein a suspension of the anhydrous CDCH .in an aqueous medium is stirred until hydration and conversion of the crystals is complete.

5. A process according to claim 3, wherein in preparing the monohydrate in the form of prisms, anhydrous CDCH or CDCH monohydrate in the form of needles is dissolved in a medium composed of water and a solvent which medium has a water content which is stoichiometrically sufficient but limited to 10% and the solvent is then removed.

6. A process according to claim 5, wherein the solvent component of the medium is ethanol.

7. A process according to claim 3, wherein anhydrous CDCH is exposed to humidity until the crystals have been converted quantitatively.

8. A medicament comprising a monohydrate of CDCH according to claim 1 or 2 together with a pharmaceutically acceptable diluent or carrier.

9. A medicament according to claim 8 for use in the treatment of bacterial infections.

10. An antibacterial composition comprising a monohydrate of CDCH according to claim 1 or 2 together with a suitable diluent or carrier.

11. An antibacterial composition according to claim 10 for the preservation of materials.

> 12. Use of a monohydrate of CDCH according to claim 1 or 2 for the treatment of bacterial infections.
>
> 13. Use of a monohydrate of CDCH according to claim 1 or 2 for the preservation of materials.
>
> 14. Use of a monohydrate of CDCH according to claim 1 or 2 in the preparation of a medicament for the treatment of bacterial infections.

[9] The NOA dated May 5, 2014, regarding the 418 Patent alleges that Claims 3-7, 11 and 13 are not relevant and need not be addressed under the *PM (NOC) Regulations*. With respect to the remaining claims, the NOA alleges, that no claims for the medicinal ingredient, formulation, dosage form and use of the medicinal ingredient in those claims would be infringed by Fresenius making, constructing, using or selling Fresenius-moxifloxacin.

The Notice of Allegation

[10] Note that the NOA was originally delivered by Pharmaceutical Partners of Canada [PPC]. Fresenius has since stepped into the shoes of PPC.

[11] The relevant portions of the NOA are:

> **II. Non-infringement of claims 1, 2, 8, 9, 10, 12 and 14. No use of monohydrate**
>
> PPC alleges, pursuant to section 5(1)(b)(iv) of the NOC Regulations that no claim for the medicinal ingredient, formulation, dosage form or use of the medicinal ingredient in claims 1, 2, 8, 9, 10, 12 and 14 of the 418 Patent will be infringed by PPC making, constructing, using or selling PPC-moxifloxacin.
>
> An essential element of all claims of the 418 Patent is CDCH monohydrate. The only independent claim, Claim 1 requires a monohydrate of CDCH which has a characteristic peak at 168.1

ppm in the ^{13}C-NMR spectrum and a band at 2θ=26.7 in the X-ray diffractogram.

As PPC-moxifloxacin is a solution, it will not contain CDCH (moxifloxacin hydrochloride) in any crystalline form. Once the moxifloxacin is dissolved in solution, no crystal structure exists and the product will not have [essential patent claim C-NMR and XRPD spectra]. PPC-moxifloxacin will not contain moxifloxacin in crystalline form let alone in the claimed monohydrate form and therefore will not infringe any of the claims of the 418 Patent.

Further, characteristics of a crystalline form and differences in crystalline form have no bearing on the final product in solution. The solid form of the API used to produce PPC-moxifloxacin is therefore trivial and merely incidental to PPC-moxifloxacin.

In addition, PPC-moxifloxacin does not use the claimed monohydrate form of CDCH. Rather, it uses a different form of moxifloxacin. Specific details of the PPC formulation, API and product will be provided under a confidentiality agreement. PPC-moxifloxacin will not contain moxifloxacin monohydrate […]. Moxifloxacin monohydrate will not be used in the manufacture of PPC-moxifloxacin or in the manufacture of the moxifloxacin API used in the manufacture of PPC-moxifloxacin.

Finally, to the extent that Bayer may assert that the claims of the 418 Patent extend beyond the claimed monohydrate form of moxifloxacin to include other forms of moxifloxacin, PPC relies on the principle in *Gillette Safety Razor Company v. Anglo American Trading Company* (1913), 30 R.P.C. 465, such that should the claims include prior art uses, they are invalid for reading on the prior art. Specifically, the product PPC intends to sell will contain an old and known form of moxifloxacin. Thus, if PPC infringes the 418 Patent, then the 418 Patent is invalid.

Further, PPC does not use the prismatic crystal form of claim 2; nor does it use the processes of claims 3-7; nor does it seek approval for compositions and uses for the preservation of materials of claims 11 and 13.

Accordingly, no claim for the medicinal ingredient, formulation, dosage form or use of the medicinal ingredient in claims 1-14 of the 418 Patent will be infringed by PPC making, constructing, using or selling PPC-moxifloxacin.

[emphasis added]

[12] **[……..Redacted……**

……

……

……

…….].

[13] The NOA alleges Fresenius would not infringe the 418 Patent on the moxifloxacin hydrochloride monohydrate through making, constructing, using or selling Fresenius-moxifloxacin. Fresenius alleges its product is in solution form, which cannot contain the crystalline form required by Claim 1 of the 418 Patent. Moreover, Fresenius alleges it would not use the monohydrate moxifloxacin specified by the 418 Patent in its manufacturing of Fresenius-moxifloxacin or in the manufacture of the active pharmaceutical ingredient used in the manufacture of Fresenius-moxifloxacin.

Non Disclosure of Offshore Manufacture and Importation of Fresenius-moxifloxacin

[14] Fresenius did not disclose in its NOA the fact that its proposed new drug is to be manufactured, processed and packaged offshore and imported into Canada. Instead, Fresenius disclosed its offshore manufacture and importation of Fresenius-moxifloxacin to Bayer only after Bayer commenced these proceedings, and then only after the parties entered into a confidentiality agreement.

[15] However, Fresenius in its NOA stated that the solid form of the active pharmaceutical ingredient used to produce Fresenius-moxifloxacin was “trivial and merely incidental” to

Fresenius-moxifloxacin. Fresenius says the words “trivial and merely incidental” are words from which Bayer should have known that the drug in question would be manufactured offshore and imported into Canada. Fresenius says this because these words are found in decisions of this Court under the *PM (NOC) Regulations* and under the *Patent Act*, RSC 1985, c P-4, in which proposed new drugs were manufactured offshore for importation into Canada. These decisions interpret the *Saccharin Doctrine* to which Fresenius did not refer in its NOA, and which will be discussed in detail later in these Reasons.

III. Issues

[16] There are essentially two issues in this application:

1. Whether Fresenius’ NOA dated May 5, 2014, is defective in that it does not contain the necessary “detailed statement” required by subparagraph 5(3)(b)(ii) of the *PM (NOC) Regulations*; and
2. In the alternative, whether Bayer has shown on a balance of probabilities that Fresenius’ allegations of non-infringement are not justified.

Issue 1: Whether Fresenius’ Notice of Allegation dated May 5, 2014, is defective

[17] In my respectful view, Fresenius’ NOA is defective because it fails to satisfy the requirement of subparagraph 5(3)(b)(ii) of the *PM (NOC) Regulations*: the NOA does not contain “a detailed statement of the legal and factual basis” on which it was sought. The NOA fails to satisfy the legal tests established by this Court and by the Federal Court of Appeal construing what is meant by “detailed statement”.

[18] Specifically, while Fresenius alleges in its NOA that it will not infringe the 418 Patent, it does not say whether non-infringement will take place in Canada, or offshore where it will be made for importation into Canada. The essence of Fresenius' allegation of non-infringement is as follows:

> Moxifloxacin monohydrate will not be used in the manufacture of PPC-moxifloxacin [Fresenius-moxifloxacin] or in the manufacture of the moxifloxacin API [active pharmaceutical ingredient] used in the manufacture of PPC-moxifloxacin.

[19] Bayer, on the other hand and as noted, argues that Fresenius uses Bayer's patented moxifloxacin hydrochloride monohydrate as part of or as an intermediate in the manufacturing process of Fresenius-moxifloxacin.

[20] Fresenius' argument is that the drug to be sold in Canada does not itself infringe the 418 Patent, a point conceded by Bayer in that the imported drug for which the NOC is sought does not contain Bayer's patented product.

[21] In the alternative however, Fresenius argues there is no infringement because the drug is manufactured outside Canada and imported into Canada. In addition, Fresenius argues that even if the patented substance is used or appears during the manufacturing process outside Canada, such use is a "trivial and merely incidental" use of the product which is insufficient for the Court to find infringement by importation.

[22] However, as noted above, Fresenius did not disclose in its NOA the facts of manufacture offshore and importation. It disclosed these facts only after Bayer initiated these proceedings and

only then after a confidentiality agreement was obtained. This is a point of contention to which I will return. Fresenius' NOA is dated May 5, 2014. Bayer's Notice of Application is dated June 18, 2014 (amended July 31, 2014). A confidentiality order was issued July 21, 2014. Fresenius' disclosure of the facts of manufacture abroad and importation took place when it sent Bayer material from its Abbreviated New Drug Submission [ANDS] on July 16, 2014 pursuant to the agreed upon confidentiality order.

[23] Fresenius' disclosure of the offshore manufacture and importation of its proposed drug into Canada (albeit not made in its NOA) raises the so-called *Saccharin Doctrine* (after *Saccharin Corp v Anglo-Continental Chemical Works, Ltd* (1900), 17 RPC 307 (HCJ) [*Saccharin*]), by which importers of products manufactured outside of Canada infringe Canadian patents if there is a "strong link" between the use of the patented product abroad and the product imported into Canada: *Pfizer Canada Inc v Canada (Health)*, 2007 FC 898 [*Pfizer-Atorvastatin*] at para 91. Infringement by importation arises even where the product ultimately imported into Canada does not infringe the Canadian patent. Indeed, the *Saccharin Doctrine* comes into play where there is no infringement by the imported product itself, in this case a drug, but where nonetheless the offshore manufacturing infringes the Canadian patent by using or producing the patented product offshore, after which the drug is then imported into Canada.

[24] The Supreme Court of Canada confirmed the application of the *Saccharin Doctrine* in Canadian patent law: *Monsanto Canada Inc v Schmeiser*, 2004 SCC 34 [*Monsanto*]. The Court said the rule is an "expansive" one, and at para 43 stated that "[i]nfringement through use is thus possible even where the patented invention is part of, or composes, a broader unpatented

structure or process". The dissent confirmed at para 155: "[i]t is well established that the use or sale of unpatented subject matter may still infringe a patent where the unpatented subject matter is made employing a patented process: *Saccharin Corp* v. *Anglo-Continental Chemical Works, Ld.* (1900), 17 R.P.C. 307 (H.C.J.); *F. Hoffmann-Laroche, supra*, at p. 415; *Wellcome Foundation Ltd. v. Apotex Inc.* (1991), 39 C.P.R. (3d) 289 (F.C.T.D.); *American Cyanamid Co. v. Charles E. Frosst & Co.* (1965), 29 Fox Pat. C. 153 (Ex. Ct.)" [emphasis in original]. The *Saccharin Doctrine* has been recognized to apply to infringement by importation: for example, *Pfizer-Atorvastatin* at paras 80-88.

[25] It is also well established that use of a patented substance at an intermediate step or stage in the production of a proposed new drug constitutes infringement for the purposes of "making, constructing, using or selling" in subparagraph 5(1)(b)(iv) of the *PM (NOC) Regulations*. See, for example, the Federal Court of Appeal's decision in *Abbott Laboratories v Canada (Minister of Health)*, 2006 FCA 187 at para 16:

> The phrase "making, constructing, using or selling" in subparagraph 5(1)(b)(iv) describes a range of activities that is broader than merely including a patented substance in the proposed new drug. In my view, that phrase is broad enough to include the use of the patented substance at an intermediate stage in the production of the proposed new drug. I reach that conclusion based on the ordinary and grammatical meaning of the phrase. I see nothing in the purpose or object of the *NOC Regulations* that compels a narrower interpretation.

And to the same effect: *Abbott Laboratories v Canada (Minister of Health)*, 2007 FCA 73 at para 4.

[26] There is no dispute that offshore manufacture and importation of Fresenius' drug gives rise to different legal and factual tests relating to non-infringement by importation as per the *Saccharin Doctrine*, as opposed to the tests for non-infringement in Canada. Fresenius' NOA did not set out any detail of the legal basis on which an allegation of non-infringement by importation could be based. However, a major argument advanced by Fresenius both in its written and oral pleadings was that the imported drug did not infringe by importation.

[27] In fact, given the new drug does not infringe the 418 Patent, a point Bayer conceded, infringement by importation became the major issue in this proceeding.

[28] This situation gives rise to the first issue on this Application: whether Fresenius should have alleged non-infringement by importation in its NOA with respect to its proposed importation into Canada of a new drug manufactured and processed offshore. That is, was Fresenius required to state the factual and legal details of the basis for its alleged non-infringement by importation in the required "detailed statement of the legal and factual basis" as interpreted in the case law? This requires an examination of the *PM (NOC) Regulations* and the authorities on point.

(1) The *PM (NOC) Regulations* require a "detailed statement" of all factual and legal issues in a NOA

[29] The starting point are the *PM (NOC) Regulations* themselves of which in this context subsection 5(3) is most relevant:

5 (1) <u>If a second person files a submission for a notice of</u>	5 (1) <u>Dans le cas où la seconde personne dépose une</u>

compliance in respect of a drug and the submission directly or indirectly compares the drug with, or makes reference to, another drug marketed in Canada under a notice of compliance issued to a first person and in respect of which a patent list has been submitted, the second person shall, in the submission, with respect to each patent on the register in respect of the other drug,	présentation pour un avis de conformité à l'égard d'une drogue, laquelle présentation, directement ou indirectement, compare celle-ci à une autre drogue commercialisée sur le marché canadien aux termes d'un avis de conformité délivré à la première personne et à l'égard de laquelle une liste de brevets a été présentée — ou y fait renvoi —, cette seconde personne doit, à l'égard de chaque brevet ajouté au registre pour cette autre drogue, inclure dans sa présentation :
(a) state that the second person accepts that the notice of compliance will not issue until the patent expires; or	a) soit une déclaration portant qu'elle accepte que l'avis de conformité ne sera pas délivré avant l'expiration du brevet;
(b) allege that	b) soit une allégation portant que, selon le cas :
(i) the statement made by the first person under paragraph 4(4)(d) is false,	(i) la déclaration présentée par la première personne aux termes de l'alinéa 4(4)d) est fausse,
(ii) the patent has expired,	(ii) le brevet est expiré,
(iii) the patent is not valid, or	(iii) le brevet n'est pas valide,
(iv) no claim for the medicinal ingredient, no claim for the formulation, no claim for the dosage form and no claim for the use of the medicinal ingredient would be infringed by the second person making, constructing, using or selling the drug for which the submission is filed.	(iv) elle ne contreferait aucune revendication de l'ingrédient médicinal, revendication de la formulation, revendication de la forme posologique ni revendication de l'utilisation de l'ingrédient médicinal en fabriquant, construisant, utilisant ou vendant la drogue pour laquelle la présentation est déposée.

…	…
(3) A second person who makes an allegation under paragraph (1)(b) or (2)(b) shall	(3) La seconde personne qui inclut l'allégation visée à l'alinéa (1)b) ou (2)b) doit prendre les mesures suivantes :
(a) serve on the first person a notice of allegation relating to the submission or supplement filed under subsection (1) or (2) on or after its date of filing;	a) signifier à la première personne un avis de l'allégation à l'égard de la présentation ou du supplément déposé en vertu des paragraphes (1) ou (2), à la date de son dépôt ou à toute date postérieure;
(b) include in the notice of allegation	b) insérer dans l'avis de l'allégation :
…	…
(ii) a detailed statement of the legal and factual basis for the allegation;	(ii) un énoncé détaillé du fondement juridique et factuel de l'allégation;
…	…
[emphasis added]	[soulignement ajouté]

[30] Subparagraph 5(1)(b)(iv) requires that a second person requesting a NOC in respect of a drug listed on the Patent Register "5(1)(b) … shall … allege that … (iv) no claim for the medicinal ingredient, no claim for the formulation, no claim for the dosage form and no claim for the use of the medicinal ingredient would be infringed by the second person making, constructing, using or selling the drug for which the submission is filed."

[31] Further, and also material to the present discussion, where a NOA is filed, subparagraph 5(3)(b)(ii) requires that "(3) [a] second person who makes an allegation under paragraph (1)(b)

… shall … (b) include in the notice of allegation… (ii) a detailed statement of the legal and factual basis for the allegation."

[32] Stripped to their essentials, the *PM (NOC) Regulations* require Fresenius to set out "a detailed statement of the legal and factual basis for the allegation" of non-infringement. There is no dispute that Fresenius was obliged to set out such "detailed statement". However, the parties dispute the application of this law to the present case. I turn to the authorities.

(2) Jurisprudence requires a "detailed statement": i.e., factual and legal issues must be set out in a NOA

A – The Jurisprudence

[33] The requirement to set out "a detailed statement" of allegations of non-infringement has been considered on several occasions by this Court and the Federal Court of Appeal, as set out below.

[34] *Bayer Inc v Cobalt Pharmaceuticals Company*, 2013 FC 1061 [*Cobalt*], per Hughes J. stands for the proposition that a second person must raise "all the facts and legal arguments upon which it relies in support of its allegations." Importantly, the decision says that the second person cannot craft new arguments, or raise new allegations or new facts or new prior art documents not set out in its NOA. This Court observed that this may seem draconian, but that it is equally draconian for the first person who decided to institute proceedings to face shifting allegations and facts:

GOING BEYOND THE NOTICE OF ALLEGATION

> [34] It has been firmly established by the Court of Appeal that the second person, a generic such as Cobalt, has an obligation in its Notice of Allegation to raise all the facts and legal arguments upon which it relies in support of its allegations. It cannot craft new arguments, or raise new allegations or new facts or new prior art documents not set out in the Notice of Allegation. (*AB Hassle v Canada (Minister of National Health and Welfare*) (2000), 7 CPR (4th) 272, at paras 21-24; *Proctor & Gamble Pharmaceuticals Canada, Inc v Canada (Minister of Health*), 2002 FCA 290, at paras 21-26.
>
> [35] While this may seem draconian since, undoubtedly, new matters may be raised as experts are consulted and evidence emerges, it is equally draconian for the first person who decides to institute proceedings to face shifting allegations and facts. The process is in need of change, but no interested person seems to be pressing for that change.
>
> [36] As matters stand now, the Court must reject arguments based on facts or documents not set out in the Notice of Allegation nor can the Court address new allegations.
>
> [emphasis added]

[35] *AB Hassle v Canada (Minister of National Health and Welfare)* (2000), 7 CPR (4th) 272 (FCA), per Stone JA [*AB Hassle*], is perhaps one of the most frequently cited cases of the Federal Court of Appeal regarding the required "detailed statement". It stands for the proposition that the NOA is a pivotal step in the process, and puts the patentee on notice of the grounds on which the second person considers that the making, constructing, using or selling of the drug will not infringe. The theory of the regime is to enable the patentee to confidently decide whether to resist the issuance of a NOC. The NOA casts a long shadow over proceedings such as those before the Court now. Indeed it is upon the content of the NOA that patentees must decide whether or not to commence a section 6 proceeding and to assess its chances of success or failure. Therefore, the Federal Court of Appeal concluded that a second person must do what, in

fact, paragraph 5(3)(a) requires, i.e., set forth in its NOA a "detailed statement" of "the legal and factual basis" for its allegation. The Court emphasized that the second person must do so in a sufficiently complete manner as to enable the patentee to assess its course of action in response to the allegation. The Court of Appeal said that the regulatory intent appears to be that the entire factual basis be set forth in the NOA, adding that the second person could not cure deficiencies nor add to the facts set forth in its "detailed statement":

> [19] The detailed statement is not a pleading per se but represents a pivotal step in the process leading up to the issuance of an NOC. By taking that step the second person puts the patentee on notice of the grounds on which he or she considers that the making, constructing, using or selling of the drug will not infringe the second person's patent rights during the unexpired term of the patent. In theory, this procedure ought to enable the patentee to confidently decide within the 45-day time limit whether to resist the issuance of an NOC.
>
> [20] While it is true that the detailed statement is not filed in a section 6 proceeding, it nevertheless casts a long shadow over that proceeding. Indeed, it is upon the content of that statement that the patentee must decide whether or not to commence a section 6 proceeding and to assess its chances of success or failure.
>
> [21] In my view, all of these considerations suggest that a second person must do what, in fact, paragraph 5(3)(a) requires, i.e. set forth in the detailed statement "the legal and factual basis" for the paragraph 5(1)(b) allegation and to do so in a sufficiently complete manner as to enable the patentee to assess its course of action in response to the allegation. See *Pharmacia Inc. v. Canada (Minister of National Health and Welfare)* (1994), 58 C.P.R. (3d) 209 (F.C.A.) at 216, per Strayer J.A.
>
> [23] The respondent suggests that the list of prior art in the detailed statement was not intended to be exhaustive, hence the presence of the word "including", so that the way was left open to add to that list in the section 6 proceeding. I am of the view, however, that paragraph 5(3)(a) does not contemplate such possibility. The intent appears to be that the entire factual basis be set forth in the statement rather than be revealed piecemeal when some need happens to arise in a section 6 proceeding. This Court has cautioned persons in the position of the respondent that they

> assume a risk that a particular allegation may not be in compliance with the Regulations and that the deficiency cannot be cured by the Court in a section 6 proceeding.
>
> [24] … This Court decided in *Hoffmann-LaRoche Ltd. v. Canada (Minister of National Health and Welfare) (1996),* 70 C.P.R. (3d) 1, that a second person could not in a section 6 proceeding add to the facts that were set forth in its detailed statement.
>
> [emphasis added]

[36] *Proctor & Gamble Pharmaceuticals Canada, Inc v Canada (Minister of Health),* 2002 FCA 290 per Rothstein JA [*Proctor & Gamble*], is a further decision of the Federal Court of Appeal emphasizing that the second person's NOA must provide all the facts it intends to rely upon in subsequent prohibition proceedings, and cannot rely on facts that exceed those laid out in its "detailed statement":

> [22] However, the notices of allegation and the detailed statement of legal and factual basis for the allegation must provide all the facts the generic producer intends to rely upon in subsequent prohibition proceedings. It cannot rely on facts that exceed those laid out in its detailed statement. See *Merck Frosst Canada Inc. v. Canada (Minister of Health)* (2002)12 C.P.R. (4th) 447 at paragraph 19 per Stone J.A.
>
> [emphasis added]

[37] *Astrazeneca AB v Apotex Inc* 2005 FCA 183, per Evans JA [*Astrazeneca*], confirms that a NOA is insufficient if it leaves the patent holder having to guess at the real grounds for the allegation that the patent would not be infringed:

> [12] Third, a detailed statement of the bases of an allegation must be sufficiently complete to enable a patentee to make an informed decision as to whether to respond to the allegation by instituting proceedings for an order of prohibition: *AB Hassle v. Canada (Minister of National Health and Welfare)* (2000), 7 C.P.R. (4th) 272 (F.C.A) at para. 21. In *SmithKline Beecham Inc. v. Apotex*

> *Inc.* (2001), 10 C.P.R. (4th) 338 (F.C.A.) at para. 27, Noël J.A. held that the detailed statement in that case was not insufficient "in the sense that it left SmithKline having to guess at the real grounds for the respondents' allegation that the patent would not be infringed."

[38] *Novopharm Ltd v Pfizer Canada Inc*, 2005 FCA 270, per Malone JA [*Pfizer*], is a further enunciation of the purpose of a NOA which is that a NOA must be sufficient to make the patentee fully aware of the grounds on which the generic claimed the patent would not be infringed if a NOC issued. In addition, there are limits to what must be disclosed. A second person is not required to anticipate all possible grounds of infringement including speculative theories:

> [4] In its more recent jurisprudence, this Court has repeatedly stated that the test of the adequacy of a NOA is whether the detailed statement was sufficient to make the patentee (Pfizer) fully aware of the grounds on which the generic (Novopharm) claimed that the relevant patent would not be infringed if a NOC was issued by the Minister (see *AB Hassle v. Canada (Minister of National Health and Welfare)* (2000), 7 C.P.R. (4th) 272 (F.C.A.) at paragraph 17, *per* Stone J.A. (*AB Hassle 1*); *SmithKline Beecham Inc. v. Apotex Inc.* (2001), 10 C.P.R. (4th) 338 (F.C.A.) at paragraph 26, *per* Noël J.A.; and also *Pfizer Canada Inc. v. Apotex Inc*. (2004), 38 C.P.R. (4th) 400 (F.C.A.) at paragraph 24, *per* Evans J.A.).
>
> …
>
> [16] … The legal test of adequacy does not require [the generic] to anticipate all possible grounds of infringement, including [the first person's] speculative theory that the dihydrate could be used in the process of manufacturing [the second person's] bulk monohydrate. As noted by Evans J.A. in *AstraZeneca v Apotex Inc.* 2005 FCA 183 … :
>
> > A second person [the generic] should not be required to anticipate every theory of possible infringement, however speculative, in the detailed statement supporting its allegations.

[emphasis added]

[39] *Bayer Inc v Cobalt Pharmaceuticals Company*, 2015 FCA 116, on appeal from Hughes J.'s decision in *Cobalt* is the Federal Court of Appeal's most recent statement on what must be included in the detailed statement required in a NOA. The Federal Court of Appeal held that it is not open for a second person in prohibition proceedings under the *PM (NOC) Regulations* to stray from its NOA.

> [61] It is not open to Cobalt in prohibition proceedings under the NOC Regulations or appeals therefrom to stray from its notice of allegation: *Procter & Gamble Pharmaceuticals Canada, Inc. v. Canada (Minister of Health)*, 2002 FCA 290, [2003] 1 F.C. 402 at paragraph 22. Therefore, Cobalt's submission must be rejected.
>
> [emphasis added]

B – Summary of the cases

[40] From the foregoing, I conclude that Fresenius' NOA must allege all the facts and legal arguments upon which it intends to rely in support of its allegations. In a word, Fresenius must do what paragraph 5(3)(a) requires it to do, namely to set out in its NOA a "detailed statement" of "the legal and factual basis" for its allegations. However, a second person is not required to anticipate every theory of possible infringement, however speculative, in its detailed statement. Those who file inadequate NOAs must assume their own risks when it comes to attacks on the adequacy of such allegations once prohibition proceedings are commenced.

[41] The test of the adequacy of a NOA is whether the detailed statement is sufficient to make the patentee fully aware of the grounds on which the generic claimed that the relevant patent

would not be infringed if a NOC is issued. The first person must be informed in a sufficiently complete manner to enable it to confidently decide and assess its course of action and chances of success or failure.

[42] Conversely, the second party may not craft new arguments, or raise new allegations or facts not set out in the NOA. A second person may not cure deficiencies in the NOA. It may not stray from its NOA.

[43] The Courts have cautioned that second persons assume a risk that a particular allegation may not comply with the *PM (NOC) Regulations* and that such a deficiency cannot be cured by the Court in a section 6 proceeding. While this may seem draconian, it is equally draconian for the first person who decides to institute proceedings to face shifting allegations, legal arguments, and facts.

(3) Application of *PM (NOC) Regulations* and Case Law to the Fresenius NOA

[44] With these principles in mind, I turn to the NOA in this case, the material parts of which state:

> … PPC-moxifloxacin will not contain moxifloxacin in crystalline form let alone in the claimed monohydrate form and therefore will not infringe any of the claims of the 418 Patent.
>
> Further, characteristics of a crystalline form and differences in crystalline form have no bearing on the final product in solution. <u>The solid form of the API used to produce PPC-moxifloxacin is therefore trivial and merely incidental to PPC-moxifloxacin.</u>
>
> In addition, PPC-moxifloxacin does not use the claimed monohydrate form of CDCH. Rather, it uses a different form of

> moxifloxacin. Specific details of the PPC formulation, API and product will be provided under a confidentiality agreement. PPC-moxifloxacin will not contain moxifloxacin monohydrate […]. Moxifloxacin monohydrate will not be used in the manufacture of PPC-moxifloxacin or in the manufacture of the moxifloxacin API used in the manufacture of PPC-moxifloxacin.

[45] As noted already, Fresenius' NOA does not detail the fact that the drug for which it seeks a NOC is manufactured and processed outside Canada. It does not set out the fact that the drug is imported into Canada from abroad. Fresenius does not set out in detail that it relies on the legal principles surrounding non-infringement by importation as developed in the *Saccharin Doctrine*.

[46] Given the law cited above, on the facts of this case, Fresenius' NOA is defective on its face because it does not do what the *PM (NOC) Regulations* require it to do – it does not provide the necessary detailed statement either of the facts or of the law relied upon by Fresenius in relation to its alleged non-infringement by importation.

[47] Fresenius takes a different position and advances several reasons to support its argument that its NOA is not defective.

(4) Did Fresenius make adequate disclosure by use of "code words" for non-infringement by importation?

[48] Fresenius says it made adequate disclosure by stating in the NOA that the "[s]olid form of the API used to produce PPC-moxifloxacin is therefore trivial and merely incidental to PPC-moxifloxacin." Fresenius argues it was not required to make more fulsome disclosure in referring to non-infringement by importation than its use of these indirect allusions to what may or may

not have been the infringement or non-infringement by importation rules. While Fresenius nowhere states its new drug is manufactured offshore, nor that the new drug is to be imported into Canada, and does not detail any factual or legal arguments concerning non-infringement by importation, it says Bayer, indeed anybody in the field, should have known from these words that the drug was manufactured abroad and imported into Canada. It says the use of what appear to be code words ("trivial and merely incidental") gave sufficient notice of non-infringement by importation to Bayer.

[49] The words "trivial" and "merely incidental" do appear in patent cases relating to non-infringement by importation. The concepts of trivial and non-essential use appear in the decision of Justice Gauthier, as she then was, in *Eli Lilly and Company v Apotex Inc*, 2009 FC 991 at paras 327 and 355, where the Court reviews the law of infringement by importation and the *Saccharin Doctrine*. This decision was subsequently approved by the Federal Court of Appeal in *Eli Lilly and Company v Apotex Inc*, 2010 FCA 240 at para 19. These words also appear in the decision of Justice Snider in *Pfizer-Atorvastatin* at paras 77 ("merely incidental") and 90 ("incidental, non-essential, or could readily be substituted"), as will be discussed later, as they do in the original *Saccharin* decision itself.

[50] However, in my respectful view, the use of code words in Fresenius' NOA does not satisfy the statutory duty imposed on Fresenius by the *PM (NOC) Regulations* to set out a "detailed statement of the legal and factual basis" for its allegations. In my respectful view, these words provide no "detail" at all. They may constitute hints or clues as to the basis(es) which Fresenius might or might not be using to support an allegation of non-infringement. But in my

view, giving clues is not enough to satisfy the mandatory and direct regulatory requirement to provide a "detailed statement".

[51] Neither do these code words satisfy the jurisprudence. The authorities make it clear that all the facts and legal arguments must be set out in the "detailed statement": *Cobalt* at para 34, *AB Hassle* at para 23, *Proctor & Gamble* at para 22, *Pfizer* at para 4. In my view, the material facts and legal arguments relating to non-infringement by importation should have been present in, but contrary to the *PM (NOC) Regulations* are absent from, this NOA. This Court insisting on more than vague clues or code words does not ask Fresenius to detail speculative theories of possible infringement. Fresenius is simply asked to detail the very non-infringement by importation which it says it intended to set out by using these code words in the first place.

[52] In my respectful view, Fresenius was obliged to set out in its "detailed statement" that the new drug is manufactured outside and imported into Canada. Fresenius should also have set out the legal basis of non-infringement by importation. The obligation to set out a detailed statement is conjunctive – both facts and law must be detailed. Failure to detail the factual basis put Fresenius offside the regulations; so did its failure to provide details of its legal basis.

[53] Nor do I agree that these code words satisfy the purposes of the NOA in terms of it being sufficient to make Bayer fully aware of the grounds on which the generic claims Bayer's patent would not be infringed if a NOC is issued: *AB Hassle* at para 19; *Pfizer* at para 4. Although it was Fresenius' submission, there is no evidence to support the proposition that Bayer, let alone anybody in the field, should have known from these words that Fresenius' new drug was

manufactured and processed outside and imported into Canada. I am not persuaded that Bayer could confidently decide if Fresenius' new drug would infringe (*AB Hassle* at para 19), let alone know that it would be imported or manufactured outside Canada. Nor am I satisfied in this case that Bayer knew or should have known that Fresenius was putting the *Saccharin Doctrine* into play: *AB Hassle* at para 19.

[54] For these reasons, in my respectful view, this NOA was not sufficiently detailed.

(5) Should Bayer have brought a motion to determine if Bayer could argue the NOA was insufficiently detailed if the new drug was imported?

[55] Fresenius argued that Bayer should have brought a motion to determine whether the NOA was sufficiently detailed, or what was meant by the code words. I disagree for several reasons. First, it was Fresenius' legal duty to provide a "detailed statement", which it did not do. Secondly, first persons have a short timeframe (45 days) within which to decide to challenge the issuance of a NOC which makes the bringing of such a motion, (presumably if that is possible prior to filing a prohibition application) difficult if not impossible. Most importantly, however and in my respectful view, requiring Bayer to guess at the factual and legal bases for non-infringement, launch a prohibition proceeding, and then move to find out what the NOA meant, turns the regulatory requirement on its head. Such a process relieves the second person of its direct regulatory duty and instead imposes a new obligation on first persons. In my view, the whole purpose of the *PM (NOC) Regulations'* requiring a "detailed statement" is to avoid just such guesswork, ambiguity and complexity. The obvious solution was for Fresenius to do that which the *PM (NOC) Regulations* required it to do in the first place, and which Fresenius failed

to do, namely, to provide a "detailed statement". As said by the Federal Court of Appeal in *AB Hassle v Canada (Minister of National Health and Welfare)* (2000), 7 CPR 272 (4th) at para 21:

> [21] … a second person must do what, in fact, paragraph 5(3)(a) requires, i.e. set forth in the detailed statement "the legal and factual basis" for the paragraph 5(1)(b) allegation and to do so in a sufficiently complete manner as to enable the patentee to assess its course of action in response to the allegation.

(6) Is post-NOA disclosure allowed under Justice Snider's decision in *Pfizer-Atorvastatin*?

[56] Fresenius relied heavily on *Pfizer-Atorvastatin*, a decision of Justice Snider, for the proposition that it did not need to disclose either the facts of importation and manufacture abroad, or the legal basis of its non-infringement by importation argument in its NOA. Fresenius says it was enough to disclose importation to Bayer, not in the NOA, but only after Bayer filed its Notice of Application and signed a confidentiality agreement. I disagree for several reasons.

[57] In my respectful view, a proper analysis of this argument starts with Justice Snider's reasons in *Pfizer-Atorvastatin*, where the Court stated:

> [32] Both parties referred to the following criteria set out in *Pfizer Canada Inc. v. Apotex Inc.*, (2004), 31 C.P.R. (4th) 214 (F.C.T.D.), 2003 FC 1428 at para. 32, aff'd (2004), 38 C.P.R. (4th) 400 (F.C.A.):
>
> > In assessing the adequacy of the NOA, the following guidance can be taken from a number of decisions of the Federal Court of Appeal, including *Bayer AG v. Canada (Minister of National Health and Welfare)* (1993), 51 C.P.R. (3d) 329 (F.C.A.); *Glaxo Group Ltd. v. Canada (Minister of National Health and Welfare)* (2000), 6 C.P.R. (4th) 73 at 81 (F.C.T.D.), aff'd (2001) 11 C.P.R. (4th) 417 (F.C.A.);

> – A bald assertion of non-infringement is insufficient.
>
> – It is permissible for the second person to withhold certain information regarding its formulation until subsequent to a confidentiality order being in place.
>
> – The NOA will be adequate if further disclosure elaborates on the basis for which the allegation of non-infringement was made such that there is sufficient evidence upon which to evaluate the allegation.

[58] Fresenius relies on the second and third bullets set out above. I will deal with each.

(7) The Second Bullet in *Pfizer-Atorvastatin*

[59] The second bullet says certain aspects of a non-infringement argument regarding a drug's formulation may be left out of a NOA provided they are subsequently revealed after the first person starts a prohibition proceeding and signs a confidentiality agreement:

> - It is permissible for the second person to withhold certain information regarding its formulation until subsequent to a confidentiality order being in place.

[60] At first blush, to be frank, this allowance may appear to offend the regulatory and jurisprudential requirement for a "detailed statement", because the starting principle is that a second person is under a duty to set out a detailed statement of its facts and legal issues on which it bases its non-infringement arguments; thereafter that detailed statement may not be expanded on.

[61] On the other hand, one may see that there may be legitimate business confidentiality issues concerning the formulation of a proposed new drug that may militate in favour of allowing a second person to withhold some drug formulation matter that is truly confidential. But confidentiality claims made in a NOA, with concomitant promises to disclose additional information if a prohibition proceeding is commenced, should not be permitted to withhold too much without offending the wish of the legislator who, it is noted, made no such exception. Without a limit on what a second person may conceal from the first, a NOA could become a sort of Trojan horse. That of course would be unfair to the first person who counts on the second person to make the full and adequate disclosure discussed above. Also, care should be given to the construction of confidentiality claims in a NOA because they have the obvious potential to undo much of what the legislator intended in enacting the *PM (NOC) Regulations* in the first place.

[62] It is my respectful view Justice Snider balanced the competing interests in the need to keep confidential formulation matters confidential, on the one hand, with the second person's undoubted duty to provide detailed disclosure in the "detailed statement" per the *PM (NOC) Regulations*. That is why, in my respectful view, Justice Snider limited the second bullet to the new drug's formulation, i.e., to "certain information regarding its formulation". Restricting claims of confidentiality to matters of "formulation" is understandable where it relates to truly confidential drug formulation matters. However, I am unable to see how protecting a confidential "formulation" of a new drug allows a party to then claim confidentiality over the fact a drug is manufactured offshore and imported into Canada. If it were so, non-infringement by importation, as an issue in prohibition proceedings, would never be disclosed in a NOA. In my view, that

would neither accord with the regulatory duty to provide a "detailed statement", nor the case law discussed above. I should add that Justice Snider's analysis and restricted view of what may be withheld was affirmed by the Federal Court of Appeal through its approval of the reasons of Justice Gauthier, as she then was, referred to earlier: *Eli Lilly and Company v Apotex Inc*, 2009 FC 991 at paras 327 and 355, upheld in *Eli Lilly and Company v Apotex Inc*, 2010 FCA 240 at para 19. I also note that Justice Snider's decision in *Pfizer Canada Inc v Apotex Inc*, 2003 FC 1428 at para 32 which Her Ladyship quotes and relies upon in *Pfizer-Atorvastatin*, was subsequently conceded to be correct by counsel and as such affirmed by the Federal Court of Appeal in 2004 FCA 398 at para 25.

[63] I turn now to the actual claim for confidentiality made in Fresenius' NOA. It states:

> Specific details of the PPC formulation, API and product will be provided under a confidentiality agreement.
>
> [emphasis added]

[64] In my respectful view, this claim is impermissibly broader than that allowed by Justice Snider in the second bullet in *Pfizer-Atorvastatin*, which carefully balanced and restricted such claims to matters of "formulation" in the following terms:

> It is permissible for the second person to withhold certain information regarding its formulation until subsequent to a confidentiality order being in place.
>
> [emphasis added]

[65] In my respectful view, Fresenius' claim to confidentiality in this NOA is impermissible because it reaches further than what Justice Snider allowed and approved as noted above.

Fresenius cannot rely on the second bullet in *Pfizer-Atorvastatin* to justify its failure to disclose manufacture offshore, importation and non-infringement by importation.

(8) The Third Bullet in *Pfizer-Atorvastatin*

[66] I am also unable to accept Fresenius' argument that the third bullet in Justice Snider's decision in *Pfizer-Atorvastatin* relieves Fresenius of its regulatory duty to set out the manufacture offshore, importation and non-infringement by importation in its "detailed statement". First, it is very clear that adding facts and legal issues not contained in the NOA after the fact is the exception and not the rule. Second, while further disclosure may be allowed after a NOA is filed, Justice Snider's third bullet said that could only be done where after the fact disclosure is 'elaborative', i.e., where it "elaborates on the basis for which the allegation of non-infringement was made":

> The NOA will be adequate if further disclosure elaborates on the basis for which the allegation of non-infringement was made such that there is sufficient evidence upon which to evaluate the allegation.
>
> [emphasis added]

The key word is "elaborates".

[67] Once again, Justice Snider took a measured, balanced approach to the issue of post-NOA disclosure. It is not just anything that may be disclosed post-NOA; only 'elaborative' facts and legal arguments may be disclosed post-NOA.

[68] The difficulty Fresenius faces with its NOA in this case is that its NOA neither refers to manufacture offshore nor to importation, nor to non-infringement by importation. There is nothing in that regard on which Fresenius could "elaborate" in post-NOA filings. It is one thing to elaborate on an allegation of non-infringement detailed in the NOA; it is another to add a new basis of non-infringement for the first time after a prohibition proceeding is commenced. Therefore I conclude that Fresenius is not assisted by the third bullet.

(9) Pleadings Issues

[69] The discussion of non-infringement by importation in this case raises pleadings issues in another sense. Fresenius says Bayer may not complain about non-infringement by importation because Bayer was aware of but did not raise infringement by importation in either its original or amended Notice of Application, in its evidence, or in its Memorandum of Argument. I am unable to accept these submissions. Having made inadequate disclosure of the point in the first place, Fresenius cannot be heard to complain that Bayer failed to respond. It was Fresenius that filed a NOA without the required full and complete "detailed statement". In any event, I note that Bayer did refer to infringement by importation albeit fleetingly in its Memorandum, where at para 88 it stated that "a claim to a product is infringed even when it is manufactured offshore". Indeed, Bayer gave as authority for that proposition both *Monsanto* and *Pfizer-Atorvastatin*.

[70] This case evolved over time. Fresenius' NOA at best gave clues to non-infringement by importation but failed to comply with the Regulations. Bayer's reference to importation was limited to a clause in a sentence in para 88 of its Memorandum. Fresenius expanded on importation in its Respondent's Memorandum by alleging in some detail why in its view Bayer

could not establish infringement by importation. Both parties filed Outlines of Argument prior to the hearing in which both sides dealt in detail with non-infringement by importation and the *Saccharin Doctrine*. Also at the hearing, both counsel dealt in detail with non-infringement by importation and the *Saccharin Doctrine*.

[71] Fresenius did not come out and give a detailed statement regarding importation and non-infringement by importation; instead it alluded to the doctrine by use of legally insufficient code words. Bayer did not address non-infringement by importation in its Memorandum, except by claiming (correctly) that "a claim to a product is infringed even when it is manufactured abroad." Bayer says that Fresenius should not be allowed to argue non-infringement by importation because it was not raised in the NOA (which it was not). Fresenius says Bayer should not be allowed to address infringement by importation because it was not adequately raised in Bayer's Memorandum. In my view, all of this could and should have been avoided; Fresenius should have done what the Regulations required it to do, and detail in its NOA its allegation of non-infringement by importation.

(10) Must Bayer Prove Prejudice or Surprise by Affidavit?

[72] Fresenius further alleges that to establish Fresenius' NOA is defective, Bayer must provide affidavit evidence establishing it was surprised or prejudiced. However, on review, the cases cited by Fresenius in support of this argument (*Astrazeneca AB v Apotex Inc*, 2005 FCA 183; *Aventis Pharma Inc v Apotex Inc*, 2006 FCA 64; *Pfizer Canada Inc v The Minister of Health*, 2007 FC 642) lay down no such general rule. Nor am I able to see how an adequate NOA may be rendered inadequate through a first person's affidavit of surprise and prejudice. It

seems to me that a NOA is either adequate or it is defective. In my view, adequacy of a NOA is not established by the first person's subjective opinion one way or the other; it is determined objectively by the Court by the application of legal principles to the facts.

(11) Who Should Raise Non-infringement by Importation: The First Person or the Second?

[73] Fresenius further argues that simply alleging in its NOA that neither the product nor the API used infringe the patent is sufficient. Fresenius says it had no obligation to raise non-infringement by importation. As can be seen from the foregoing analysis, I disagree. At the time it drafted its NOA, Fresenius was the only party that knew its proposed new drug was manufactured abroad. Fresenius alone knew its offshore produced drug would be imported. In this case, and in my respectful view, the non-infringement by importation issue would have been obvious to Fresenius. It was hardly a speculative issue. Only Fresenius had reason to know that it would or likely would have to rely on non-infringement by importation in prohibition proceedings. In my view, non-infringement by importation were very real possibilities, neither speculative nor in any way remote in this case.

[74] Fresenius says it had no obligation to detail either the factual or legal basis of non-infringement by importation. This however is also inconsistent with its argument that in fact it did just that, albeit by use of code words. Fresenius' obligation to detail non-infringement by importation was particularly strong in this case where it actually set out to do just that. In my view, Fresenius knew it had to detail the basis for non-infringement by importation, failed to meet its statutory obligation, and now faces the consequential issuance of prohibition.

(12) Confidentiality of Manufacture and Processing Abroad

[75] Fresenius finally argues that the fact its new drug is manufactured abroad for importation into Canada is confidential, and therefore could not be disclosed in the NOA. I agree the case law supports non-disclosure of the "formulation" of a new drug that otherwise must be in the required "detailed statement"; this was established by Justice Snider in *Pfizer-Atorvastatin*. However, I cannot accept the specific claim to confidentiality in this case for two reasons. First, there is no evidence on which to base such a finding of confidentiality; such a finding would be speculative on my part. Secondly, when Fresenius says Bayer would or should have known Fresenius was alleging non-infringement by importation, it is of course saying that all of Bayer's similarly-situated competitors also would or should have known its proposed new drug was manufactured abroad for importation into Canada. Indeed, Fresenius alleged that anybody in the field would know from its NOA that its new drug was manufactured offshore and imported. I also note the fact that the entire NOA including the code words "trivial and merely incidental" is in the public domain, i.e., the public version of the Application Record in this Court file. This assertion that offshore manufacture and importation cannot be sustained on these facts.

[76] The conclusion that the NOA is defective disposes of this application; the Minister of Health may not issue a NOC where an applicant for a new drug by comparison has failed to comply with its duty to file the detailed statement required under subparagraph 5(3)(b)(ii) of the *PM (NOC) Regulations*. Therefore, Bayer is entitled to the prohibition order it seeks.

[77] That said, the parties devoted a great deal of time and attention to the issue of whether or not Bayer established that the NOA was not justified in terms of non-infringement or non-infringement by importation. Therefore, I will also address this issue.

Issue 2: Whether Bayer has shown on a balance of probabilities that Fresenius' Notice of Allegation is not justified

(1) The Evidence

Experts' Testimony and Evidence

[78] The parties agree there is no issue as to expert qualification in these proceedings. However, the parties argue and I agree that the Court must make credibility determinations concerning the evidence and opinions provided by the experts. I will discuss each expert in turn.

Dr. Adam Matzger – Bayers' Expert

[79] Dr. Matzger is a Professor of Chemistry and of Macromolecular Science and Engineering at the University of Michigan. He obtained a Ph.D. in structural and organic chemistry in 1997 and has over 120 publications in peer reviewed journals to his credit. Dr. Matzger edits the academic journal "Crystal Growth and Design", and he has co-founded a company to provide analytical services, including solid-state chemical characterization of materials.

[80] Dr. Matzger submits he conducted a number of experiments and in doing so replicated what Bayer claims was a "key" stage of the Fresenius process, **[……..Redacted…… ……..……]**. He said his experiment

showed the Fresenius process yields Bayer's patented moxifloxacin hydrochloride monohydrate [the Monohydrate] as an intermediate during this step of the manufacture of the moxifloxacin hydrochloride [Fresenius-moxifloxacin] Fresenius is seeking approval to market.

[81] Dr. Matzger construed the patent as requiring an x-ray powder diffraction [XRPD] with a band at $2\theta = 26.7°$, and by Carbon-13 nuclear magnetic resonance [C-NMR] with a characteristic peak at 168.1 ppm. "2θ" is pronounced "two theta" and refers to the angle of incidence of the diffracted x-rays. XRPD analysis is especially powerful to examine and characterize the structure of crystalline materials. Crystalline materials may appear in various structures, or "polymorphs", for which the XRPD testing is diagnostic.

[82] Dr. Matzger's evidence was that the 418 Patent disclosed a new monohydrate form of the Monohydrate which had a previously known anhydrous form. The Patent teaches that storage of the anhydrous form could be problematic due to the instability of the crystal structure. The Patent teaches that physical instability of anhydrous moxifloxacin hydrochloride results from changes in its crystal structure when stored at ambient humidity or when placed in aqueous suspensions.

[83] The 418 Patent teaches that the Monohydrate has increased stability and is better for the preparation of stable pharmaceutical products. The Monohydrate can be characterized by XRPD with a band at $2\theta = 26.7°$, and by C-NMR with a characteristic peak at 168.1 ppm.

[84] While Claim 1 of the Patent requires a monohydrate which has a "characteristic peak" at 168.1 ppm in the C-NMR spectrum, and a "band" at $2\theta = 26.7°$ in the XRDP analysis, the parties

confirmed there is no difference between a “peak” and a “band” and that in fact the terms “peak” and “band”, are used interchangeably. This was indeed the case: peak and band are used interchangeably in the evidence and in argument.

[85] Dr. Matzger is the only expert in this proceeding who actually conducted experiments and tests of the chemicals obtained, which tests were based on his reconstruction of the ANDS and components of the Drug Master File [DMF] provided to him through Fresenius and by the offshore third party API manufacturer. Fresenius’ witness, Dr. Brittain, conceded Dr. Matzger’s tests were faithful except for the fact they were done on a reduced scale compared to the actual manufacturing process.

[86] Dr. Matzger obtained his results by performing two experiments replicating scaled-down stages of the Fresenius process where there was a hypothesized formation of the Monohydrate, with ratios of 1/8000 and 1/4000. As hypothesized, Dr. Matzger said he had identified the presence of the Monohydrate through XRPD testing in his first experiment. No other testing, including C-NMR testing, was conducted on the samples from the first experiment. In the second experiment, Dr. Matzger doubled the scale of his experiment, thereby creating and collecting a greater volume of the sample, which he also found to be the Monohydrate. On this sample he performed both XRPD and C-NMR testing.

[87] While in two of the experiments he ran, Dr. Matzger did not find the Monohydrate, Dr. Matzger explains the Monohydrate was formed in two other experiments at this **[..Redacted..]** step. According to Dr. Matzger, the Monohydrate transforms into another compound, **[….**

……..….Redacted……..], as the reaction progresses. The use of the Monohydrate is transient as an intermediary. Dr. Matzger does not state that the Monohydrate would not be produced at other stages, though this stage is the only one for which he performed experiments. Dr. Matzger also explained the intensity of the bands is not relevant for identifying the compound, so long as said bands are present in the band pattern. Dr. Matzger indicated that in order to properly identify a compound from the XRPD spectrum, all of the bands should match. Dr. Matzger posits all the bands from the XRPD matched. He explained the discrepancies and lack of clarity and resolution within the peaks were due to **[……. Redacted… ……].** There is only Dr. Matzger's own testimony as an expert in support of the **[..Redacted..]**.

[88] From the second experiment, Dr. Matzger was able to test the product on the C-NMR spectrum. In this test, there was a "signal" at 168.1 ppm, which to Dr. Matzger confirmed the presence of the Monohydrate. This result was not as resolved **[…....Redacted…….…].** Dr. Matzger explained this lack of resolution was due to **[…..……Redacted……..……].** A signal, at a greater than 3:1 signal to noise ratio, was nonetheless observed at 168.1 ppm. The United States Pharmacopeia [USP] specifies a peak may be found at a ratio of 2 or 3 to 1 signal to noise ratio. Dr. Matzger deposed:

> 84. I note that Claim 1 of the 418 Patent specifies an XRPD diffractogram with a peak at 2θ = 26.7 ppm and a ^{13}C-NMR spectrum with a peak at 168.1 ppm. As I explained above, my experiments demonstrated a peak at 2θ = **[..Redacted..]** which is within an acceptable range of 0.1 degrees. This element of the claim is therefore satisfied.
>
> 85. My experiments also demonstrated that PPC produces moxifloxacin hydrochloride monohydrate that yields a ^{13}C-NMR spectrum that has a signal at 168.1 ppm. In my opinion, this

> spectrum is consistent with the presence of moxifloxacin hydrochloride monohydrate.
>
> 86. It is important to note that the sample I analysed under ^{13}C-NMR**[……Redacted…… …… …… …… …… ……..].**
>
> [emphasis added]

[89] Even in his reply affidavit, Dr. Matzger refers to the intensity at 168.1 ppm and falls short of concluding that there is a peak or band at 168.1 ppm in the C-NMR spectrum:

> 25. The graph reproduced at paragraph 143 of the Brittain Affidavit clearly shows that there is signal at 168.1 ppm with a greater than 3:1 signal to noise ratio. Dr. Brittain has improperly considered the noise to be a lack of signal and did not account for the fact that **[…….Redacted…… ……].**
>
> (…)
>
> 41. In response to paragraphs 62 and 63 of the Zaworotko Affidavit, it is no surprise that the peak at 168.1 ppm is not very resolved since **[……. Redacted…….. …….. ……].** However, had there been an absence of intensity at 168.1 ppm, I would have been less confident that the monohydrate was in fact present.
>
> [emphasis added]

Dr. Brittain – Fresenius' Expert

[90] Dr. Brittain has over 40 years of experience with the chemistry, design, and development of solid and aqueous drug formulations. The author of over 200 publications on the

characterization of solid-state pharmaceutical substances, Dr. Brittain is highly skilled in the art of performing and interpreting the results of XRPD analyses, having performed 5 to10 such analyses per week for over ten years, totalling 2,500 to 5,000 XRPD analyses. Dr. Brittain also had extensive experience as a member of the USP, with a focus on physical test methods for pharmaceutical substances, including XRPD. Dr. Brittain taught various chemistry topics as a tenured university professor. Dr. Brittain also worked in private industry in drug development.

[91] **[……..Redacted……**

……

……

…….]. He further lists forms of moxifloxacin hydrochloride in crystal form which have been listed in several patents abroad. These forms are not present in the Cambridge Structural Database [CSD]. Dr. Brittain asserts part of Dr. Matzger's error in identifying the substance he analyzed was Dr. Matzger's faulty underlying assumption that only three forms of moxifloxacin hydrochloride exist (anhydrous, monohydrate and methanolate/hydrate). If the universe of possibilities had been properly expanded, as the presence of other various patented forms suggests, Dr. Matzger may have determined that the moxifloxacin compound in his experiment was not the Monohydrate, but rather one of the many other existing forms of moxifloxacin disclosed in other patents.

[92] Based on the data collected by Dr. Matzger, Dr. Brittain concluded the Fresenius-moxifloxacin and the process used for its manufacture do not fall within the scope of the 418 Patent.

[93] Dr. Brittain states that in an XRPD pattern, usually a match to a crystal form and substance will be found with the ten most intense peaks on the XRPD spectrum. In this connection, Dr. Brittain indicated his approach followed that of the USP, which states: "It is generally sufficient to scan past the ten strongest reflections identified in the Powder Diffraction File." In the data from Dr. Matzger, Dr. Brittain attempts to match the ten most intense peaks from the spectrum in the 418 Patent to peaks in Dr. Matzger's data set, but he finds at most only **[Redacted]** of the ten peaks would be present in Dr. Matzger's submitted data sets. This, Dr. Brittain says, indicates that the compound is not the Monohydrate posited by Dr. Matzger.

[94] Dr. Brittain also explains how he attempted to match the peaks in the context of significant noise in the samples. For example, in the C-NMR, the scale in Dr. Matzger's presentation was expanded to such an extent that small features looked like peaks. This does not achieve a 2 or 3 to 1 signal to noise ratio necessary to find the presence of a peak. Dr. Brittain explains the signal identified at 168.1 ppm by Dr. Matzger is merely part of a sloping baseline and cannot be deemed a peak, let alone a characteristic peak.

[95] Dr. Brittain also explains that **[……Redacted…….. ……..…….].** He did not adhere to Dr. Matzger's explanation of **[……Redacted…….].**

Dr. Zaworotko – Fresenius' Expert

[96] Dr. Zaworotko is the Bernal Chair of Crystal Science and Science Foundation of Ireland Research Professor in the Department of Chemical and Environmental Sciences at the University

of Limerick, Ireland. Dr. Zaworotko has expertise in the fields of crystallization, x-ray crystallography, crystal engineering, crystal packing, polymorphism and hydrates. He has published over 320 peer-reviewed journal articles.

[97] Dr. Zaworotko puts forward a hypothesis of isostructural channel solvates, which would provide an alternative explanation to Dr. Matzger's results with an unresolved peak at 168.1 ppm. In this hypothesis, Dr. Zaworotko explains that Dr. Matzger likely did not obtain **[….. ……Redacted……..]**, as advanced by Dr. Matzger. Instead, Dr. Zaworotko said Dr. Matzger probably had a continuum of channel solvates, with a varying content of **[…….Redacted……]** within the crystal lattice of the moxifloxacin hydrochloride. Dr. Zaworotko did not conduct any testing of his own; notwithstanding he advances this continuum of channel solvates could explain the unresolved peaks found in Dr. Matzger's data.

[98] Dr. Zaworotko had few areas of agreement with Dr. Matzger.

Other Affidavit Evidence

Mira Cameron

[99] Ms. Cameron affirms the NOA was sent to Bayer on May 5, 2014. Bayer first filed a Notice of Application with this Court on June 18, 2014. On July 16 and 17, Fresenius (then PPC) provided Bayer with documents from its ANDS for the PPC product. On July 31, 2014, Bayer filed an amended Notice of Application. Fresenius made further productions on August 19, 2014.

[100] Ms. Cameron set out the timeline for the proceedings before this Court in the remainder of her affidavit.

Josephine Holmes

[101] Ms. Holmes is Senior Manager, Regulatory Affairs at Fresenius. Ms. Holmes provided evidence relating to the moxifloxacin product for which Fresenius is seeking regulatory approval in Canada.

Bruce Jordan

[102] Mr. Jordan is Senior Manager, Commercial Supply Chain at Fresenius Kabi US, LLC, a US company that is an affiliate of Fresenius. Mr. Jordan provided evidence relating to the development, manufacturing, and importation of Fresenius-moxifloxacin.

Sabrina Del Rosso

[103] Ms. Del Rosso is a legal assistant to Gilbert's LLP, lawyers for the Respondent. Ms. Del Rosso affirms some of the ANDS submissions were voluntarily produced to Bayer's lawyers on July 16, 2014. The entire ANDS was produced on August 19, 2014, in CD form. Fresenius took steps starting on September 20, 2014, to obtain information contained in the Drug Master File from the API manufacturer abroad. Documents obtained from the API manufacturer were sent to Bayer on November 6, 2014 and on November 11, 2014. Although more efforts were made to obtain further information from the third party, the API manufacturer, no further productions were obtained.

IV. Submissions of the Parties

Applicants

[104] Bayer asserts Fresenius' allegation of non-infringement is an inadequate, even bald, assertion that it will not use the Monohydrate in its manufacture of the Fresenius product or of the API in its product. Although Fresenius refused to produce samples from its process, Dr. Matzger was able to reproduce a key stage of the Fresenius process. The evidence shows the non-infringement allegations are demonstrably false.

[105] Bayer asserts Claims 1, 2, 8 to10, 12 and 14 of the 418 Patent. These go to the independent claim (Claim 1), the preferred prismatic crystal form (Claim 2), the medicament comprising the Monohydrate along with a pharmaceutically acceptable diluent or carrier (Claim 8) for use in the treatment of bacterial infections (Claim 9), or an antibacterial composition comprising the Monohydrate of Claim 1 or Claim 2 with a suitable diluent or carrier (Claim 10), used to treat bacterial infections (Claim 12). Claim 14 recites a use of the Monohydrate of Claim 1 or Claim 2 in the preparation of a medicament for treatment of bacterial infections.

[106] As discussed under Issue 1 above, Bayer alleged that the NOA was defective on the grounds Fresenius failed to adequately disclose, in its NOA, its allegations that the manufacturing process took place abroad, that Fresenius' new drug was imported into Canada, and that bringing the Fresenius product into Canada constituted non-infringing importation. Bayer also alleged the NOA did not provide sufficient information to determine whether PPC's allegation of non-infringement of the claims of the 418 Patent is justified. Finally, Bayer argued

the PPC letter did not provide any basis for raising the claimed Gillette Defence (named after *Gillette Safety Razor Company v. Anglo American Trading Company* (1913), 30 R.P.C. 465) in the context of non-infringement.

[107] Bayer argues the evidence of Fresenius' experts should be discounted because they only criticized Dr. Matzger's experiments instead of conducting their own testing. Bayer further argues that Fresenius' failure to produce samples of intermediates obtained during the manufacturing process impeded Bayer's ability to adduce proper evidence and conduct proper testing to more fully and conclusively demonstrate to the Court that Fresenius' allegation of non-infringement was not justified. Bayer suggests an adverse inference should be drawn against Fresenius on this point.

[108] Although Fresenius did not provide samples of intermediates obtained during the manufacturing process or of the active pharmaceutical ingredient, Dr. Matzger performed two experiments replicating scaled-down stages of the Fresenius process where there was a hypothesized formation of Bayer's patented Monohydrate. As proposed, Dr. Matzger testified he identified the presence of the Monohydrate through XRPD testing in his first experiment. He found that the Monohydrate was formed but chemically transformed into another compound, **[.. ……Redacted…….],** as the reaction progressed. Dr. Matzger also explained the intensity of the peaks on the XRPD pattern is not relevant to identifying the compound, so long as said peaks are present in the peak pattern. Dr. Matzger's first experiment yielded results containing some irregularities. Dr. Matzger felt confident these were due to the **[…….Redacted……].**

[109] In the second experiment, Dr. Matzger doubled the scale of his first experiment, thereby creating and collecting a greater volume of the product. From this second experiment, he was able to test the product on the XRPD and on the C-NMR spectra. In the C-NMR test, there was a signal at 168.1 ppm, which confirmed the presence of the Monohydrate. This result was not as resolved **[……Redacted……].** Dr. Matzger explained this observation was due to **[…**
……..Redacted……..]. A signal, at a greater than 3:1 signal to noise ratio, was nonetheless observed at 168.1 ppm. The USP specifies a peak may be found at a ratio of 2 or 3 to 1 signal to noise ratio.

[110] Bayer submits the Fresenius experts did not conduct their own experiments but simply criticized Dr. Matzger's methodology and test results. Bayer characterizes this approach as "mud-slinging", arguing this should not be encouraged where there are allegations by Fresenius' experts that Dr. Matzger smoothed the data or otherwise did not analyze it properly. Moreover, Bayer argues there are no other monohydrate forms of the moxifloxacin, contrary to Fresenius' experts' opinions. An appropriate source to establish which crystal forms exist for this chemical is the CSD, as opposed to the literature which is plagued by inaccurate reporting on alleged but unproven "novel" compounds by patentees in their patent filings.

[111] Bayer alleges that Fresenius' experts, in context, wrongfully criticized Dr. Matzger's procedures. For example, Dr. Matzger was unreasonably criticized by Dr. Zaworotko for failing to indicate in his notes whether he had ground the sample before testing. Dr. Matzger explained he would have kept a record if he had ground his sample before testing; this step being critical in a potential phase change of the sample. Dr. Zaworotko would not yield in his criticism.

[112] Bayer argues that infringement occurs where a patented substance is produced at an intermediate stage of manufacture, even if the intermediate is not in the final drug product: *Abbott Laboratories v Canada (Minister of Health)*, 2006 FCA 187 at paras 15-17; *Abbott Laboratories v Canada (Minister of Health)*, 2007 FCA 73 at para 4. Here, Fresenius infringed the 418 Patent by producing the Monohydrate in its manufacturing process, as demonstrated with certainty by the expert evidence tendered by Dr. Matzger.

[113] Bayer cites the Supreme Court of Canada to argue that the main purpose of patent protection is to prevent others from depriving the inventor, even in part and even indirectly, of the monopoly that the law provides: only the patentee is entitled to the full enjoyment of the monopoly conferred. The Supreme Court also confirmed that a claim to a product is infringed even when it is manufactured offshore: *Monsanto Canada Inc v Schmeiser*, 2004 SCC 34 at para 43; *Pfizer-Atorvastatin* at paras 87-90.

[114] Bayer notes that Fresenius' experts went to great lengths to point out that the presence of the peaks identified in Claim 1 do not, in and of themselves, demonstrate that the product is the Monohydrate. Bayer asks the Court rather to consider all of the experimental data to determine the nature of the product.

Respondent - Fresenius

[115] Fresenius first discusses the evidence led by its witnesses, who consist not only of their expert witnesses but also witnesses who spoke to Fresenius' product and API, the third-party manufacturer of Fresenius' API, and Fresenius' efforts to obtain and use non-infringing API.

Fresenius advances the following main arguments to support the justification of the allegation of non-infringement. First, Fresenius argues Bayer cannot establish infringement by importation, nor was it properly argued by Bayer. Second, Fresenius submits the Monohydrate is not used in the process to create the Fresenius product. Finally and partly as a result of the previous arguments, Fresenius argues its allegation of non-infringement is justified and Bayer has not met its burden to establish that Fresenius' allegation of non-infringement presented in its notice of allegation is not justified.

[116] Fresenius construes the claim as did Justice Phelan in *Alcon Canada Inc v Cobalt Pharmaceuticals Company*, 2014 FC 462 [*Vigamox*]. In that case, Bayer had attempted to construe the claim as disjunctive. In that case, Dr. Matzger served as an expert witness for Bayer and did not adduce evidence on one of the tests mentioned in Claim 1. Justice Phelan construed the 418 Patent claim at issue in the present case, and found that based on Dr. Matzger's evidence, Bayer had not met its burden of adducing all the evidence relevant to the essential elements of the 418 Patent. Fresenius submits, and Bayer now agrees, this Court should follow the construction in that case. In *Vigamox*, this Court stated:

> [193] In the prior art, the form of CDCH was anhydrous. The 418 Patent identifies problems associated with the prior art. In particular, the anhydrous form is hygroscopic and absorbs water under adverse storage conditions and during pharmaceutical processing, resulting in impaired dosing accuracy and preparation quality. The invention of the CDCH monohydrate with improved stability overcame this problem.
>
> …
>
> [196] Claim 1 reads:
>
> > A monohydrate of CDCH, of the formula [Formula (I)]…which has a characteristic peak at 168.1 ppm

> in the 13 C-NMR spectrum and a band at 2Θ=26.7 in the X-ray diffractogram.
>
> [197] Claim 1 of the 418 Patent has three essential elements:
>
> a. the compound is moxifloxacin monohydrate;
>
> b. the compound displays a characteristic band in the powder X-ray diffractogram at 2Θ=26.7; and
>
> c. the compound displays a characteristic peak in the 13C-NMR spectrum at 168.1 ppm.
>
> [198] Cobalt submits that elements (b) and (c) are conjunctive; both must be established. In contrast, the Applicants submit that elements (b) and (c) are redundancies and it is only necessary to determine that a substance is the CDCH monohydrate and displays either the characteristic band or peak.
>
> [199] Cobalt's position is made out on the language of the patent. The use of the conjunctive "and" in Claim 1 linking the peak and band requirements makes it clear that the substance claimed in the 418 Patent must display both the characteristic peak and the characteristic band.
>
> …
>
> [201] Any issue as to whether increased stability is also an essential element is a secondary issue. Given the Court's ultimate conclusion, it is not necessary to find on this point.

[117] From this claim construction, Fresenius retains the following three essential, conjunctive elements of the claim:

i The compound is the 418 Patent moxifloxacin hydrochloride monohydrate;

ii A characteristic band at $2\theta = 26.7°$ in the XRPD pattern; and

iii A characteristic peak in the ^{13}C-NMR spectrum at 168.1 ppm.

[118] Fresenius argues Bayer has not established these three essential elements of the 418 Patent claim. Bayer bears the burden of establishing that Fresenius' NOA claim of non-infringement of the Fresenius-moxifloxacin was not justified. Fresenius qualifies the Monohydrate as necessarily a crystal form, which could not exist in solution as the Fresenius-moxifloxacin. Further, a characteristic peak would be one of the most intense peaks on a given spectrum, which were not observed either on the XRPD or on the C-NMR spectra provided in Dr. Matzger's evidence.

[119] Fresenius asserts that the presence of the Monohydrate has not been established. According to Dr. Brittain, to establish the presence of this compound, the XRPD would act as a "fingerprint", where at least the ten most intense peaks of the XRPD spectrum from the 418 Patent's Figure 5 would match the data obtained from Dr. Matzger. When analyzing this data, Dr. Brittain at best only finds **[..Redacted..]** corresponding peaks in the first but not the second experiment. However, at least **[..Redacted..]** of those peaks are shifted **[Redacted]** the spectrum, whereas the remaining peaks are not shifted at all. Dr. Brittain finds the data not to show characteristic peaks, but rather at best perhaps showing "signals" in the areas identified by Dr. Matzger, and mere sloping baselines otherwise.

[120] Dr. Brittain also explains that Dr. Matzger's explanation pertaining to **[…..Redacted…**

…….] is not accurate. **[…….**

……Redacted……

……].

[121] Fresenius also explains that Dr. Zaworotko's evidence provides an alternative, valid explanation for the lack of clarity in the C-NMR peak that should have been achieved at 168.1 ppm had the monohydrate appeared in the crystal formed in Dr. Matzger's experiments.

[122] In this context, Fresenius says Bayer failed to meet its burden of establishing any of the three essential claims for the 418 Patent on a balance of probabilities. Bayer did not establish that the compound was the Monohydrate; Bayer did not establish the presence of a characteristic band at $2\theta = 26.7°$ on the XRPD spectrum; and Bayer did not establish the presence of a characteristic peak on the C-NMR spectrum at 168.1 ppm.

[123] Furthermore, should the Court disagree and find that Bayer has established that the Monohydrate appears as an intermediate in the manufacturing process, Fresenius argues that Bayer would still have to establish that the Court has jurisdiction over the infringement by virtue of the *Saccharin Doctrine,* or infringement by importation.

[124] In order to find infringement by importation where the potential act of infringement occurs abroad and in the formation of a patented substance through an intermediary, the Court must have sufficient evidence before it to examine the factors as laid out by Justice Snider in *Pfizer-Atorvastatin* at para 90. These factors were later adopted in a Federal Court decision by Justice Gauthier in *Eli Lilly and Company v Apotex Inc*, 2009 FC 991 at para 326, which was upheld at the Federal Court of Appeal in *Eli Lilly and Company v Apotex Inc*, 2010 FCA 240. These factors must be examined in order to determine whether there is "a strong link established

between the use of the patented process or product and the product sold into Canada": *Pfizer-Atorvastatin* at para 91. *Pfizer-Atorvastatin* at para 90 enumerates the following factors:

> - The importance of the product or process to the final product sold into Canada. Where the use is incidental, non-essential or could readily be substituted (such as the Italian scissors example), a Court might be less inclined to find infringement.
>
> - Whether the final product actually contains all or part of the patented product. Where the patented product can actually be identified in the product sold into Canada, there may be a strong case for a finding of infringement.
>
> - The stage at which the patented product or process is used. For example, use of a process as a preliminary step of a lengthy production process may lead to a conclusion that the patentee has suffered little deprivation.
>
> - The number of instances of use made of the patented product or process. Where the same patented product is used repetitively through the production of the non-patented end product, there may be clearer evidence that the advantage of the patentee has been impaired.
>
> - The strength of the evidence demonstrating that, if carried out or used in Canada, the product or process would constitute infringement. On this point, my opinion would be that, where there is ambiguity in the evidence, the benefit of the doubt should go to the party using the product or process. This is, perhaps, simply another way of expressing the established principle that the patentee bears the burden of proving infringement.
>
> [emphasis added]

[125] Bayer did not adduce evidence on any of the factors of the *Saccharin* test, except for the already adduced evidence on the Monohydrate. Even if the Court found that the expert evidence did establish the use of the Monohydrate in the offshore manufacturing process, this evidence

does not establish the remaining factors of the test as set out above. There is not enough evidence for the balance of the test to establish infringement by importation.

[126] Fresenius stated that importation could be one reason for the Court to find that there was no infringement. Fresenius argued its NOA would be sufficient and valid where the only allegation is that Fresenius did not infringe. Details on the process in this case were deemed confidential and were released on July 16, 2014 after a Confidentiality Agreement was entered by the parties. As discussed and rejected above, Fresenius said that its NOA did not have to contain confidential information, which according to Fresenius, included the fact the product was manufactured offshore and imported.

V. Analysis

Person Skilled in the Art

[127] The parties substantially agree on the qualifications of the person skilled in the art. Bayer's Factum describes the skilled person as having education and experience in producing and identifying different physical forms of pharmaceutical compounds, polymorphs and solvates, including hydrates and anhydrates. Such a person has at a minimum, a Ph.D. degree in chemistry or pharmaceutics and several years of relevant experience in an academic or industrial setting. The skilled person also has experience in the theory and practice of interpreting the data from XRPD and solid state C-NMR spectroscopy. Fresenius agrees with this description, but adds that the skilled person would also be expected to have experience in interpreting data obtained by other techniques used for testing, such as thermogravimetric analysis [TGA], differential

scanning calorimetry [DSC], and infrared [IR] spectroscopy, in order to properly determine the first essential element of Claim 1 in the patent construction, which asks to find that the Monohydrate be present.

[128] In my view, the skilled person would have a graduate degree in chemistry or a related field such as chemical engineering or pharmaceutics, experience with polymorphs; a minimum of one to two years practical experience in the production of pharmaceutical compounds; ability to understand data from X-ray powder diffraction and C-NMR spectroscopy; and familiarity with crystallography.

[129] Of note, the experts called by both parties benefit from significant experience in the requisite fields, as well as the supplementary testing fields identified in the 418 Patent and in Fresenius' pleadings.

Claim Construction

[130] The parties agree, as do I, that the prior construction of the patent by Justice Phelan should be adopted by this Court (see *Vigamox*).

[131] In *Vigamox*, the second person's product was in solution form and did not contain any crystals. The parties agreed that the product to be imported itself did not infringe the 418 Patent. The issue was whether the *process* of making Vigamox used the Monohydrate. Dr. Matzger, a witness in the present case, also acted as an expert witness for Bayer in *Vigamox*.

[132] Following submissions by experts and counsel, Justice Phelan concluded the 418 Patent contains one independent claim and thirteen dependent claims. Justice Phelan established Claim 1 as the critical claim, and I agree. Claim 1 reads:

> 1. A monohydrate of CDH, of the formula which has a characteristic peak at 168.1 ppm in the 13C-NMR spectrum and a band at 2[θ] =26.7 in the X-ray diffractogram.

[133] Constructing the claim is a matter of law, and as such, the Court is not bound by expert evidence or party submissions. Comity is usually present for such cases where a patent considered in a previously-determined case is at issue: *Apotex Inc v Pfizer Canada Inc*, 2013 FC 493; and *Pfizer Canada Inc v Canada (Minister of Health)*, 2007 FC 446.

[134] In light of these similarities, and absent additional modifying evidence, I construe the patent claim as did Justice Phelan, with the conjunctive tests expressed in Claim 1:

i The compound is a monohydrate of moxifloxacin hydrochloride;

ii The compound displays a characteristic band in the powder X-ray diffractogram at 2θ = 26.7; and

iii The compound displays a characteristic peak in the C-NMR spectrum at 168.1 ppm.

Infringement

(1) Burden of Proof

[135] Once a NOA is submitted to a first person, the allegations contained therein are presumed to be true. The burden shifts to the first person, in this case Bayer, to demonstrate that the allegations of non-infringement are not justified: *Pfizer*; *Vigamox* at para 226). Within this burden of proof, Bayer must therefore show Fresenius' product infringes each of the three essential elements of the claim as construed above, and must do so on a balance of probabilities. Also, "where the allegation is that a form of crystal will be present at some point in the manufacturing process, it must be proven that this actually occurs rather than merely raising it as a possibility": *Vigamox* at para 225.

(2) Was there a Duty by Fresenius to Supply Samples of Intermediaries in the Fresenius Product and API Manufacturing Process?

[136] Bayer argues that this Court should consider in its weighing of the evidence that Fresenius did not request or obtain samples of intermediaries created in the manufacturing process of the Fresenius-moxifloxacin product or API. This holds for providing these samples to Bayer's and to Fresenius' experts.

[137] Fresenius argues it did not owe any duty to produce such samples, under either the *PM (NOC) Regulations* or the Production Order granted by Prothonotary Milczynski.

[138] I am persuaded that Fresenius had no duty to produce samples of intermediaries. Notably, nowhere in the evidence do I find that Bayer sought further productions from Fresenius after the consent Production Order was obtained. I also note that Bayer conceded it had no right to such

samples. In these circumstances, I cannot draw adverse inferences against Fresenius or its experts.

(3) Expert Preference

[139] In light of the experience of Dr. Brittain in analyzing and interpreting the data for over 2,500 XRPD analyses, and his extensive experience in helping draft the relevant portions of the USP, I am of the view that his evidence is to be preferred.

[140] I find Dr. Matzger's evidence helpful, though I understand he does not have the same experience and breadth of knowledge on XRPD testing as Dr. Brittain. For this reason, I give his evidence more weight for the presenting of test results, but less weight in the analysis and explanation of the identity of the compound found through his experiments, and in particular, in relation to XRPD testing.

[141] In light of Dr. Zaworotko's general failure to set out areas of agreement with Dr. Matzger in his evidence for the Court, I find he did not fully comply with the rules of this Court for expert evidence. The Rules state, at subsection 3(b) of the Code of Conduct for Expert Witnesses schedule of the Federal Courts Rules, that an expert must provide: "(f) in the case of a report that is provided in response to another expert's report, an indication of the points of agreement and of disagreement with the other expert's opinions" (emphasis added). For this reason, in general I give his evidence less weight.

(4) Number of Forms of Moxifloxacin

[142] The Cambridge Structural Database [CSD] presents two forms of moxifloxacin hydrochloride: the methanolate/hydrate and the monohydrate forms. In addition, the 418 Patent discloses the prior art anhydrous form.

[143] The experts agree the CSD is a reliable source to prove different forms. In my respectful view, mere allegations based on other uncontested patents are not enough to prove the existence of other forms of moxifloxacin hydrochloride. Therefore, I am unable to accept the evidence of Dr. Brittain to the effect that there are as many as seven different forms of moxifloxacin.

[144] In my view, for the purposes of the inquiry before this Court, there are three forms of moxifloxacin hydrochloride: the anhydrous form, the Monohydrate form and the methanolate/hydrate form.

(5) Claim Elements

Monohydrate form of moxifloxacin hydrochloride (or the Monohydrate)

[145] In order to identify the Monohydrate, the experts agree several tests could be conducted. The XRPD and C-NMR, in conjunction, and taking the entirety of the spectrum including characteristic peaks, could be sufficiently diagnostic of the chemical compound and particular crystal structure to identify the Monohydrate. Similarly, when distinguishing between the

anhydrous and the hydrate forms, thermogravimetric analysis and other analytics could be useful to the Court.

[146] In this case, the only experimental sample data evidence was provided by Bayer, which has the burden to establish the use of the Monohydrate on a balance of probabilities, through its expert, Dr. Matzger. Dr. Matzger conducted two experiments. In the first experiment, he conducted only XRPD analyses. In the second experiment, he conducted both XRPD and C-NMR testing. Dr. Brittain stated, and it is not disputed, that Dr. Matzger's experiments faithfully reproduced the API manufacturing process subject to issues with scaling down at 1/8000 and 1/4000. Any purported scaling down issue was not developed further and I have not considered it material.

[147] Dr. Brittain and Dr. Matzger agree with the USP, which asserts in its 2006 29th edition (*Physical Tests* / 941 X-Ray Diffraction at page 2789): "[i]t is generally sufficient to scan past the ten strongest reflections identified". Similarly here, at least the ten most intense peaks of the XRPD spectrum from the experimental sample should match with the spectrum provided in the 418 Patent. Though there is minor disagreement as to the requirements for relative intensities of these peaks, there is agreement that the location of the peaks is more important than these relative intensities.

[148] The experts disagree as to the identification of the peaks due to the shift in some peaks but not in others. In this respect, I favour Dr. Brittain's evidence over Dr. Matzger's, due to his considerably more significant experience in XRPD analyses and his work in drafting the main

guidance publication on this topic: the USP. According to Dr. Brittain, the best case for Dr. Matzger's hypothesis fails. First, only **[Redacted]** of the peaks are shifted by **[Redacted],** whereas the remainder did not shift; this shift of all the peaks would be expected and necessary for a positive identification of the Monohydrate. Second, Dr. Brittain explains some of the peaks identified by Dr. Matzger are barely above the sloping baseline for genuine peaks in their vicinity. This does not appear to meet the 2 or 3 to 1 signal to noise ratio indicated by the USP.

[149] I note on this issue that Dr. Matzger and Dr. Brittain disagree as to the method of measuring the noise in order to calculate the signal to noise ratio. In this connection, I prefer Dr. Brittain's sloping baseline evidence, given he has conducted thousands of these types of XRPD analyses and identification of materials over the years.

[150] Given the above explanations and absent further experimentations provided by any expert, I am unable to find on a balance of probabilities that the Monohydrate is present in the API's manufacturing process.

XRPD band at 2θ = 26.7°

[151] Dr. Matzger found there was a peak or band (these terms are interchangeable) at 2θ = **[Redacted],** which was within the ± 0.1-0.2° error referenced by the USP.

[152] Dr. Brittain, in *sur-reply* and in his cross-examination, intimated this error was usually a shift observed in the entire pattern. That is, a shift of ±0.1-0.2° would be present in the same

direction and in the same amount for each of the relevant bands. This error is usually only related to the machine which reads the samples. When only some of the bands are shifted by said amount, this is not the sort of error as permitted to properly identify the Monohydrate. This evidence was not contradicted.

[153] Significantly, in this case **[Redacted]** of the alleged bands were shifted by **[Redacted]** while **[Redacted]** others were not shifted at all. Equally of note, not all of Dr. Matzger's experiments produced a readily identifiable, characteristic band at $2\theta = 26.7° \pm 0.1\text{-}0.2°$. Moreover, the band seen by Dr. Matzger was by no means as intense as the characteristic peak portrayed in the 418 Patent for the Monohydrate. The experts agree the characteristic band at $2\theta = 26.7°$ in the 418 Patent is among the two most intense peaks, whereas the alleged peak in Dr. Matzger's evidence at its best sees a peak that has a relative intensity of less than **[Redacted]** of the most intense peak. Dr. Brittain in his *sur-reply* further explains that the feature identified by Dr. Matzger is merely above the noise level from the sloping baseline which establishes a **[Redacted]** signal to noise ratio. Therefore, it does not meet the signal to noise ratio required to find a peak.

[154] I find Bayer has not established the presence of a characteristic band at $2\theta = 26.7°$ in the XRPD spectrum on a balance of probabilities. Although on the evidence it could be open to me to find the characteristic band as posited by Dr. Matzger in at least one of the samples, this is not sufficient for the Court to conclude the presence of the Monohydrate or that a characteristic band at $2\theta = 26.7°$ in the XRPD spectrum is established on a balance of probabilities.

Characteristic peak at 168.1 ppm in the C-NMR spectrum

[155] On this point, I note none of the experts consider the "signal" or feature identified by Dr. Matzger to be a "characteristic peak" as required by the 418 Patent Claim 1 as construed here and in *Vigamox*. Significantly, Dr. Matzger himself calls the feature a "signal", instead of calling it a "peak". In a prior proceeding, Court File T-972-12, Dr. Matzger described a characteristic peak in these terms:

> Even if there was some uncertainty as to the meaning of a peak at 168.1 ppm in the C-NMR spectrum, the skilled person would examine Figure 5 of the 418 Patent and would see a prominent feature on the spectrum for the CDCH monohydrate at 168.1 ppm – this peak is one of the most intense peaks on the spectrum and would be easily identified.
>
> [emphasis added]

[156] In his affidavit, Dr. Matzger was aware of the requirements of Claim 1, yet the language he uses falls well short of the language requiring a "characteristic peak" at 168.1 ppm. I note the differences between his conclusions regarding his XRPD analysis (para 84 below) and that concerning the C-NMR analysis (paras 85 and 86):

> 84. I note that Claim 1 of the 418 Patent specifies an XRPD diffractogram with a peak at 2θ = 26.7 ppm and a ^{13}C-NMR spectrum with a peak at 168.1 ppm. As I explained above, my experiments demonstrated a peak at 2θ = **[Redacted]** which is within an acceptable range of 0.1 degrees. This element of the claim is therefore satisfied.
>
> 85. My experiments also demonstrated that PPC produces moxifloxacin hydrochloride monohydrate that yields a ^{13}C-NMR spectrum that has a signal at 168.1 ppm. In my opinion, this spectrum is consistent with the presence of moxifloxacin hydrochloride monohydrate.

> 86. It is important to note that the sample I analysed under ^{13}C-NMR**[……Redacted……**
> **……**
> **……**
> **……**
> **……**
> **……**
> **……**
> **……**
> **……].**
>
> [emphasis added]

[157] Bayer in effect asks this Court to speculate on the presence of the characteristic peak at 168.1 ppm **[……..….Redacted……..…..].** This is not a permissible approach for the Court, given the specific language in Claim 1 as constructed, i.e., all elements are essential. In this connection, I note that Bayer's expert evidence provided by Dr. Matzger failed on a similar argument in *Vigamox* at paras 216-217, where Justice Phelan held:

> 216 As regards the third element, no ^{13}C-NMR data is available regarding the Cobalt Process. The Applicants invite the Court to infer that it would indicate a peak at 168.1 ppm on the basis that the other essential elements have been met, that no other moxifloxacin hydrates are known and that Cobalt has failed to produce any ^{13}C-NMR data to rebut the inference. Cobalt, naturally, argues against this inference.

> 217 The presence of a peak at 168.1 ppm of the ^{13}C-NMR spectrum is an essential element of the patent which has not been established on the evidence. I decline to make the inference sought by the Applicants; there is nothing, other than the 418 Patent itself, which supports the argument that if moxifloxacin monohydrate has a peak at 2[Theta]=26.7 of the XRPD spectrum, it will necessarily have a characteristic peak at 168.1 ppm of the ^{13}C-NMR. There is no evidence that 13C-NMR values can be obtained as a function of XRPD values. There is no prior or subsequent art attesting to the fact that where the XRPD peak is present in the monohydrate, the ^{13}C-NMR peak will necessarily follow. In the absence of such corroborating evidence, I decline to infer that the ^{13}C-NMR peak is present.
>
> [emphasis added]

[158] Claim 1 establishes essential and conjunctive elements to be met. Dr. Matzger suggests the explanation for the lack of resolution in the data is **[…....Redacted…....]**. However, there is no evidence in support of this hypothesis. In addition Dr. Brittain contradicts this hypothesis.

[159] I find the third essential element of Claim 1 was not established by Bayer on a balance of probabilities as appearing or being used in the manufacture of Fresenius' new drug.

Conclusion on Claim 1 essential elements

[160] Based on the evidence on the essential elements of the claim, I am compelled to find that Bayer has not discharged its burden to establish on a balance of probabilities that the Monohydrate appears in the manufacturing of the Fresenius-moxifloxacin.

[161] The burden is on Bayer to establish all three elements of Claim 1 as construed. If even one of the elements is not established, I am obliged to conclude there is no infringement of the

418 Patent. Bayer has not established, on the balance of probabilities, the presence of the Monohydrate, the characteristic band on the XRPD spectrum at $2\theta = 26.7°$, or the characteristic peak on the C-NMR spectrum at 168.1 ppm. Therefore, I conclude Bayer did not meet its burden to show the allegation of non-infringement of the 418 Patent was not justified.

[162] With these conclusions in mind, I now turn to an examination of the *Saccharin Doctrine* and its application in this case.

Saccharin Doctrine

[163] The exclusive rights conferred by a Canadian patent are limited territorially to Canada. Ordinarily, acts occurring outside of Canada cannot constitute infringement of a Canadian patent: Robert H. Barrigar, *Canadian Patent Act Annotated* (2d ed), PA-462 "Place of Infringement" at s. 54:100; *Dole Refrigerating Products Ltd v Canadian Ice Machine Co* (1957), 17 Fox Pat. C. 125 (Can. Ex. Ct.) at para 8.

[164] Generally, infringement occurs where a patented substance is produced at an intermediate stage, even if the intermediate is not in the final drug product: *Abbott Laboratories v Canada (Minister of Health)*, 2006 FCA 187 at paras 15-17; *Abbott Laboratories v Canada (Minister of Health)*, 2007 FCA 73 at para 4; *Pfizer-Atorvastatin* at para 37. However, a different test is set out when the infringing act occurs abroad. In this case, the alleged patented intermediate is produced offshore.

[165] Bayer correctly argues that "a claim to a product is infringed even when it is manufactured offshore", and in doing so, relies on *Saccharin*, *Monsanto* and *Pfizer-Atorvastatin*. However, in *Pfizer-Atorvastatin* this Court stated that "it is obvious that a Court must proceed cautiously when either off-shore products or processes are concerned": *Pfizer-Atorvastatin* at para 88.

[166] In determining whether offshore use of a patented product produced at an intermediate stage of manufacturing the final product to be imported into Canada, and its subsequent importation constitutes infringement, this Court in *Pfizer-Atorvastatin* said it must have regard to such factors as at para 90:

- The importance of the product or process to the final product sold into Canada (…);
- Whether the final product actually contains all or part of the patented product (…);
- The stage at which the patented product or process is used (…);
- The number of instances of use made of the patented product or process (…); and
- The strength of the evidence demonstrating that, if carried out or used in Canada, the product or process would constitute infringement (…).

[167] In order to find infringement under the *Saccharin Doctrine*, Justice Snider also determined that: "[i]n sum, there must be a strong link established between the [offshore] use of the patented process or product and the product sold into Canada": *Pfizer-Atorvastatin* at para 91.

[168] Fresenius denies that the Monohydrate is used by its offshore manufacturer at any stage of the manufacturing process. In light of the evidence, I found in the prior section that in this case, Bayer failed to establish otherwise on a balance of probabilities. However, even if this Court accepted Bayer's evidence in its entirety and drew the requisite inferences to find the Monohydrate was present in the manufacturing process, consideration of the *Saccharin* factors demonstrates that the alleged infringing use would be insufficient to establish infringement by importation.

[169] I now turn to reviewing each *Saccharin* factor in connection to my findings as to the presence of the Monohydrate.

(1) The Importance of the Product or Process to the Final Product Sold in Canada

[170] The Court must examine whether or not the use is incidental, non-essential or could readily be substituted. I note it is conceded by Bayer that the end product does not contain the Monohydrate and nor does the API. Also I note the beginning products are not the Monohydrate but **[……Redacted…….].**

[171] Dr. Brittain's evidence is that "[t]o the extent any moxifloxacin hydrochloride monohydrate might ever be present during [the foreign] manufacturing process (as suggested by Dr. Matzger), it could only be transiently present and would ultimately be irrelevant to the final product." This expert evidence on the lack of importance of the patented product to the final product sold into Canada is not contradicted. In addition, in my view on the facts I have found,

any use of the Monohydrate in the offshore manufacturing of the new drug would be trivial and merely incidental to the Fresenius-moxifloxacin product sold into Canada.

[172] Counsel for Bayer repeatedly stated that Dr. Matzger reproduced a "key stage" of the multi-step API manufacturing process. I note the stage reproduced is **[……Redacted……]**. In oral arguments, Bayer argued this step was a "key stage" in the manufacturing process, such that this part of the *Saccharin Doctrine* was met. However, Bayer's witness, Dr. Matzger, did not give that evidence; it was counsel's submission to the Court. While whether the step at which the patented Monohydrate was produced was a "key stage" or not is ultimately for the Court to make, and as such, may certainly be advocated by counsel. I am troubled that despite many opportunities to do so, the expert assisting the Court did not give that evidence. Indeed, no expert evidence on this characterization of the step was adduced. In my view, each step of a chemical reaction may be an irreplaceable "key stage", but the Court would need expert evidence to allow it to make this finding. In the circumstances, the Monohydrate's production, if it took place at all, which I found it did not, may not be said to have occurred at a "key stage" as contemplated by the *Saccharin* factors.

[173] Therefore, I cannot conclude that the Monohydrate is of particular importance to the end product to be sold in Canada.

(2) Whether the Final Product Actually Contains all or Part of the Patented Product

[174] The experts and the parties all agree that the Fresenius-moxifloxacin product will not contain the Monohydrate.

(3) The Stage at Which the Patented Product or Process is Used

[175] Justice Snider indicates that this factor should serve to analyze the patentee's alleged deprivation if there is use of a process as a preliminary step of a lengthy production process. The parties disagree as to the nature of the stage at which the Monohydrate would be produced. If I look at the entire manufacture on the evidence, the Monohydrate would be used, if at all, at step **[Redacted].** This step occurs within the first half of the manufacture of the API. Dr. Matzger only identified possible infringement at a single step of the **[Redacted]** API manufacture. Following API manufacture, the API is packaged, sold and shipped to another country, where it is formulated by Fresenius into a solution product involving multiple additional steps. Taken together, these facts indicate the step is more of a preliminary stage in a lengthy process than one of the final steps.

(4) The Number of Instances of Use Made of the Patented Product or Process

[176] As just noted, the evidence is that the Monohydrate would be used or produced once in a multistage process. Bayer argued Dr. Matzger's experiments did not preclude the use of the Monohydrate at other steps in the manufacturing process. Bayer asked the Court to make a positive inference as to the possible existence of such other infringing steps. I am unable to

extend such an inference because I am unable to go against well-established jurisprudence on drawing inferences for possible infringement without evidence: *Vigamox* at para 217; *Takeda Canada Inc v Canada (Health)*, 2015 FC 751 at para 62.

[177] I find that absent any evidence to the contrary, there is only one possible instance of use of the Monohydrate in the manufacturing process.

(5) The Strength of the Evidence Demonstrating that, if Carried Out or Used in Canada, the Product or Process Would Constitute Infringement

[178] The final *Saccharin* factor is the strength of the evidence tending to show infringement. Justice Snider explains: "[o]n this point, my opinion would be that, where there is ambiguity in the evidence, the benefit of the doubt should go to the party using the product or process. This is, perhaps, simply another way of expressing the established principle that the patentee bears the burden of proving infringement": *Pfizer-Atorvastatin* at para 90.

[179] Bayer's evidence did not establish that the Monohydrate would be produced or used in the manufacturing process. Of significant importance, on the strength of Dr. Matzger's evidence, there is no characteristic peak at 168.1 ppm on the C-NMR spectrum as required by Claim 1; there is at best merely a "signal".

[180] Even if this C-NMR peak was found, the remaining evidence on the XRPD spectrum remains tenuous. The XRPD findings by Dr. Matzger are contested by Dr. Brittain on multiple grounds. For example, Dr. Brittain asserts Dr. Matzger's evidence does not meet the ten-peak

analysis USP guidance on compound analysis. Of note, the **[Redacted]** band does not appear at all in Dr. Matzger's sample, though it is of high relative intensity according to the teachings of the 418 Patent. I also note the alleged characteristic band at 2θ = 26.7° is shifted **[Redacted]** where many of the other most intense bands are not shifted at all.

[181] These facts, among others discussed in prior sections, amount to the type of doubt which creates an ambiguity in the evidence. Because the burden is on Bayer, in the presence of tenuous evidence on essential claim elements, I am obliged to resolve the ambiguity in favour of Fresenius.

[182] Looking at all the factors, I find that, at best, Bayer could establish (although I found it did not) that the Monohydrate is transiently manufactured at what may be an important stage in the chemical process **[……Redacted…… ……].** However, Bayer is unable to establish any of the following: the final product contains any Monohydrate; there is more than one instance at which the Monohydrate is produced; and the manufacturing process, if carried out in Canada, would constitute infringement.

[183] Therefore, in balancing the factors in the test set out above, I find Bayer's evidence insufficient to establish infringement by importation on a balance of probabilities. Therefore, I am unable to find infringement by importation under the *Saccharin Doctrine*.

VI. Conclusion

[184] The NOA is defective for failing to set out the "detailed statement" required by the *PM (NOC) Regulations*. Therefore, the requested order of prohibition must issue. Had that not been the case, this Application would be dismissed on the ground that Bayer failed to establish on a balance of probabilities that Fresenius' NOA was not justified.

VII. Costs

[185] Costs should follow the normal rules, and therefore follow the event. Therefore, Bayer will have its costs payable by Fresenius. The parties may seek further direction regarding costs by written submissions filed within 15 days of the date of this Judgment if necessary.

VIII. Confidential Reasons

[186] These reasons contain information subject to a Confidentiality Order. The Parties shall have 30 days to advise what, if any, portions they wish redacted, failing which these Reasons will become the public Reasons and be placed on the public file. Note: the foregoing sentence was included in the Confidential Reasons and judgment; these present reasons contain redactions requested by the Respondent and thus redacted are now public.

JUDGMENT

THIS COURT'S JUDGMENT is that:

1. The Minister of Health is prohibited from issuing a NOC to Fresenius for its moxifloxacin hydrochloride product for injection [Fresenius-moxifloxacin] as requested in Fresenius' Notice of Allegation dated May 5, 2014, until the expiry of Canadian Patent No. 2,192,418.

2. Bayer shall have its costs of this proceeding payable by Fresenius. The parties may seek further direction regarding costs by written submissions filed within 15 days of the date of this Judgment if necessary.

3. The Parties shall have 30 days to advise what, if any, portions of this Confidential Judgment and Reasons they wish redacted, failing which these Reasons will become the public Reasons and placed on the public file accordingly. Note: this part of the Judgment was included in the Confidential Reasons but having heard from the parties is now spent; see para 186.

"Henry S. Brown"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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PLACE OF HEARING:	TORONTO, ONTARIO
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