Federal Court  Cour fédérale

Date: 20120705

Docket: T-991-10

Citation: 2012 FC 741

Ottawa, Ontario, July 5, 2012

PRESENT: The Honourable Mr. Justice Zinn

BETWEEN:

FOURNIER PHARMA INC. and LABORATOIRES FOURNIER S.A.

Applicants

and

THE MINISTER OF HEALTH and SANDOZ CANADA INC.

Respondents

[*] PUBLIC REASONS FOR JUDGMENT AND JUDGMENT
(Confidential Reasons for Judgment and Judgment released June 15, 2012)

Notice of Compliance proceedings "should not be likened to actions for determining validity or infringement but are of the nature of proceedings in judicial review, to be held expeditiously, whose aim is to determine whether the Minister is free to issue the notice of compliance requested:" *Apotex Inc v Canada (Minister of National Health and Welfare)*, [1997] FCJ No 1251 (FCA), at para 6.

[*] As is customary, the Reasons for Judgment were issued as Confidential Reasons to the parties who were then provided with an opportunity to make submissions regarding redaction of confidential information. Those submissions were considered and the Public Reasons reflect the redactions the Court views as necessary in order to protect confidential information.

I would add that because the scope of the proceeding is confined to administrative purposes only and not a final determination that may be made following a trial, it is reasonable for the Court to expect that the parties will focus their submissions, both written and oral, on the one or two or three serious, credible issues in dispute. These proceedings ought not to be seen as an occasion for parties to throw everything at the applications judge in order to see what might "stick."

Reasons are issuing contemporaneously in two related applications: T-991-10, Judgment 2012 FC 741, and T-1184-10, Judgment 2012 FC 740. Both deal with the drug fenofibrate; however, each involves a different patent. Both were brought into play as a result of Sandoz Canada Inc. seeking permission to market its fenofibrate composition in Canada. The result in one application is not determinative of the other, although some substantive and procedural issues are common to both. A Table of Contents follows.

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PARA.

OVERVIEW

The Proceeding and its Background

[1] Fournier Pharma Inc. markets LIPIDIL EZ in 48 mg and 145 mg tablets. The active pharmaceutical drug in LIPIDIL EZ is fenofibrate which reduces LDL (bad) cholesterol and increases HDL (good) cholesterol in patients.

[2] Sandoz Canada Inc. (Sandoz) has sought approval from the Minister of Health (Minister) to market Sandoz Fenofibrate E (the Sandoz Tablet), its generic version of LIPIDIL EZ. In its Abbreviated New Drug Submission (ANDS) filed with the Minister, Sandoz referenced LIPIDIL EZ "for the purpose of demonstrating bioequivalence or bioavailability characteristics" of the Sandoz Tablet. Three patents are listed on the register in respect of LIPIDIL EZ: Canadian Patent 2,219,475 (the '475 Patent), Canadian Patent 2,372,576 (the '576 Patent), and Canadian Patent 2,487,054 (the '054 Patent). Laboratoires Fournier S.A. is the owner of the '576 Patent. The '576 Patent is in the French language. It has been translated and the parties used the English translation that forms part of the record. The title of the '576 Patent is *Pharmaceutical Composition of Fenofibrate Presenting a High Biodisponsibility and its Preparation Process*. The applicants will be collective referred to as "Fournier" in these Reasons.

[3] The *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, as amended (*PMNOC Regulations*) provide that the person seeking a Notice of Compliance (NOC) (Sandoz in this case), referred to in the legislation as the "second person," must serve a Notice of Allegation (NOA) on the person who filed the new drug submission which it references in its ANDS (Fournier Pharma Inc. in this case), referred to in the legislation as the "first person."

[4] Three separate applications were commenced in this Court each seeking an order, pursuant to subsection 6(1) of the *PMNOC Regulations*, prohibiting the Minister from issuing a NOC to Sandoz in connection with the Sandoz Tablets until after the expiration of the relevant Canadian patents. These applications, and the patents at issue are as follows:

a. Court File T-991-10 filed June 24, 2010, in relation to the '576 Patent;

b. Court File T-1054-10 filed June 30, 2010, in relation to the '475 Patent; and

c. Court File T-1184-10 filed July 22, 2010, in relation to the '054 Patent.

[5] Court File T-1054-10 was discontinued on January 25, 2012. The application in Court File T-1184-10 was heard the week commencing March 26, 2012, and that in Court File T-991-10 was heard the following week. Each application was heard separately; however, as noted below, an Order was issued prior to the hearings directing that some of the evidence filed in one proceeding could be referenced by the parties in the other proceeding.

[6] Unless Fournier is granted an order of prohibition, the Minister is prohibited from issuing a NOC to Sandoz until twenty-four (24) months after this proceeding commenced, i.e. until June 24, 2012, unless prior to that date the Court declares that the '576 Patent is invalid or if one of the other conditions in paragraph 7(2)(b) of the *PMNOC Regulations* apply.

[7] Sandoz alleges that the Sandoz Tablet does not infringe the '576 Patent because the size of the fenofibrate particles in the Sandoz Tablet does not fall within the particle size set out in the

claims of the '576 Patent, which Sandoz submits is a particle size greater than 1 µm and less than 20 µm. It further submits that to the extent of any infringement, the '576 Patent is invalid.

Burden of Proof

[8] Subsection 43(2) of the *Patent Act*, RSC 1985, c P-4 provides that an issued patent is presumed to be valid "in the absence of any evidence to the contrary." In a proceeding under the *PMNOC Regulations* if there is evidence in the record that, if accepted, is capable of establishing the invalidity of the patent, then the burden is on the applicant to establish on a balance of probabilities (the civil standard) that the allegations of invalidity are not justified: *Abbott Laboratories v Canada (Minister of Health)*, 2007 FCA 153. Such evidence is in the record in this proceeding; accordingly, the issue for the Court is whether Fournier has proved on the balance of probabilities that all of the allegations raised by Sandoz are not justified.

The Drug and the '576 Patent

[9] Fenofibrate is known to reduce bad cholesterol in the blood and the risk of a heart attack; however, fenofibrate comes with two central problems. First, it is almost insoluble in water. As a result, the patient must take large doses if an effective quantity of fenofibrate is to make its way into the blood stream. The '567 Patent is directed to the problem of dissolution and bioavailability of fenofibrate. Second, the pharmacokinetics (the absorption and distribution) of fenofibrate vary on whether the patient takes it in a fed or a fasted state. It is better absorbed when taken in a fed state and particularly when taken with fatty foods. Dr. Mayersohn described as "diabolical" the fact that the patient is instructed to take fenofibrate with fatty food when the patient, on a low cholesterol

diet, is otherwise instructed to avoid fatty food. The '054 Patent is directed to the problem of bioequivalence in the fed and fasted state.

[10] The disclosure of the '576 Patent describes its object as follows:

> The present invention has as its object a novel pharmaceutical composition presenting a high bioavailability through improved dissolution, and a method for its preparation.

[11] The '576 Patent contains both formulation claims (claims 1-28) and process claims (claims 29-30). Fournier is not asserting the process claims in this application.

The '576 Patent

[12] Fournier asserts that the Sandoz Tablet infringes two separate sets of claims, labelled by the parties as Claim 27A and Claim 27B. Claim 27A is claim 27 when read with claims 1-6, 14-16, 19, 21, 23, and 24. Claim 27B is claim 27 when read with claims 1-6, 14-16, 19, and 21-24. The relevant claims from the '576 Patent are reproduced in Appendix A.

[13] Fournier, in its Memorandum of Fact and Law, describes these two sets of claims, which I reproduce with slight amendment, as follows:

> Claim 27A
> (a) An immediate release fenofibrate composition;
> (b) in the form of a tablet;
> (c) comprising an inert hydrosoluble carrier that is lactose having an individual particle size comprised between 100 and 400 microns;
> (d) and fenofibrate in a micronized form having a particle size less than or equal to10 μm;
> (e) wherein the fenofibrate represents from 20% to 45% by weight;
> (f) further comprising a hydrophilic polymer chosen from polyvinylpyrrolidone, poly (vinyl alcohol), hydroxypropylcellulose,

> hydroxymethylcellulose, hydroxypropylmethylcellulose, gelatin and their mixtures;
> (g) further comprising a surfactant that is sodium lauryl sulfate which represents from 0.1 to 3% by weight; and
> (h) having a dissolution of at least 10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopoeia in a dissolution medium constituted by water with 2% by weight of polysorbate 80 or 0.025 M sodium lauryl sulfate.
>
> Claim 27B
> Claim 27B has all of the elements of Claim 27A with the additional limitation of claim 22, which requires that the fenofibrate and the surfactant are co-micronized.

THE EVIDENCE

[14] The filing of evidence was partially reversed: Fournier filed its evidence on infringement and its factual evidence on invalidity first. Sandoz then filed all of its evidence on the application and Fournier then filed its responding expert evidence on invalidity.

[15] Fournier filed two affidavits sworn by its proposed expert, Dr. Fernando Muzzio: the first dealing with the issue of infringement and the second dealing with the issues relating to invalidity. It also filed an affidavit by sworn by its proposed expert Dr. Elizabeth Vadas relating to invalidity. Sandoz filed affidavits sworn by its proposed experts: Dr. Joseph Bogardus, Dr. Eugene Cooper, and Dr. David Fairhurst. It also filed affidavits from Alexandra Blin-Rogierie and Valerie Baubet speaking to dissolution testing done on Lipanthyl 200M, Catherine Herry speaking to dissolution testing done on compositions allegedly covered by the '576 Patent, and Vincent Cailly-Dufestel speaking to the fenofibrate particle size in the Sandoz Tablet. It also filed an affidavit of Deborah Zak, a law clerk, attaching as exhibits the prior art referenced by Sandoz in its NOA together with various other documents.

Person of Ordinary Skill in the Art (POSITA)

[16] The identification of the POSITA identifies the person or group of persons to whom the patent is addressed. Because the patent is addressed to the POSITA, that person may assist the Court which will have no or little familiarity with the subject matter of the patent. However, that assistance is limited as was observed by Justice Hughes in *Merck & Co v Pharamscience Inc*, 2010 FC 510, at para 70:

> Experts may assist in two ways; first they may inform the Court as to the knowledge that a person skilled in the art would have had at the relevant time, so as to bring that knowledge to bear reading both the description and the claims; second, an expert may assist in explaining any technical terms not within the experience expected of a Court.

[17] Fournier's expert, Dr. Fernando Muzzio, attests that the POSITA "would have a PhD in pharmaceutics along with 1-3 years of experience in the area of formulation of pharmaceutical products. Alternatively, the POSITA could have a Masters degree in pharmaceutics with 5-7 years of experience in the area of formulation of pharmaceutical products." That description of the relevant POISTA does not vary significantly from that offered by Sandoz's experts and I accept it as a statement of the qualifications of the POSITA. It is the same description accepted to be the POSITA in T-1184-10.

Expert Evidence Filed By Fournier

Dr. Fernando Muzzio (On Infringement)

[18] Dr. Muzzio has a B.Sc. in Chemical Engineering from the University of Mar del Plata, Argentina and a Ph.D. from the University of Massachusetts in Chemical Engineering. He is a

Professor II of Chemical Engineering at Rutgers University and teaches a course called Pharmaceutical Unit Operations which includes lectures on size reduction of particles and milling. He directs a staff of approximately 130 persons at the National Science Foundation Engineering Research Center (NSFERC) where he oversees projects relating, in part, to nanoparticle stabilization of pharmaceutical products. As part of NSFERC's industrial mentor program, he interacts and collaborates closely with an additional 120 representatives. He is also the director of the National Science Engineering and Research training program in Nanopharmaceutical Engineering at Rutgers University. Additionally, he teaches courses for industry and regulatory agencies such as the U.S. Food and Drug Administration and he has authored approximately 200 peer-reviewed scientific papers and book chapters on subjects which include powder mixing fundamentals and mixing and segregation in tumbling blenders.

[19] In Dr. Muzzio's affidavit on infringement, he says that Sandoz's allegation that the Sandoz Tablet would not infringe any claims of the '576 Patent is incorrect. Sandoz's allegation of non-infringement of claim 1, the only independent claim, is based on Sandoz's claim that the Sandoz Tablets do not contain fenofibrate in a micronized form in which all, or substantially all, have a particle size less than or equal to about 20 µm and greater than 1 µm.

[20] Dr. Muzzio disagrees with Sandoz's view that the POSITA would read a lower limit on the particle size of fenofibrate into the '576 Patent. In his view, the POSITA would understand that the composition of claim 1 must include, but is not limited to, fenofibrate with a particle size less than or equal to about 20 µm. He says that if there was a lower limit to be read into the '576 Patent, it

would be 0.1 µm; not 1 µm. Anything above 0.1 µm in 1998 was measured in microns and he says that in 1998 he was even not familiar with the use of the term "nano-milling" used by Sandoz.

[21] […]

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[22] […]

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[23] Dr. Muzzio notes that Sandoz's only allegation that it does not infringe claim 22 is that the fenofibrate in their tablets is not co-micronized. He disagrees with that assertion […]

[…] .

[24] […]

[…]

[…]

[…] .

Dr. Fernando Muzzio (On Validity)

[25] Dr. Muzzio provides an overview of the ‘576 Patent and opines that the inventive concept is that “the dissolution profile claimed in the ‘576 Patent can be achieved by the claimed fenofibrate compositions where micronized fenofibrate is adhered to the inert hydrosoluble carrier and can be prepared by spray coating as described in the ‘576 Patent or other methods known to the POSITA.”

[26] Dr. Muzzio disagrees with Dr. Bogardus that the promised utility is a superior dissolution profile and bioavailability to Lipanthyl 200M, the prior art. First, he says that the POSITA would understand the “improvement” stated in the ‘576 Patent relates to the claimed dissolution profile and not any particular Lipanthyl formulation. He explains that the POSITA would know that commercially available products like Lipanthyl 200M could change over time in such a way as to affect its dissolution profile. Second, he gives the following four reasons to explain that the POSITA would not understand improved bioavailability to be a promise:

(a) The claims as drafted refer to a specific dissolution profile and include a testing protocol for measuring dissolution; the claims do not include any reference to bioavailability.

(b) The inventors describe as an aspect of their invention the claimed dissolution profile, as claimed, without reference to bioavailability.

(c) The inventors state that an “object” of the invention is “high bioavailability through improved dissolution.” There is no promise of improved bioavailability over every Lipanthyl 200M formulation.

> (d) As with the dissolution profile, the POSITA would know that commercially available products like Lipanthyl 200M can and often do change over time in such a way as to affect its pharmacokinetic profile, including its bioavailability. As such, it would be illogical to suggest that the inventors were purporting to promise improved bioavailability over any Lipanthyl 200M formulation knowing as they must have – just as the POSITA would know – that such formulations can change [footnotes omitted].

[27] Dr. Muzzio opines that none of the ten documents listed as anticipatory disclose all of the elements of Claim 27A or Claim 27B. He says that none of the documents disclose adhering fenofibrate to the inert hydrosoluble carrier as described in the '576 Patent. In addition, they do not disclose formulating fenofibrate by spraying it onto a hydrosoluble carrier and they do not disclose fenofibrate in the range of 20% to 45% by weight. Finally, he explains that the only document that refers to co-micronization of a surfactant with fenofibrate does not disclose adherence.

[28] Responding to the allegations of obviousness, Dr. Muzzio attests the inventive concept, as he has described it, would not have been self-evident to the POSITA prior to conducting the work needed to achieve the invention. Specifically, he attests that the POSITA would not have known that the dissolution profile claimed in Claim 27A and Claim 27B could be achieved by "adhering the fenofibrate to an inert hydrosoluble carrier."

[29] As to inutility, Dr. Muzzio asserts that there are no experiments proving that the tablets described in Claim 27A and Claim 27B do not achieve the dissolution profile claimed. He asserts that the inventors do not promise improved bioavailability but says that it is demonstrated when working the '576 Patent.

[30] He also says that the invention does not lack sound prediction. He states that the POSITA would have predicted that the tablets claimed in the '576 Patent would achieve the stated dissolution profile. The claims are not broader than the invention made or disclosed and that no undue experimentation would be required to carry out the invention.

Dr. Elizabeth Vadas

[31] Dr. Vadas earned her Ph.D. in Physical Chemistry from McGill University where she was also a Postdoctoral Fellow in biochemistry. She worked at Merck & Co., Inc. for over 20 years where she was the Executive Director, Pharmaceutical Research & Development. In 2002, she started her own consulting firm. A key focus of her career has been on pharmacokinetic properties and improving the bioavailability of poorly water soluble drugs by improving the dissolution characteristics of a formulation.

[32] After reviewing the '576 Patent, Dr. Vadas explains that the compositions tested in Examples 1 and 2 demonstrate an improved dissolution rate compared to LIPANTHYL 200 M. She says that when Example 3 is included, the inventors also demonstrated improved bioavailability in comparison to LIPANTHYL 200 M and Secalip 100. She does not share Dr. Bogardus' view that the inventors could not soundly predict what they claimed. In her opinion, the '576 Patent is based on a sound line of reasoning.

[33] Dr. Vadas states that none of the Ethypharm reports referenced by Dr. Bogardus achieves the dissolution or improved bioavailability in Claims 27A or 27B.

Expert Evidence Filed By Sandoz

Dr. Joseph Bogardus

[34] For over 30 years, Dr. Bogardus has been involved in the pharmaceutical industry and in consultancy relating to the design and evaluation of drug products. He obtained his B.Sc. from the University of Kentucky and his Masters and Ph.D. in Pharmaceutical Chemistry from the University of Kansas.

[35] Dr. Bogardus, based on the common general knowledge in 1997, states that the POSITA would understand that the inventors of the '576 Patent were promising an improved dissolution profile and bioavailability over that provided by Lipanthyl 200 M, the existing composition. He reviews the claims and highlights that claims 1 and 2 cover a very broad dissolution profile. He explains that any dissolution profile that is faster than the claimed profile would be covered by the '576 Patent.

[36] It is his opinion that the claimed compositions do not provide the promised dissolution profile and bioavailability. He references two Ethypharm reports wherein a composition he says is claimed by the '576 Patent did not achieve the dissolution profile. In addition, he says that the promised utility is not predictable because: (1) the range of polymers covered is too broad; (2) there is no indication of the amount of polymers required in the composition; (3) the process for preparing the polymers is not explained; and (4) the dissolution profiles cover too large of a range. Furthermore, he says that practicing the claimed invention would require undue experimentation because the scope of the claims is too broad.

[37] Dr. Bogardus compares prior publications with the elements of the '576 Patent and provides his opinion that this prior art would have provided the POSITA with sufficient information to prepare pharmaceutical compositions covered by the claims of the '576 Patent. In his opinion, the differences between the prior art and the '576 Patent would have been obvious.

[38] Dr. Bogardus disagrees with Dr. Muzzio that the inventors did not intend to place a lower limit to the particle size of the micronized fenofibrate. He says that if they did not intend for there to be a lower limit, they would not have used the term "micronized." He emphasizes that Sandoz does not "co-micronize" the fenofibrate found in their tablets. Rather, he says that the fenofibrate in the Sandoz Tablets is micronized before it is mixed with the surfactant.

Dr. Eugene R. Cooper

[39] Dr. Cooper obtained his Bachelors in Physics, Chemistry and Mathematics from Austin College. He received his Ph.D. in Physical and Theoretical Chemistry from Iowa State University. He has worked on various research and development projects and is now a consultant to the pharmaceutical industry on matters of general drug delivery.

[40] Dr. Cooper says that the POSITA would understand the term "micronized form" found in the '576 Patent to mean fenofibrate particles with a D50 between 3 µm and about 20 µm. He says that the inventors of the '576 Patent gave no explanation as to how the boundary for the dissolution profile in claim 1 was selected. In his opinion, the POSITA would understand that the dissolution

profile in claim 1 was marginally better than the dissolution profile of the prior art, Lipanthyl 200 M.

[41] Dr. Cooper reviews patent European Patent 256,993 (EP '993 Patent), US Patent 5,145,684 (US '684 Patent), US Patent 5,510,118 (US '118 Patent), US Patent 4,721,709 (US '709 Patent), and US Patent 4,895,726 (US '726 Patent) and says that each individually would have provided the POSITA with sufficient information to make a composition covered by the claims of the '576 Patent.

[42] It is his view that the only difference between the common general knowledge and the '576 Patent was the "marginally" better dissolution profile and this, he says, was not inventive.

Dr. David Fairhurst

[43] Dr. Fairhurst holds an *emeritus* position as Corporate Research Fellow at Particle Sciences Inc. For 50 years he was involved in the theory and practical application of colloid and surface chemistry and dispersion/emulsion technologies. He has a B.Sc. in Applied Chemistry and a Ph.D. in Physical Chemistry from Liverpool Polytechnic.

[44] Dr. Fairhurst explains that the POSITA "would have understood the phrase 'fenofibrate in a micronized form' as used in the claims of the '576 Patent to refer to fenofibrate in which substantially all of the fenofibrate had a particle size greater than 1 micron (i.e. a mean particle size of a few microns or more)." He also says that the POSITA would not consider the claims of the

‘576 Patent to cover a formulation that has relatively few micronized particles since that would not provide the benefit of the invention.

[45] Dr. Fairhurst reviews Dr. Muzzio’s statement that “even today the term ‘micronized’ is not used to imply a lower size limit of one micro, and it never has been.” He notes that the brochure used by Dr. Muzzio to support his statement only shows one example where the size of the particles is reduced to below 1 μm. Also, admitting that the efficiency of the “jet-milling” process used in the brochure has improved over the past 15 years, Dr. Fairhurst cites an article from 1996 in which “jet-milling” could only reduce the particle size to “a few microns.”

Additional Expert Evidence

[46] One issue of material significance in this application is the particle size of the fenofibrate particles in the Sandoz Tablet. It is also an issue of material significance in T-1184-10. Days prior to the hearing of these applications, Fournier brought a motion seeking an order allowing the cross-referencing of certain affidavits and cross-examination transcripts as between Court Files T-1184-10 and T-991-10, on the basis that the evidence filed in these two applications by Sandoz relating to particle size was contradictory and that the interests of justice demanded that all of this evidence be before the applications judge in both matters.

[47] Sandoz resisted the motions, in part, on the basis that there is no conflict in the evidence, and in part of the basis that it would suffer prejudice because it has not had an opportunity to file expert evidence to assist the Court is assessing whether there truly is a conflict in the evidence.

[48] The motion was granted on the basis that:

> [T]he interests of justice in having all of the relevant evidence before the Court and avoiding the possibility of conflicting findings of fact outweigh any prejudice of the sort Sandoz asserts it will suffer. Further, it is not clear that expert evidence of the type it says it would file is necessary or helpful to the Court in assessing what are statements of fact by the various expert witnesses.

[49] The issue as to whether there was any actual conflict in the evidence was to be determined as part of the decision on the merits of each application, if necessary.

[50] The portions of the Order relevant to this application are paragraphs 5 and 6 which read as follows:

> 5. The portions of the affidavit of Dr. Muzzio dated February 23, 2011 in T-1184-10 on particle size, as well as the portions of his cross-examination transcript relating to particle size, is incorporated into the Record of T-991-10.
>
> 6. The portions of the affidavits of Drs. LeClair, Serajuddin, and Ruddy and Christoph Heinemann, sworn June 16, 2012 in T-1184-10 on particle size, as well as the portions of their cross-examination transcripts relating to particle size, are incorporated into the Record of T-991-10.

[51] The evidence set out in these documents and the relevance, if any, in this application is discussed below.

Challenges to the Opinions of the Experts

[52] Both Fournier and Sandoz complained about the expert(s) proposed by the other and made representations as to whether that evidence ought to be accepted and, if so, the weight it ought to be given.

[53] Fournier, at paragraphs 6 and 7 of its Memorandum of Fact and Law, asked the Court to approach with caution the evidence of the experts put forward by Sandoz:

> Sandoz's experts did not have the benefit of proper legal instruction and gave conflicting testimony on important issues. Fourier has serious problems with their qualifications and evidence and submit that they should be given little weight. A few of the issues include:
>
> > a) Dr. Bogardus has never worked on the formulations of fenofibrate, on conducting bioavailability studies, or expertise to opine on micronization.
> >
> > b) When impeached on question of bioavailability, Dr. Cooper attempted unreasonably to cling to his opinions despite clear concession by his co-expert, Dr. Bogardus.
> >
> > c) Dr. Fairhurst has no experience in making oral dosage forms.
>
> In addition, Sandoz thwarted Fournier's ability to conduct any meaningful cross-examination on these affidavits [references omitted].

[54] Sandoz, for its part, at paragraphs 12 and 13 of its Memorandum of Fact and Law, challenges the evidence of Fournier's experts, Dr. Vadas and Dr. Muzzio:

> Dr. Vadas' evidence in-chief should be afforded little weight. Counsel for Fournier repeatedly objected to relevant lines of cross-examination. In addition, she readily assumed the role of an advocate for Fournier. For example, she personally attacked Dr. Henry as "either very stupid or dishonest."
>
> Sandoz vigorously challenges the qualifications and expertise of Dr. Muzzio. The evidence establishes that he does not have the qualifications to meet his own definition of an [Ordinary Skilled Worker] at the relevant date. In addition, he is not an expert in bioavailability. Dr. Muzzio assumed the role of advocate for Fournier. He did not provide direct or comprehensible answers to simple questions and gave nonsensical responses in an attempt to avoid clear contradictions in his evidence. Sandoz was unable to

> complete Dr. Muzzio's cross-examination and his evidence in-chief should be given little or no weight [references omitted].

[55] Shortly before this application was heard, Sandoz brought a motion to strike from the Application Record in this proceeding the affidavits of Dr. Muzzio on the ground that he was unresponsive and long winded, and because the respondent had been prevented from completing the cross-examination, despite having additional time. I dismissed that motion and provided the following short endorsement setting out my reasons for so doing:

> I accept that Dr. Muzzio's responses to the questions asked were neither brief nor direct. He was, as was suggested by counsel, a difficult witness. However, that was known prior to the Order of the Prothonotary, which ultimately issued on consent, required that he re-attend for an additional three hours and which contained the proviso that if the cross-examination was not then completed, "counsel will have regard to the time required for the witness to provide answers having regard to the nature and scope of the question posed in determining whether or not additional time will be provided to complete the cross-examination."
>
> It is clear from the Order that counsel for Sandoz accepted the possibility that the cross-examination would not be completed even after three hours. I do not find, on the balance of probabilities, that the applicants' refusal to permit additional time for cross-examination was a decision made in bad faith or capriciously. I do not find that the refusal was contrary to the Order of the Prothonotary. While it might have been argued at the time that Sandoz did not have a full three hours of active cross-examination due to the breaks taken, that was not raised by counsel at the time nor afterwards and it is unfair that it be raised now at the eleventh hour when counsel for the applicants is not in a position to ameliorate that breach, if there was one.

[56] I find inappropriate and unfair the submission that Dr. Vadas, an expert put forward by Fournier, was an advocate for the position being advanced by Fournier. I have reviewed the transcript of her cross-examination. Her evidence certainly supported the position of Fournier and

not that of Sandoz and she was most certainly firm in maintaining her opinion. That does not make her an advocate for the party whose position her evidence supports. Further, she provided an affidavit as required by Rule 52.2 of the *Federal Courts Rules* attesting that she had read and agreed to be bound by the Code of Conduct for Expert Witnesses. Paragraphs one and two of that Code provides as follows:

> 1. An expert witness named to provide a report for use as evidence, or to testify in a proceeding, has an overriding duty to assist the Court impartially on matters relevant to his or her area of expertise.
>
> 2. This duty overrides any duty to a party to the proceeding, including the person retaining the expert witness. An expert is to be independent and objective. An expert is not an advocate for a party. [emphasis added]

[57] For these reasons, I reject the submissions that her evidence ought to be given little weight because she was an advocate for the party putting her forward. Her evidence, like all evidence, must be weighed and considered within the context of the case as a whole, the other evidence, and the submissions made by the parties.

[58] All but one of the other complaints raised by the parties go to the weight to be given the testimony of the expert.

[59] There is merit to the submission of Sandoz that Dr. Muzzio does not have the credentials of the POSITA by his own definition. He does not profess to have these credentials; rather, in his affidavit sworn February 21, 2011, he states with respect to the POSITA: "I have worked with many individuals with these credentials and can speak to their knowledge, their understanding of this area of science and their capabilities." Some of the evidence of Dr. Muzzio might best be

described as "scientific hearsay" insofar as it is the evidence of a scientific witness without the required education offering an opinion on what scientists with the relevant education would understand a patent that is directed to them to mean. Taken to the extreme, it is akin to a physicist saying that he has worked with biologists and chemists and therefore can speak to their understanding of a document that is directed to biologists or chemists. The evidence of that physicist, in my view, should be given little weight.

[60] The situation of Dr. Muzzio is not quite akin to the extreme example offered. Dr. Muzzio does have an education and expertise that is relevant to the extent that I am not prepared to simply strike his affidavit. For example, as a chemical engineer, he is able to speak to the meaning of some of the terms used in the '576 Patent and assist the Court in understanding basic chemistry and formulations relevant to the invention. However, whenever his evidence is in conflict with that of the experts put forward by Sandoz, or is not supported by another expert or scientific evidence on a matter properly within the role of an expert, I prefer their evidence as Fournier made no challenge to their credentials or the fact that they were experts and met the definition of the POSITA.

THE INTERPRETATION OF THE '576 PATENT

[61] What is the invention captured by the '576 Patent? The Supreme Court in *Whirlpool Corp v Camco Inc*, 2000 SCC 67, at para 45, has instructed that patent claims are to be purposively interpreted, the key to which is "the identification by the Court, with the assistance of the skilled reader, of the particular words or phrases in the claims that describe what the inventor considered to be the "essential" elements of his invention." Claims construction is a question of law: *Bristol-Myers Squibb Co v Apotex Inc*, 2007 FCA 379, at para 27. The purposive approach to construction

ought to be used when construing the patent as a whole. The aim is to determine the inventor's view as to what it is that he or she has invented and how that invention is to be made or the process described followed; how the invention is to be used or the result obtained from the invented process; and what the invention does.

[62] The parties are in disagreement about three aspects of the claims and their construction:

a. Whether the phrase "having a particle size less than or equal to about 20 µm" in claim 1 means the particle has a minimum as well as a maximum particle size;

b. Whether the phrase "an immediate release fenofibrate composition comprising an inert hydrosoluble carrier and fenofibrate in a micronized form" in claim 1 means that the fenofibrate is adhered to the inert hydrosoluble carrier; and

c. Whether "co-micronized" in claim 22 means that the fenofibrate and the surfactant are micronized together or whether it means that they are micronized by themselves and not together.

Particle Size

[63] Two construction issues must be decided regarding particle size. The first relates to the meaning of "in micronized form" and the second relates to the meaning of a "composition …having a particle size less than or equal to."

[64] Fournier submits that properly construed, the '576 Patent places an upper limit on the size of the fenofibrate particles of "about 20 µm" but no lower limit. Sandoz submits that "[i]n 1997/1998,

the term "micronized" would have been understood to refer to the process of reducing the particle size of fenofibrate where substantially all of the particles have a size greater than 1 µm." It provides six bases for that submission:

(i) The US '726 Patent, which is equivalent to the '576 Patent, refers to co-micronized powders with a median particle size of 3 µm and 6-7 µm;

(ii) The limits of detection of the Coulter Counter used to measure particle size was 1-120 µm;

(iii) The literature which the POSITA would be familiar defined "micronized" as "to reduce to particles that are only a few microns in diameter;"

(iv) In the 1990's the most commonly used equipment for micronizing powders reduced particles sizes in the 1 µm and greater range;

(v) Standard micronization of oral drug products was not an acceptable process for making particles in the nanometer range; and

(vi) Particles that are less than 1 µm assume different properties that make them difficult to handle.

[65] I find these submissions and the evidence of Sandoz's experts on the meaning of "micronized" unhelpful in the context of the '576 Patent because they are focused on defining the word "micronized" in the phrase "in a micronized form" in claim 1, when that phrase is specifically defined elsewhere in the patent. At page 6 of the specification, the inventors set out a number of definitions. In the context of this discussion, they write: "In the framework of the present invention,

we understand by the expression 'in micronized form' a substance in a particulate form, the dimensions of the particles being less than or equal to 20 µm." If one substitutes that definitional phrase in claim 1, it reads, in relevant part, as follows: "An immediate release fenofibrate composition comprising an inert hydrosoluble carrier and fenofibrate in a particulate form, the dimensions of the particles being less than or equal to 20 µm." It will be seen that the focus of the phrase is now on the term "in a particulate form" and there is no reference at all to the word "micronized."

[66] None of the experts address this definition in their evidence. In my view, where an inventor specifically provides a definition of a phrase used in the patent, that definition must be the prime consideration when interpreting the phrase and not the meaning that may or may not be ascribed any particular word in the phrase so defined.

[67] There is no evidence before the Court that a substance in a particulate form would be understood to have a size of greater than 1 µm. In fact, the evidence of the experts when speaking of nanoparticles makes it clear that substances in particulate form would include a powder having particles in the nanometre range. Accordingly, I interpret claims 1 and 2 to include no lower limit.

[68] The parties are in substantial agreement as to the meaning of a "composition …having a particle size less than or equal to." The experts of both Fournier and Sandoz say that this means that "substantially all of the particles" are under the stated size. In claim 1 this means that substantially all of the fenofibrate particles in the composition are less than or equal to 20 µm; and in the case of

claim 2 that substantially all of the fenofibrate particles in the composition are less than or equal to 10 µm.

Adherence

[69] Dr. Muzzio says that it is clear that the inventors claim to have achieved an improved dissolution profile by "adhering fenofibrate onto an inert hydrosoluble carrier, for instance by using a process that is best described as 'spray coating,' as opposed to merely mixing the fenofibrate and carrier together." He offers five reasons supporting that view.

[70] First, he notes that at page 3 of the specification of the '576 Patent, the inventors write: "Applicant has found that, surprisingly, it is possible to resolve this problem by a new process of preparing a pharmaceutical composition by spraying a suspension of the active ingredient onto an inert hydrosoluble carrier. The present invention also relates to pharmaceutical compositions thus prepared."

[71] Second, he notes that at page 5 of the specification of the '576 Patent, the inventors emphasize that the carrier is "covered" with at least one layer of fenofibrate. "Thus, the present invention provides an immediate-release fenofibrate composition comprising: (a) an inert hydrosoluble carrier covered with at least one layer of a fenofibrate active ingredient in a micronized form having a size of less than 20 µm."

[72] Third, he says that "the use of the word 'carrier' itself implies the formation of an outer layer around the larger hydrosoluble carrier."

[73] Fourth, he notes that at page 10 of the specification, in one embodiment, the inventors state that "the invention, as has been indicated, comprises spraying a suspension of an active ingredient micronized with a hydrophilic polymer onto an inert carrier." He says that the POSITA would have understood from this that "the hydrophilic polymer acts to adhere (or, stick) the fenofibrate to the carrier."

[74] Fifth and last, he notes that at page 10 of the specification the inventors explain that the invented composition, in addition to spray-coating the fenofibrate onto the inert hydrosoluble carrier may be prepared by other procedures, including other spray coating methods and the POSITA would have understood that these alternative procedures "would also have lead to the formation of an external layer of fenofibrate around the hydrosoluble carrier."

[75] Sandoz submits that Fournier is asking the Court to interpret claim 1 by reference to the specification and one embodiment set out in the patent. It says that "it is an error of law to construe the claims by reference to the embodiments illustrated and described in the disclosure of the patent" and cites as its authority *Dableh v Ontario Hydro*, [1996] FCJ No 767 (CA), at para 39. However, that decision does not stand for the unqualified statement proposed by Sandoz. It is clear from reading paragraph 39 that the Court was stating that reliance on the specification will be an error of law where the terms in the claims are not ambiguous:

> In summary, the Trial Judge erred in construing the meaning of the terms varying electric current and electromagnetic coil by reference to the embodiments illustrated and described in the disclosure of the Patent. The terms are not ambiguous, and on their face encompass AC current and coils other than the type used by the appellant. In doing so he committed an error in law [emphasis added].

[76] The evidence of the experts advanced by Sandoz leads to the view that it is ambiguous whether the wording of claim 1 requires adherences. Dr. Bogardus at pages 1155-1156 of the Applicants' Record, in cross-examination pointed to this ambiguity.

> Q: Whether it's necessary or not, given what you've said about the importance of the hydrophilic polymer in ensuring that the fenofibrate adheres to the inert hydrosoluble carrier, the person of ordinary skill in the art, reading Claim 1, would understand that that's what the inventors mean when they describe the composition in Claim 1, in light of Claim 27 and 5, that it's a composition in which the fenofibrate is adhered to the inert hydrosoluble carrier?
>
> A: That is one (1) interpretation.
>
> Q: It's a …
>
> A: I… I…
>
> Q: …reasonable interpretation that the person…
>
> A: It is … one would be led to that interpretation, but that may not …
>
> Q: Well, will you…
>
> A: … be the only interpretation [emphasis added].

[77] Similarly, Dr. Cooper in his affidavit at paragraph 167(a) when describing the meaning the POSITA would ascribe to the phrase "inert hydrosoluble carrier" in claim 1 notes the ambiguity of the phrase and its possible meanings:

> [A]n Ordinary Skilled Worker would understand that the inventors provided an explicit definition of the term "inert hydrosoluble carrier" and that they intended to apply to the claims of the patent with no limitation on the function of the carrier. Alternatively, the term would be understood to mean an inert hydrosoluble carrier on which the fenofibrate has been adhered [emphasis added].

[78] Given this ambiguity as noted by two of Sandoz's experts, it is proper to turn to the specification and the embodiment contained therein to ascertain what the POSITA would have understood claim 1 to mean. All of the experts, including Dr. Bogardus, are agreed that the invention as set out in the disclosure speaks of the adherence of the fenofibrate onto the inert hydrosoluble carrier. In this respect, and on this basis, they support the opinion of Dr. Muzzio that adherence is an essential element of the invention; and I so find.

Co-Micronized

[79] At paragraph 44 of its Memorandum of Fact and Law, Sandoz submits that its composition is not one wherein "the fenofibrate and surfactant are co-micronized" as required by claim 22 of the '576 Patent because "Sandoz does not 'co-micronize' fenofibrate […]

[…]

[…] ."

[80] The prefix "co" in co-micronize has at least two meanings. It may have the meaning of jointly or mutually in which case for two substances to be co-micronized they must both be micronized and micronized together; this is Sandoz's position. Alternatively, it could have the meaning of together with, in which case the two substances are mixed together prior to the micronization process and it does not matter if only one of the two substances is then being micronized; this is Fournier's position.

[81] None of the experts is helpful in resolving this ambiguity. Dr. Muzzio simply states his opinion as to the meaning without providing any foundation for it. Dr. Bogardus describes the Sandoz process and suggests strongly, but never states, that it is not co-micronization within the meaning of the '576 Patent. Accordingly, it is appropriate to turn to the specification for assistance in resolving this apparent ambiguity.

[82] The specification references as prior art US '726 Patent which is said to relate "to a novel dosage form of fenofibrate containing fenofibrate and a solid surfactant which have been co-micronized." It is clear, and the parties are not in disagreement, that the US '726 Patent requires that these two substances (fenofibrate and a surfactant) and no others are each micronized and they are micronized together. I find that the inventors in the '576 Patent intended claim 22 to be understood as meaning co-micronization within the meaning given in the prior art.

INFRINGEMENT

[83] Sandoz makes a number of submissions on infringement. First, it says that its composition does not infringe the '576 Patent because the fenofibrate in its formulation is […]

. . I have already found that properly construed there is no minimum particle size of the fenofibrate particles in the '576 Patent. This submission therefore fails.

[84] Second, Sandoz submits that even if the particle size of the fenofibrate in the Sandoz Tablet falls within that described in the '576 Patent, […]

[…] and, it is submitted, all the experts agree that micronization

means reduction in size. I am unable to accept this submission because it relies on the meaning of the word "micronized" in the phrase "in a micronized form" when, as discussed previously, that phrase is defined in the specification to mean a "substance in a particulate form, the dimensions of the particles being less than or equal to 20 µm." If that definition is substituted for the defined phrase it does not matter whether the particles grew or were reduced – what matters is that, in the final tablet, they are below the stated size.

[85] Third, Sandoz submits that it does not infringe the '576 Patent because in its process the fenofibrate is not co-micronized with the surfactant as required by claim 22. The Sandoz composition does not employ a technique wherein fenofibrate and a surfactant are each micronized and micronized together. […]

[…] . In light of the earlier finding as to the meaning of co-micronized, Sandoz does not infringe claim 22. Accordingly, I find that Fournier has not shown on a balance of probabilities that the Sandoz Tablet infringes claim 22 of the '576 Patent and thus Claim 27B. However, this finding has no impact on whether the Sandoz Tablet infringes Claim 27A.

[86] The last submission on infringement has to do with the particle size of the fenofibrate in the "immediate-release fenofibrate composition." Sandoz submits that there is no evidence as to the particle size of the fenofibrate in its composition and therefore no evidence that it is less than or equal to about 20 µm as described in claim 1, or less than or equal to about 10 µm as described in claim 2.

[87] As was noted in T-1184-10, the companion application, all of the submissions of the parties as to the particle size in the Sandoz Tablet rely on evidence of the particle size in either an earlier state (the dispersion) or a later state (the redispersion). There is no direct specific evidence of the particle size of the fenofibrate in the Sandoz Tablet; no one actually measured the particles in those tablets. Dr. Muzzio in cross-examination in T-1184-10 advises that Scanning Electron Microscopy-Energy Dispersive Spectroscopy would have determined the particle size in the Sandoz Tablet but it was not done:

> The particle size in the Sandoz tablets is what it would have been measured if anybody had bothered to use the right method, which is SEM with EDS, where you can actually see the particles and then you can answer your question the size is this. … The right method was to use EDS. Nobody did it, so the exact answer to your question is not there [emphasis added].

[88] In T-1184-10 it was also noted that there is evidence of the particle size of the fenofibrate in the Sandoz Tablet. In that application, for the reason given therein, the evidence of Dr. Serajuddin as to the size of the fenofibrate particles in the Sandoz Tablet was preferred. That evidence was brought into this application as a result of the Order referenced earlier. Dr. Serajuddin's evidence was a follows:

> […]
> […]
> […]
> […]
> […]
>
> […]
>
> […]
>
> […]

[89] Dr. Serajuddin's evidence, which I accept as the best evidence of the particle size of the fenofibrate in the Sandoz Tablet – it is that 90% of the particles are at least […] However, 90% is not "substantially all" of the fenofibrate particles. Dr. Muzzio in cross-examination stated at page 2362 of Respondent's Record that "substantially all" means "probably 99%." Even if it means less that 99%, even if it meant 90%, then all we know from Dr. Serajuddin is that 90% is at least […] . On cross-examination he was asked for his opinion as to the maximum size of the fenofibrate particle size and he stated that he could not offer any opinion and said that it might be as high as 20 microns:

> Q. Dr. Serajuddin, it's your considered opinion in this case that the particle size distribution of fenofibrate in the Sandoz tablets has a D-90 particle size distribution of […] , correct?
> A. At least […] or higher, much higher, because I mentioned at least ten times here what I mention is […] D-50 and it has to be at least ten times higher. What is the lowest number is […] .
> My considered opinion is it has to be at least 10 times. That means […] or higher. I don't know what is the higher limit.
>
> Q. And it could be as high as 20 micrometers based on the '986 Patent?
> A. It could be. It could be [emphasis added].

[90] The only other evidence of the size of the fenofibrate particles in the Sandoz Tablets comes from Drs. Muzzio and Fairhurst. As previously noted, their evidence was rejected in favour of Dr. Serajuddin's evidence because they offered no scientific support for their view that there would be no appreciable agglomeration of the fenofibrate particles from the dispersion to the tablet; whereas Dr. Serajuddin had scientific support for his view that there would be significant agglomeration.

[91] Accordingly, there is no evidence from which the Court can conclude, on the balance of probabilities, that the particle size of the fenofibrate is less than 10 µm or less than 20 µm or indeed

less than any number. We do not know what size most of the fenofibrate particles are less than; all we know is that the D90 is at least […] and from that evidence we cannot deduce the D99 of the fenofibrate. Quite simply, we have not been provided with the evidence from Fournier that is required in order to be able to conclude that the size of the fenofibrate particles in the Sandoz Tablet infringes that set out in the '596 Patent.

[92] I expect this result will surprise Fournier as Sandoz spent much of its time trying to convince the Court that there was a lower limit of 1 µm implied in the patent and […] […] . However, the burden of proof is on Fournier to establish, on the balance of probabilities, that substantially all of the fenofibrate particles in the Sandoz Tablet, not in the dispersion, is less than or equal to 20 µm for claim 1, and 10 µm for claim 2. It has failed to do so. It has failed to provide any evidence as to the particle size in the composition other than that of Drs. Muzzio and Fairhurst, which has been rejected.

[93] This finding is dispositive of this application because Fournier cannot be granted the prohibition order it seeks unless it disproves all of the allegations of Sandoz that, if unchallenged, would allow the Minister to issue a NOC. For completeness, I will briefly address the allegations of invalidity raised by Sandoz and addressed by Fournier.

ANTICIPATION

[94] Anticipation requires that there be a single prior art reference that discloses all of the essential elements of the invention at issue: *Eli Lilly & Co v Apotex Inc*, 2009 FC 991, at para 410. Anticipation may be found when an essential element of the invention is not specifically disclosed

in the prior art if, when the prior art is performed, the patent under review will be infringed. In that circumstance the prior art anticipates the invention even if it was not apparent to anyone at the time of the prior art. However, in that circumstance, "the infringement must be more than merely a possible or even likely consequence of performing the invention disclosed by the prior disclosure. It must be necessarily entailed:" *Synthon BV v Smithkline Beecham plc*, [2005] UKHL 59, at para 23.

[95] When determining whether the prior art discloses the invention, experimentation is not permissible. As was noted by the Supreme Court in *Sanofi-Synthelabo Canada Inc v Apotex Inc*, 2008 SCC 61 [*Sanofi-Synthelabo*] at paras 25 and 27:

> When considering the role of the person skilled in the art in respect of disclosure, the skilled person is "taken to be trying to understand what the author of the description [in the prior patent] meant" (para. 32). At this stage, there is no room for trial and error or experimentation by the skilled person. He is simply reading the prior patent for the purposes of understanding it.
> …
> Once the subject matter of the invention is disclosed by the prior patent, the person skilled in the art is assumed to be willing to make trial and error experiments to get it to work. While trial and error experimentation is permitted at the enablement stage, it is not at the disclosure stage. For purposes of enablement, the question is no longer what the skilled person would think the disclosure of the prior patent meant, but whether he or she would be able to work the invention.

[96] Sandoz put forward the affidavit of Dr. Bogardus who expresses, as he was asked to do, his opinion as to whether a POSITA, based on common general knowledge would have determined the elements of Claim 27A of the '576 Patent "were previously disclosed in a single Prior Art Publication." He asserts that no single piece of prior art disclosed each of the elements contained in the various claims comprising Claim 27A. On cross-examination and with reference to the prior art

relied upon by Sandoz and which he examined, he stated: "All of the elements of the 576 patent are not disclosed in any one of the publications or the references here."

[97] Sandoz attempted to neutralize the opinion of its expert by asserting that while no publication contained all of the elements of these claims, his admission cannot be taken as support for the proposition that no publication contained all of the essential elements of these claims. While I accept this, I also accept the submission of Fournier that the elements in each of the relevant dependant claims sets out an essential element because each is carefully and precisely drafted so that each claim contains but a single feature that distinguishes it from the others, and that feature is essential. As was noted by Justice Binnie in *Camco Inc v Whirlpool Corp et al*, 2000 SCC 67, [*Whirlpool*] at para 79 relying on previous authority: "It is well understood that '[w]here one claim differs from another in only a single feature it is difficult to argue that the different feature has not been made essential to the claim'."

[98] I agree with the observation of Fournier that in its NOA Sandoz listed some essential elements of claim 1 and that it is now attempting to resile from that characterization in its Memorandum of Fact and Law and its oral submission. Moreover, it references elements in its NOA in the dependant claims that it now says are not essential when no such allegation was made in the NOA. A party seeking a NOC cannot raise issues nor rely on facts that are not set out in its NOA: *Eli Lilly Canada Inc. v Apotex Inc*, 2007 FC 455, para 122; aff'd 2008 FCA 44. These new issues raised by Sandoz that are not contained in its NOA relating to essential elements are not permitted. Even if Sandoz had been permitted to raise these issues, I agree with Fournier, on the basis of *Whirlpool*, that these elements are essential elements.

[99] I find that Fournier has proven on the balance of probabilities that the ‘576 Patent was not anticipated.

OBVIOUSNESS

[100] Obviousness is to be determined in accordance with the four-part analysis outlined by the Supreme Court in *Sanofi-Synthelabo* at para 67:

> (1) Identify the notional "person skilled in the art" and the relevant common general knowledge of that person;
>
> (2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;
>
> (3) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;
>
> (4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

The Supreme Court at paragraphs 69 and 70 set out additional factors to consider within the fourth step, the “obvious to try” step:

> a. Is it more or less self-evident that what is being tried ought to work? Are there a finite number of identified predictable solutions known to persons skilled in the art?
>
> b. What is the extent, nature and amount of effort required to achieve the invention? Are routine trials carried out or is the experimentation prolonged and arduous, such that the trials would not be considered routine?
>
> c. Is there a motive provided in the prior art to find the solution the patent addresses?

> d. The actual course of conduct which culminated in the making of the invention.

[101] The POSITA has previously been identified. Sandoz submits that the relevant common general knowledge was the following:

> (1) Micronizing drug particles was a widely accepted formulating technique for improving bioavailability of poorly water soluble drugs if there was a need to improve bioavailability.
>
> (2) Surfactants, PVP, HPMC and lactose were commonly used in formulating.
>
> (3) Spray coating techniques in the '576 Patent would have been well known to an [POSITA].
> [references omitted]

[102] Fournier asserts that "the inventive concept of the claims of the '576 Patent is that the particular compositions (where micronized fenofibrate is adhered to a carrier) prepared in accordance with the process described in the patent can achieve the favourable claimed dissolution profile."

[103] Sandoz responds by submitting that "claims 29-30 are process claims and are no longer being asserted by Fournier. The absence of this aspect of the inventive concept in Claims 27A and 27B is fatal to their validity." Accordingly, Sandoz submits that "[t]he inventive concept (to the extent one exists) of the claims would appear to relate to potential compositions (containing known ingredients of fenofibrate compositions) that have the specific dissolution profile claimed in the composition claims 1-28."

[104] Even if it is appropriate, as Sandoz submits, to sever claims 29-30 when examining the patent's inventive concept, I do not accept its characterization of the inventive concept.

[105] In many patents a proper analysis of the claims will reveal the invention; but not in all. In *Sanofi-Synthelabo* the Supreme Court found that determination of the inventive concept for the patent at issue required it to look to the disclosure. The claims in the *Sanofi-Synthelabo* patent claimed the compound (the right-handed enantiomer of the racemate), its pharmaceutically acceptable salt and processes for obtaining them. Unable to find an "inventive step" in the claim itself, the Supreme Court looked outside the claim to find it:

> A bare chemical formula in a patent claim may not be sufficient to determine its inventiveness. In such cases, I think it must be acceptable to read the specification in the patent to determine the inventive concept of the claims.

The inventive concept of the claims in *Sanofi-Synthelabo* was held to be "a compound useful in inhibiting platelet aggregation which has greater therapeutic effect and less toxicity than the other compounds of the genus patent and the methods for obtaining that compound." None of those characteristics were to be found in the claims alone.

[106] Justice Crampton, as he then was, in *Allergan Inc v Canada (Minister of Health)*, 2011 FC 1316, at paras 49-51, undertook a similar analysis:

> Generally speaking, the Representative '764 Claims simply claim the Composition for topical use in an affected eye for treating glaucoma. Sandoz submits that the inventive concept of those claims must be discerned from this description alone. Dr. Jampel took the same position.
>
> I disagree. If that were the case, it would not be possible in this and similar cases to fully ascertain the differences between the state-of-

> the-art and the inventive concept of the claim, for the purposes of performing the third step of the obviousness test.
>
> In cases such as this, where "the inventive concept of the claims is not readily discernible from the claims themselves," it is both necessary and permissible to look to the balance of the patent "to determine its inventiveness" (*Sanofi*, above, at para 77). In other words, "to ascertain the nature of the invention" that is articulated in the claims, and to understand the extent to which the claimed invention differs from the prior art, the Court may "look to the whole of the disclosure" in the patent (*Whirlpool*, above, at para 49(g), quoting *Consolboard Inc v MacMillan Bloedel (Saskatchewan) Ltd*, [1981] 1 SCR 504, at 520-21). That said, it bears underscoring that "it is not permissible to read the specification in order to construe the claims more narrowly or widely than the text will allow" (*Sanofi*, above, at para 77) [emphasis added].

[107] This case is similar to those two in that the inventive concept is not readily ascertainable from the claims. Perhaps that is why Sandoz in its Memorandum of Fact and Law wrote: "The inventive concept (to the extent one exists) of the claims would appear to relate to potential compositions (containing known ingredients of fenofibrate compositions) that have the specific dissolution profile claimed in the composition claims 1-28 [emphasis added]."

[108] Once the disclosure is taken into account, the inventive concept is readily apparent: It is that a suspension of fenofibrate in a micronized form in a solution of a hydrophilic polymer and, optionally, a surfactant, sprayed onto an inert hydrosoluble carrier, achieves the claimed dissolution profile.

[109] When one compares this inventive concept against the prior art, one finds that there was nothing in the prior art that involved the spraying of micronized fenofibrate on an inert hydrosoluble

carrier and although US ‘726 Patent referred to the adherence of fenofibrate to an inert carrier, it was not done in the manner described in the ‘576 Patent.

[110] I cannot find that a skilled technician would directly and without difficulty try a suspension of fenofibrate in a micronized form in a solution of a hydrophilic polymer and, optionally, a surfactant, sprayed onto an inert hydrosoluble carrier, thinking that it would achieve the claimed dissolution profile. There is nothing in the record from which one can conclude that it would have been obvious to the skilled technician that the invented composition would achieve that result.

[111] I therefore find that Sandoz’s allegation of obviousness is unjustified.

OVERBREADTH

[112] A patent claim which claims more than what was invented or disclosed can be found invalid for being overly broad. An example of an overly broad claim is found in *Amfac Foods Inc v Irving Pulp & Paper, Ltd*, [1986] FCJ No 659 (FCA). The invention was for cutting potatoes for french fries and the patent as a whole made it clear that an essential aspect of that invention was a blade configuration of outer stabbing blades and the separation of the outer slabs at the cutter. The Court found that there was no reference to this essential element of the invention in the claims. This omission resulted in the finding that the claim was broader than the invention disclosed because the claimed invention covered a number of blade arrangements not having the essential feature necessary to produce the results claimed by the invention. Accordingly, the claims were broader than the invention described in the disclosure.

[113] Sandoz submits that the claims of the '576 Patent are overly broad because: (1) the claims are not limited to adherence of the fenofibrate on the inert hydrosoluble carrier; (2) the claims are not limited to the process in the disclosure for achieving the dissolution profile; (3) the claims are not limited to the specific hydrophilic polymer used in Example 1; (4) the claims do not limit the concentration of hydrophilic polymer used in Example 1; and (5) the dissolution profile covers a range broader than that shown in Example 2.

[114] I reject the first submission because the patent has been construed to include adherence in the claims.

[115] I reject the second submission as well. Fournier submitted in its reply that:

> [W]e never asked that the process be [read] in, no witness suggested that it [ought] to be read in. The only interpretation we've asked to be read into the claim is the one explicitly described in the patent, which is the adherence limitation. The second is that the experts are all in agreement that adherence and layering are the same thing.

Fournier says that "the process is something we have described as part of the inventive concept and it's entirely appropriate to have an inventive concept that differs from a construction of the claims."

[116] If Sandoz is correct that the spray application process is part of the invention then I would still reject its submission that the claims are overly broad as they are not limited to this process. I accept the evidence of Dr. Vadas who, on cross-examination at pages 2900-2901 of the Respondent's Record, stated that the POSITA would have understood the phrase "an inert hydrosoluble carrier and fenofibrate" in claim 1 to mean: (1) that the fenofibrate adhered to the inert hydrosoluble carrier; (2) that the fenofibrate must be adhered by hydrophilic polymer; (3) that the

fenofibrate must form a layer of fenofibrate particles adhered to the carrier; (4) that there could be more than one layer; and (5) that the fenofibrate is adhered to the inert hydrosoluble carrier by spray coating.

[117] I also accept the evidence of Dr. Vadas with respect to the third and fourth allegations of the claims being overly broad regarding the polymer component of the invention. Sandoz submits that the claim ought to have been limited to the polymer used in Example 1 and to the grade used. Dr. Vadas states in her affidavit that the fact that the patent describes an immediate release composition entails that many grades are scientifically excluded. I accept her statement at paragraph 92 of her affidavit that "the POSITA would either know from his or her experience the appropriate ranges of molecular weight of PVP (or any other claimed polymer) to use in the formulation, or could easily determine the appropriate range."

[118] Dr. Vadas makes the same observation concerning the use of polymers other than PVP. She writes: "The POSITA, though not imaginative, nonetheless has advanced credentials and would readily predict, as the inventors did, that each of the six hydrophilic polymers could successfully be used despite differences in their structure, at appropriate concentrations and grades to create fenofibrate compositions, as described in the '576 Patent, that achieved improved dissolution rates." Further, she says that the POSITA would be able to soundly predict, as the inventors did, that a range of concentrations of these hydrophilic polymers would likewise be effective at achieving an improved dissolution rate for the fenofibrate compositions claimed in Claims 27(A) and (B)." As was noted by Justice Mactavish in *Aventis Pharma Inc v The Minister Of Health*, 2005 FC 1283 at para 156:

> The law is clear that a patentee is not to be limited to specific compounds that he or she has actually made and tested prior to filing for patent protection. A patentee is able to claim more broadly, so as to cover a class of compounds, as long as the claim is based upon a sound prediction [emphasis added].

[119] Sandoz submits that that there can be no sound prediction as some aspects of the claims would require the POSITA to undertake a routine amount of work to choose, for example, another polymer to meet the dissolution profile. Sandoz asserts that the doctrine of sound prediction "does not contemplate conducting testing (routine or otherwise) in order to establish utility." In support, it cites a passage from *Hughes and Woodley on patents*, 2nd ed., Volume 1, at 149: "In a field where utility can be predicted in advance of actual testing, a patent may be afforded on the basis of 'sound prediction'."

[120] First, it is noted that what is being described in the cited passage is a situation where there has been no testing at all and thus no proof that the invention works; that is not our situation. Second, experimentation or routine tests may be done to determine other methods of production, polymers and excipients. Justice Snider in *Merck & Co Inc v Apotex et al*, 2010 FC 1265, at paras 531 & 532, dealt with a similar submission to that being advanced here by Sandoz and rejected it:

> The second of Apotex's submissions is that the '380 Patent fails to disclose the methods for determining which strains of the genus *Aspergillus* will produce the desired compounds. As discussed in the section of these reasons on claims construction, I have concluded that the patent only claims compounds produced from *Aspergillus terreus* and, further, that it does not promise that lovastatin can be produced from all strains of *Aspergillus terreus*. Apotex argues that, even on this narrower construction and promise, Merck was required to disclose the methods for identifying producing strains. Apotex argues that the specification does not disclose this information and that to find the producing strains would require excessive and inventive experimentation by the skilled person.

> The courts have recognized that "routine trials and experiments not amounting to new inventions might be required to put [an invention] into practice" (*Proctor & Gamble Co. v. Bristol-Myers Ltd.* (1978), 39 C.P.R. (2d) 145 at para. 51, [1978] F.C.J. No. 812 (QL) (F.C.T.D.); see also, *Mobil Oil Corp. v. Hercules Canada Inc.* (1995), 63 C.P.R. (3d) 473, [1995] F.C.J. No. 1243 (QL) (F.C.A.)); *Aventis Pharma Inc. v. Apotex Inc*. 2005 FC 1283, 43 C.P.R. (4th) 161 at para. 207). The evidence before me does not support Apotex's assertion that inventive experimentation would be required to find producing strains of *Aspergillus terreus*. I have already discussed this issue (see paragraphs 57 to 130) under claims construction. To repeat, I am satisfied that the skilled person could use well-known techniques to rapidly screen a large number of isolates of strains of *Aspergillus terreus* to determine which strains are producing. Moreover, since, on my construction, the claims are limited to strains of the species *Aspergillus terreus*, there are manageable boundaries on the testing that would be required [emphasis added].

[121] Lastly, Dr. Bogardus at paragraphs 155-159 of his affidavit notes that there is a difference between the dissolution profiles of the composition tested in Example 2 of the '576 Patent and that in claim 1. Specifically, he notes that the Example has a better dissolution profile than that set out in the claim. He states: "The inventors did not invent formulations that have a dissolution profile below the dissolution profile obtained in Example 2 that results in improved bioavailability … As such claims 1-30 are broader than the invention made by the inventors." I disagree with this statement. All the inventors are doing is stating that the invention will result in a dissolution profile that is at least that set out in claim 1, and the Example tested did just that. In claims of that sort, the inventors are entitled to claim that the invention will result in a dissolution rate that is greater than any of the rates below that tested. They run the risk, of course, that if a composition is tested and falls below that rate that the invention may be found invalid. However, the claim is not automatically too broad if a cautious inventor picks a lower dissolution rate. There is simply no

need for the inventors to show that they have invented a product that achieves each and every possible dissolution rate between that shown in the test and that claimed.

[122] For these reasons I find that Fournier has shown, on the balance of probabilities, that the allegations of Sandoz that the '576 Patent is invalid as it claims too broadly, is not justified.

UTILITY

[123] The patentee represents to the public that if the directions of the patent are followed, the subject matter of the patent will be created and it will be useful in the sense that it works.

[124] The promise is the use the inventor claims for his invention and it is the statement of that use which led to the inventor being granted a monopoly for his invention. As Justice O'Reilly put it in *Hoffman-La Roche v Apotex Inc*, 2011 FC 875 at para 20:

> [I]n construing a patent, the Court must identify the claimed invention - the purportedly new and useful thing. In analyzing the question whether the inventors have met the requirement of utility, the Court will consider whether the inventors have disclosed a "new article, a better article, a cheaper article, or affords the public a useful choice" (C*onsolboard Inc v MacMillan Bloedel (Sask) Ltd*, [1981] 1 SCR 504 at 521) [emphasis added].

[125] Sandoz submits that the promise of the '576 Patent is that "the claimed fenofibrate composition will provide an improved dissolution profile and improved bioavailability compared to the prior art (in particular, Lipanthyl 200M)." Fournier submits that the promise of the '576 Patent is more specific, it is the dissolution profile referenced in the specification and specifically set out in

claim 1: "a dissolution of at least 10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes."

[126] The Federal Court of Appeal in *Eli Lilly Canada Inc v Novopharm Limited*, 2010 FCA 197, citing *Consolboard Inc v MacMillan Bloedel (Sask) Ltd*, [1981] 1 SCR 504, stated at para 76 that "where the specification sets out an explicit 'promise', utility will be measured against that promise [emphasis added]." The promise of a patent, as that term is used in patent law, is nothing more than the utility the inventor claims for his invention. Where that promise – that claimed utility – is clearly and unequivocally expressed by the inventor in the claims of the patent, then that expression ought to be viewed as the promise of the patent. Any statement found elsewhere should be presumed to be a mere statement of advantage unless the inventor clearly and unequivocally states that it is part of the promised utility. The following from page 1 of the patent in *AstraZeneca Canada Inc v Apotex Inc*, 2010 FC 714, is illustrative of such a statement found in the disclosure:

> It is desirable to obtain compounds with improved pharmacokinetic and metabolic properties which will give an improved therapeutic profile such as a lower degree of interindividual variation. The present invention provides such compounds, which are novel salts of single enantiomers of omeprazole [emphasis added].

[127] The interpretation should be focused on the claims because an inventor is not obliged to claim a monopoly on everything new, ingenious, and useful disclosed in the specification. If, as here, the claims are certain and unambiguous in stating the promise, then the disclosure should not be examined microscopically to find additional promises that are outside the scope of the inventor's claimed monopoly.

[128] Here it is beyond question that the inventors were seeking to improve upon the existing fenofibrate composition. They were seeking to improve bioavailability of fenofibrate through improved dissolution. The patent makes it clear that the inventors were promising not merely improved dissolution but a specific degree of dissolution:

> There is thus a need to improve the bioavailability of fenofibrate in order to attain, over a very short period of time, a level close to 100% (or, in any case, better than the following limits: 10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes in a medium consisting of 1200 ml water to which 2% Polysorbate 80 is added, or 1000 ml of water to which 0.0025M sodium lauryl sulphate is added, with a blade rotation speed of 75 rpm), and this even when the dissolution media having a low surfactant content is used.
>
> Applicant has found that, surprisingly, it is possible to resolve this problem by a new process of preparing a pharmaceutical composition by spraying a suspension of the active ingredient onto an inert hydrosoluble carrier. The present invention also relates to pharmaceutical compositions this prepared [emphasis added].

[129] The "problem" referenced in the second paragraph above is not an "improved dissolution profile and improved bioavailability compared to the prior art" as Sandoz submits; rather, it is the achievement of the specific dissolution profile stated in the '576 Patent. I find, as stated in claim 1, that the promise of the patent is a "fenofibrate composition … having a dissolution of at least 10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes."

[130] Sandoz submits that if one works the '576 Patent, one will discover that the patent does not do what it says it will. In support, Sandoz says that (1) Dr. Muzzio admitted on cross-examination that formulations within claim 27 will not have the claimed dissolution profile, (2) Ethypharm prepared a tablet formulation covered by the claims and it did not meet the dissolution profile set

out in the patent, and (3) Laboratoire SMB testing of a formulation allegedly made in accordance with the '576 Patent fails to meet the dissolution profile.

[131] I agree with Fournier's submission that the passages from Dr. Muzzio's cross-examination referenced by Sandoz in support of its submission that he admitted that formulations within claim 27 will not achieve the stated dissolution profile, do not support the allegation made.

[132] The passage relied on is as follows:

> Q. Okay. Do you understand that you can have a formulation that meets the requirements of A to G [the elements of claim 27A identified by Dr. Muzzio], but doesn't have the dissolution profile, but all it would take is reengineering to fall within A to G to get that dissolution profile?
> A. I think the word "reengineering" would probably be understood to imply a lot more than what I'm saying. What I'm saying is you might very well achieve it the first time you try and if you do not you will do a couple, three more experiments and you will get it.

[133] It is clear that the "admission" amounts to nothing more than reiterating an earlier statement found at page 2204 of the Respondent's Record that "in reality every time a pharmaceutical scientist attempts to implement a formulation they would need to do some fairly routine amount of work, a few trials, to see, you know, what are the precise conditions that give you the best results." This, as stated in my discussion on overbreath, is entirely permissible.

[134] As to the Ethypharm test, Fournier submits, and I agree, that the composition it prepared is not one covered by the '576 Patent. Dr. Vadas, whose evidence I accept and prefer examined this

assertion by Sandoz in her affidavit and stated that the Ethypharm product is not one made in accordance with the invention because:

> (a) The fenofibrate composition in Ethypharm Report 2 uses a hydrophilic polymer called Metolose 90SH100000SR ("Metolose SR"). Metolose SR is not a hydrophilic polymer for use in an "immediate release" fenofibrate composition. The "SR" in the name stands for "Sustained Release" which correctly identifies its use for delaying the dissolution of a drug (the opposite of what is described in the '576 Patent). The concentration of Metolose SR in the granules is stated to be 31.6% which is high and confirms that Ethypharm was selecting Metolose SR for its use in creating a delayed release tablet (not an immediate release tablet);
>
> (b) The concentration of fenofibrate in the composition in Ethypharm Report 2 is below 20%; and
>
> (c) The particle size of lactose DCL21 in the composition in Ethypharm Report 2 is undefined and would not necessarily be within 100 to 400 microns.

[135] I prefer her evidence, in part because despite strenuous cross-examination on this passage from her affidavit, she stood her ground and showed, to my mind, that the inclusion of the 31.6% of Metolose SR would be contrary to the '576 Patent as it would result in a sustained release formulation whereas the patent speaks of an immediate release formulation.

[136] The report from Laboratoire SMB speaks to two formulations; it is the second of these that it is alleged is formulated in accordance with the '576 Patent. It is not. Dr. Bogardus at paragraph 93 of his affidavit acknowledges that it is not covered by claims 19-26, which speak to using a surfactant, and accordingly, it does not meet all of the claims referenced in Claim 27A or Claim 27B.

[137] Some time was taken at the hearing and in the written representations on a submission from Sandoz that the '576 Patent was not useful because the composition disclosed was not considerably superior to the prior art composition. This submission need not be addressed as I have not found that the alleged improvement over the prior art forms part of the promise of the patent. Rather, what the '576 Patent promises is a dissolution profile at least equal to that stated in claim 1. Whether that is better than the dissolution profile of the prior art or not is not relevant and not claimed by the inventors. Even if it had been found to be part of the promise, the allegation of inutility would not have been accepted. Sandoz relies on the evidence of Dr. Bogardus who states that the dissolution profiles in the studies of the prior art and the invention show that the Fournier composition does not have a dissolution profile considerably superior to the prior art product. Again, Dr. Vadas' evidence is preferred. She attests that "it is not scientifically sound to compare dissolution rates between studies as Dr. Bogardus has done."

SOUND PREDICTION

[138] Sandoz's submissions on sound prediction are contained in one paragraph of its Memorandum of Fact and Law, paragraph 84, which reads as follows:

> A sound prediction requires a factual basis to predict the promised utility, a sound line of reasoning and proper disclosure. Fournier has admitted that Promised Utility #1 is not soundly predictable. In paragraph 77 of its Memorandum of Fact and Law, Fournier admits "…the POSITA would require only a "routine" amount of work to choose another polymer to meet the dissolution profile." The doctrine of sound prediction does not contemplate conducting testing (routine or otherwise) in order to establish utility. If any testing was permissible, the doctrine would be rendered meaningless. In any event, on cross-examination, Dr. Muzzio indicated that the testing could take days of work. Claims 27(A) and 27(B) of the '576 Patent are not soundly predictable having regard to the broad class and amounts of hydrophilic polymers, unlimited processes and broad dissolution profile covered by the claims. [references omitted]

[139] For the reasons given above under overbreadth, I reject this submission. Routine testing is permissible, the scope of useful polymers is within the knowledge of the POSITA and the testing is not other than routine, even if one takes a number of days to do the tests necessary to achieve the result. The time required to conduct test does not necessarily indicate that they are other than routine.

INSUFFICIENCY OF DISCLOSURE

[140] Sandoz's allegation of insufficiency relies on the '576 Patent being constructed to include the dissolution profile as a functional limitation. This was not done and for that reason alone the allegation fails.

AMBIGUITY

[141] This Court has noted in that *Letourneau v Clearbrook Iron Works Ltd*, 2005 FC 1229, at para 27, that "a claim is not invalid simply because it is not a model of concision and lucidity." Allegations of ambiguity are used as a "last resort" as was noted in *Pfizer Canada Inc v Canada (Minister of Health)*, 2005 FC 1725, at para 53. Most importantly, Justice Mosley in *Letourneau v Clearbrook Iron Works Ltd* at para 38, observed:

> The Court must give a purposive construction to a claim without being too astute or technical. If there is more than one construction that can be reasonably reached, the Court must favour the construction which upholds the patent. Where the language of the specification, upon a reasonable view of it, can be read so as to afford the inventor protection for that which he has actually in good faith invented, the court, as a rule, will endeavour to give effect to that construction [authorities omitted].

[142] Sandoz does not provide any persuasive evidence from its experts that they do not understand the terms of the ‘576 Patent that are alleged to be ambiguous; rather, as noted by Fournier, it attempts to rely on “admissions” given when cross-examining Fournier’s expert witnesses. No witnesses ever stated that there was no interpretation available for the allegedly ambiguous term that resulted in it being unable to be read as providing the inventor for protection for that which he has actually in good faith invented. Accordingly, I reject the submission of Sandoz that the ‘0576 Patent is ambiguous.

CONCLUSION

[143] As Fournier has not established, on the balance of probabilities, that all of Sandoz’s allegations are not justified, this application must be dismissed. Sandoz is entitled to its reasonable costs. If the parties are unable to agree on an amount, they may advise the Court no later than fifteen (15) days after this Judgment issues and further directions will issue.

JUDGMENT

THIS COURT'S JUDGMENT is that:

1. The application is dismissed; and

2. Sandoz Canada Inc. is entitled to costs in accordance with these Reasons.

"Russel W. Zinn"
Judge

APPENDIX A

Relevant Claims of the '576 Patent

1. An immediate-release fenofibrate composition comprising an inert hydrosoluble carrier and fenofibrate in a micronized form having a particle size less than or equal to about 20 µm, having a dissolution of at 10 least 10% in 5 minutes, 20% in I0 minutes, 50% in 20 minutes and 75% in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution medium constituted by water with 2% by weight polysorbate 80 or 0.025M sodium lauryl sulfate.

2. The composition according to claim 1, wherein the fenofibrate has a particle size less than or equal to 10 µm.

3. The composition according to claim 1 or 2, wherein the fenofibrate represents 5 to 50% by weight.

4. The composition according to claim 3, wherein the fenofibrate represents 20 to 45% by weight.

5. The composition according to one of claims 1 to 4, further comprising a hydrophilic polymer.

6. The composition according to claim 5, wherein the hydrophilic polymer is chosen from: polyvinylpyrrolidone, poly (vinyl alcohol), hydroxypropylcellulose, hydroxymethylcellulose, hydroxypropylmcthylcellulose, gelatin and their mixtures.

…

14. The composition according to one of claims 1 to 12, wherein the inert hydrosoluble carrier is lactose.

15. The composition according to one of claims 1 to 14, in which the inert hydrosoluble carrier has an individual particle size comprised between 50 and 500 microns.

16. The composition according to claim 15, wherein the inert hydrosoluble carrier is lactose having an individual particle size comprised between 100 and 400 microns.

…

19. The composition according to any one of claims 1 to 18, further comprising a surfactant.

…

21. The composition according to claim 19 or 20, wherein the surfactant is sodium lauryl sulfate.

…

23. The composition according to any one of claims 19 to 22, wherein the surfactant represents up to 10% by weight.

24. The composition according to claim 23, wherein the surfactant represents from 0.1 to 3% by weight.

…

27. The composition according to any one of claims 1 to 26, in the form of a tablet.

FEDERAL COURT

SOLICITORS OF RECORD

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APPEARANCES:

Andrew J. Reddon / Steven Tanner / Steven Mason / Fiona Legere	FOR THE APPLICANTS
Warren Sprigings / Mary McMillan	FOR THE RESPONDENTS

SOLICITORS OF RECORD:

MCCARTHY TÉTRAULT LLP Barristers and Solicitors Ottawa, Ontario	FOR THE APPLICANTS
SPRIGINGS Barristers and Solicitors Toronto, Ontario	FOR THE RESPONDENTS