Federal Court  Cour fédérale

Date: 20190308

Docket: T-834-17

Citation: 2019 FC 253

Ottawa, Ontario, March 8, 2019

PRESENT: The Honourable Mr. Justice Fothergill

BETWEEN:

VALEANT CANADA LP/VALEANT CANADA S.E.C.

Applicant

and

GENERIC PARTNERS CANADA INC. and THE MINISTER OF HEALTH

Respondents

and

DEPOMED, INC.

Respondent/Patentee

PUBLIC JUDGMENT AND REASONS

Table of Contents

I. Overview

[1] The administration of some drugs benefits from a prolonged period of controlled release in the stomach and upper gastrointestinal [GI] tract, and an enhanced opportunity for absorption in the stomach and upper GI tract rather than the lower portions of the GI tract. One of these drugs is metformin hydrochloride [metformin], which is used to treat type 2 diabetes, among other conditions.

[2] In June 1998, Depomed, Inc [Depomed] applied for Canadian Patent No 2,290,624 [624 Patent], titled "Gastric-retentive oral drug dosage forms for controlled release of highly soluble drugs". The 624 Patent related to a drug delivery system that comprises a swellable, gastric retentive dosage form that releases drugs, such as metformin, in a controlled manner in the stomach over an extended period of time. The controlled release delivery of these drugs is achieved through their incorporation into a polymeric matrix which swells upon contact with gastric juice, thereby inhibiting the dosage form's exit from the stomach.

[3] In February 2001, Depomed applied for Canadian Patent No 2,412,671 [671 Patent], titled "Tablet Shapes to Enhance Gastric Retention of Swellable Controlled-Release Oral Dosage Forms". According to the 671 Patent, even with swelling, a certain proportion of dosage forms can exit the stomach if they become oriented when in the vicinity of the pylorus (the opening to the small intestine) such that their longest dimension is in alignment with the pyloric axis. This is particularly true of tablets or caplets that are elongated in shape to facilitate swallowing. A certain percentage of these swellable dosage forms will not achieve prolonged retention in the

stomach, and the beneficial effect of the swelling will be lost. The 671 Patent claims to solve this problem with a dosage shape of specified dimensions that, when projected onto a planar surface, is an oval or parallelogram. The 671 Patent specifies the swollen and unswollen dimensions of dosage forms and swelling rates ranging from within 30 minutes to within one hour.

[4] On September 13, 2016, Generic Partners Canada Inc [Generic Partners] filed an Abbreviated New Drug Submission [ANDS] with the Minister of Health. Generic Partners is proposing to manufacture and sell 500 mg extended release tablets of metformin for oral administration [the Generic Product].

[5] In the ANDS, Generic Partners compared its Generic Product to Glumetza®, a patented formulation of metformin manufactured and sold by Valeant Canada LP/Valeant Canada SEC [Valeant]. On April 24, 2017, Generic Partners served a Notice of Allegation [NOA] on Valeant under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 then in effect [Regulations], asserting that the 624 Patent and the 671 Patent are invalid pursuant to s 5(1)(b)(iii) of the Regulations. Generic Partners also alleged that no claim for a medicinal ingredient, formulation, dosage form, or use of a medicinal ingredient would be infringed by the making, constructing, using or selling of the Generic Product, pursuant to s 5(1)(b)(iv) of the Regulations.

[6] The 624 Patent expired in June 2018, and is no longer at issue in this proceeding.

[7] Valeant seeks an order prohibiting the Minister of Health from issuing a Notice of Compliance [NOC] to Generic Partners. Generic Partners alleges that its proposed Generic Product will not infringe Claims 14 to 19, 21 to 24, 26 and 27 of the 671 Patent, but does not dispute that it will infringe Claims 1 to 13, 20 and 25. Generic Partners also maintains that all claims of the 671 Patent are invalid for anticipation, obviousness, double patenting and/or insufficiency.

[8] For the reasons that follow, Valeant has met its burden of proving, on the balance of probabilities, that Generic Partners' allegations respecting the invalidity of 671 Patent are not justified. The application for an order prohibiting the Minister of Health from issuing an NOC for the Generic Product is therefore granted.

II. Parties

[9] The Applicant Valeant is a "first person" under s 4(1) of the Regulations. A first person is a person "who files or who has filed a new drug submission or a supplement to a new drug submission", and who "may submit to the Minister a patent list in relation to the submission or supplement for addition to the register." A first person is the equivalent of a patentee, or person claiming under the patentee, in an action for patent infringement.

[10] The Respondent/Patentee Depomed is the owner of the 671 Patent, and is joined as a party to this proceeding under s 6(4) of the Regulations.

[11] The Respondent Generic Partners is a "second person" under s 5(1) of the Regulations. A second person is a person who has requested an NOC from the Minister of Health for a drug that is similar to one that has previously been approved for manufacture and sale in Canada. Under s 5(3) of the Regulations, the second person must provide the first person with an NOA containing at least one of the four allegations described in s 5(1)(b) of the Regulations. These include assertions of non-infringement and invalidity of the patent in issue.

[12] The Minister of Health is also named as a Respondent, but has not participated in this proceeding.

III. Previous Litigation

[13] The 671 Patent and 624 Patent were the subject of an earlier proceeding in this Court under s 6 of the Regulations, although the Court's decision ultimately concerned only the 624 Patent (*Biovail Corporation v Canada (Minister of Health)*, 2010 FC 46 [*Biovail*]). Justice Michael Kelen described the 624 Patent in *Biovail* as follows:

> [5] The '624 patent was filed on June 5, 1998, and claimed priority from U.S. Patent application 8,870,509, which was filed on June 6, 1997. The '624 patent was issued on December 5, 2006 and expires on June 5, 2018.
>
> [6] The '624 patent teaches a drug delivery system that is a swellable, gastric retentive dosage form that releases drugs, such as metformin, in a controlled manner in the stomach over an extended period of time. The controlled-release delivery of these drugs is achieved through their synthesis into a polymeric matrix. The applicant relies on claims 6,11,16,19 and 20 of the patent. The applicant states the inventive concept disclosed in the asserted claims is the combination resulting in a controlled-release gastric

> retentive oral dosage form for use with metformin where the rate of drug release is dependent on dissolution and diffusion and that that [*sic*] the polymer stays intact during the drug delivery period, and the primary drug release mechanism is not erosional.
>
> [7] The '624 patent is entitled "Gastric-retentive oral drug dosage forms for controlled release of highly soluble drugs". The '624 patent explains that in the 1970s a variety of controlled delivery systems for drug doses were introduced for "sparingly soluble drugs" (see page 1, line 20 of the patent). However, these controlled release delivery systems did not work for highly soluble drugs. The patent explains the invention is a controlled release delivery system for highly soluble drugs like metformin.

[14] Justice Kelen found that the evidence respecting whether the inventive concepts of the asserted claims of the 624 Patent were "obvious to try" was evenly balanced (*Biovail* at para 107). He therefore refused the application of Biovail Corporation [Biovail] for an order prohibiting the Minister of Health from issuing an NOC to Apotex Inc, a Canadian generic drug manufacturer.

IV. The 671 Patent

[15] The 671 Patent claims a priority date of June 20, 2000 from US09/598,061. A Patent Cooperation Treaty [PCT] application was filed on February 26, 2001 and published on December 27, 2001. The 671 Patent application entered the national phase in Canada on December 13, 2002, and was issued on October 3, 2006.

[16] The 671 Patent is included on the Patent Register maintained by the Minister of Health under ss 3 and 4 of the Regulations. Valeant markets tablets containing the active agent

metformin in amounts of 500 mg and 1,000 mg in Canada under the brand name Glumetza® for the treatment of adults with type 2 diabetes.

[17] The 671 Patent describes the "field of invention" as follows:

> This invention is in the general field of pharmaceuticals, and relates in particular to formulations for drugs that benefit from a prolonged time of controlled release in the stomach and upper gastrointestinal (GI) tract, and from an enhanced opportunity for absorption in the stomach and upper GI tract rather than the lower portions of the GI tract. One goal of this invention is to release drugs in a controlled manner over an extended period of time. Another goal is to extend the time of delivery into the stomach of drugs that are preferentially absorbed high in the GI tract, and thereby to achieve a greater and more prolonged therapeutic effect with potentially diminished side effects. This will reduce the frequency of administration required and achieve a more efficient use of the drugs and a more effective treatment of local stomach disorders. A third goal is to minimize both lower-GI tract inactivation of the drug and drug effects on the lower intestinal flora.

[18] In its "Description of the Prior Art", the 671 Patent acknowledges that dosage forms that swell in the stomach to enhance gastric retention were known, and had been disclosed in numerous pieces of prior art including PCT Patent Application WO 98/55107, titled "Gastric-Retentive Oral Drug Dosage Forms for Controlled Release of Highly Soluble Drugs" (December 10, 1998) [WO 107]. WO 107 formed the basis for the 624 Patent.

[19] The "Description of the Prior Art" in the 627 Patent identifies the following problem to be solved:

> Even with swelling, a certain proportion of particles can pass through the pylorus regardless of whether the subject is in the fed

> mode or the fasting mode, if the particles become oriented when in the vicinity of the pylorus such that their longest dimension is in alignment with the pyloric axis. This is particularly true of tablets or caplets (cylindrical tablets with rounded ends) that are elongated in shape to facilitate swallowing. When dosage forms such as these swell due to imbibition of water, one dimension may achieve a length great enough to exceed the pyloric opening while the others may be significantly smaller. The dosage form will thus be retained in the stomach only if the form is oriented with the long dimension transverse to the pyloric opening. Accordingly, for a certain percentage of the administered units of these swellable forms, prolonged retention in the stomach is not achieved and the beneficial effect of the swelling is lost. There is thus only a limited assurance that the swelling will result in gastric retention of the dosage form.

[20] The 671 Patent claims to solve this problem in the following manner:

> It has now been discovered that by using a solid water-swellable dosage form of a particular shape, the proportion of these dosage forms that escapes through the pylorus due to a fortuitous orientation at the pylorus can be reduced or eliminated entirely while still having a dosage form that is easily swallowed. The shape that achieves this result is a non-circular and non-spherical shape which, when projected onto a planar surface, has two orthogonal axes of different lengths, the longer axis being at most 3.0 cm in length, preferably 2.5 cm or less in length, when the dosage form is in the unswollen state, and the shorter axis being long enough to achieve a length of at least 1.2 cm, preferably at least 1.3 cm, within the first one hour, and preferably thirty minutes of swelling time. In addition to enhancing gastric retention, the non-circular and non-spherical shape render the tablets of this invention convenient to swallow. The tablets are also smaller than many tablets of the prior art that were designed for a similar effect, and this offers an advantage for people who suffer from a psychological difficulty when attempting to swallow a tablet.

[21] The 671 Patent specifies a variety of shapes and sizes for dosage forms that are said to "reduce or eliminate" the proportion of dosage forms that escape through the pylorus due to the

"fortuitous orientation" described above. Unswollen and swollen dimensions are provided, together with swelling rates. The dosage form has a shape which, when projected onto a plane, is either an oval or a parallelogram.

V. Claims in Issue

[22] The 671 Patent consists of 27 claims. The only independent claim is Claim 1, which reads as follows:

> A controlled-release oral drug dosage form for releasing a drug into at least a portion of a region defined by the stomach and the upper gastrointestinal tract, said dosage form comprising a solid monolithic matrix with said drug contained therein, said matrix being non-circular in shape and having first and second orthogonal axes of unequal length, said matrix being one that swells upon imbibition of water, the longer such axis having a maximum length of 3.0 cm when said matrix is unswollen, and the shorter such axis achieving a minimum length of 1.2 cm within one hour of immersion of said dosage form in water and wherein said matrix has a shape which when projected onto a plane, is either an oval or a parallelogram.

[23] Generic Partners asserts in its NOA that its proposed Generic Product does not infringe Claims 14 to 19, 21 to 24, 26 and 27 of the 671 Patent. Generic Partners notes that Valeant has not adduced any evidence that these claims have been infringed, and says that its allegations of non-infringement in the NOA are presumed true unless Valeant proves otherwise. Valeant confirms in its Memorandum of Fact and Law that there is no assertion of non-infringement beyond Claim 1 and dependent Claims 2 to 13, 20 and 25.

[24] Claim 2 of the 671 Patent reads as follows:

> A controlled-release oral drug dosage form in accordance with claim 1 in which said shorter axis achieves a minimum length of 1.2 cm within thirty minutes of immersion of said dosage form in water.

[25] The remaining claims in issue specify different dimensions of the unswollen or swollen dosage forms, different polymers, and different times in which the swollen dosage form is achieved. Claims 20 and 25 specifically mention metformin.

VI. Expert Witnesses

A. *Valeant*

[26] Dr. Larry Sternson is a retired Professor of Pharmaceutical Chemistry at the University of Kansas and a retired pharmaceutical executive. He continues to serve as a consultant to various pharmaceutical, biotechnology and venture capital companies. Dr. Sternson has expertise in drug delivery, pre-formulation and formulation development, and other aspects of drug development and product registration.

[27] Dr. Patrick Sinko is the Associate Vice President for Research at Rutgers University and a Distinguished Professor of Pharmaceutics in the Ernest Mario School of Pharmacy. He has taught biopharmaceutics, pharmaceutics, physical pharmacy and drug delivery systems at Rutgers since 1991.

B. *Generic Partners*

[28] Dr. Ping Lee is a Professor of Pharmaceutics and Drug Delivery at the University of Toronto. He has held research and development positions at various pharmaceutical companies. His expertise includes oral solid formulations, novel drug delivery systems, material science, transport phenomena, and pharmaceutical processes and unit operations.

C. *Observations regarding the Evidence*

[29] The parties do not challenge the qualifications of the expert witnesses. However, Valeant and Generic Partners each question the impartiality of the witnesses called by the other party.

[30] Generic Partners notes that "Dr. Sternson held the positions of President, Elan Drug Delivery and VP, Elan Corporation [collectively, Elan], where he was responsible for, *inter alia*, strategic partnerships" at the priority date of the 671 Patent. Generic Partners identifies two partnerships as possible causes for concern. First, Elan began a joint venture with Depomed, the Respondent/Patentee, in June 2000 to develop gastric retentive dosage forms. This joint venture lasted until 2003. Second, Elan's relationship with Biovail, Valeant's predecessor, gave rise to restraint of competition charges by the Federal Trade Commission. Both of these strategic partnerships occurred while Dr. Sternson was an executive at Elan.

[31] Expert witnesses have a duty to the Court to give fair, objective and non-partisan opinion evidence. They must be aware of this duty, and be able and willing to carry it out. If they do not

meet this threshold requirement, then their evidence should not be admitted (*White Burgess Langille Inman v Abbott and Haliburton Co*, 2015 SCC 23 [*White Burgess*] at para 32).

[32] Once this threshold is met, however, concerns about an expert witness' independence or impartiality should be considered as part of the overall weighing of the costs and benefits of admitting the evidence. The threshold requirement is not particularly onerous, and a proposed expert's evidence will only rarely be excluded for failing to meet it. It is the nature and extent of the interest or connection with the litigation which matters, not the mere fact of the interest or connection; the existence of some interest or a relationship does not automatically render the evidence of the proposed expert inadmissible. However, an expert who assumes the role of an advocate for a party is clearly unwilling or unable to carry out the primary duty to the court (*White Burgess* at para 46).

[33] Generic Partners has offered nothing to support its allegation of bias against Dr. Sternson beyond the bare assertion of two problematic strategic partnerships. Dr. Sternson was not asked about any improper affinity he might have for Valeant based on his previous relationships with its predecessor company or the patentee. Generic Partners' allegation of bias has not been advanced in accordance with the principles of fairness, and falls well short of the standard set by the Supreme Court in *White Burgess*. I give it no further consideration.

[34] Generic Partners also cautions the Court against accepting the testimony of Dr. Sinko, given Justice Robert Barnes' characterization of some of his evidence as "disingenuous" in *Glaxosmithkline Inc v Pharmascience Inc*, 2008 FC 593 at paragraph 62 [*Glaxosmithkline*]. This

finding must be understood in its proper context. First, Justice Barnes described the evidence of Dr. Sinko (and that of another witness) on a particular point as disingenuous. The description was not levelled at Dr. Sinko generally or even exclusively. Second, Justice Barnes observed in paragraph 6 of his reasons that he could identify nothing which would tend to discredit any of the expert witnesses or which might cast doubt upon their qualifications. He continued: "Indeed, all of these witnesses appear to be eminently qualified and generally objective in the provision of their opinion evidence." I am therefore not persuaded that Dr. Sinko's testimony should be given less weight due to Justice Barnes' comments in *Glaxosmithkline*.

[35] For its part, Valeant alleges that Dr. Lee did not examine the 671 Patent with "a mind willing to understand". This assertion is based on the skepticism expressed by Dr. Lee regarding the utility of the invention disclosed by the 671 Patent. I discuss Dr. Lee's analytical approach later in these reasons. Suffice it to say that any concerns I have regarding his testimony do not arise from his credibility or alleged partisanship, but rather from his methodology.

[36] Justice Barnes' acknowledgment in paragraph 6 of *Glaxosmithkline* of the "obvious limitations presented by attempting to evaluate the credibility of any witness based on affidavits and cross-examination transcripts" is applicable here. Justice Roger Hughes was similarly unwilling to make an adverse finding of credibility in a proceeding under the Regulations (*Eli Lilly Canada Inc v Novopharm Limited*, 2009 FC 235 at para 73): "The differences between [the witnesses] cannot be resolved on the basis of credibility, I have not seen the witnesses, I have only affidavits and transcripts. No exchange in cross-examination is so striking as to enable a credibility assessment to be made. Thus, they both are credible."

[37] While acknowledging the limitations in the Court's ability to assess the credibility of witnesses who have not appeared in person, I am satisfied that all of the experts who provided evidence in this proceeding were generally credible. They understood and respected their obligation to give impartial testimony before the Court. My reasons for preferring some witnesses' evidence over that of others are explained in the analysis that follows.

VII. Issue

[38] The issue before this Court is whether Valeant has demonstrated that the allegations in Generic Partners' NOA are unjustified. Generic Partners alleges that the 671 Patent is invalid on four grounds:

A. Anticipation/*Gillette* Defence;

B. Obviousness;

C. Double-patenting in relation to the 624 Patent; or

D. Insufficiency.

VIII. Onus and Burden of Proof

[39] In *Pfizer Canada Inc v Canada (Minister of Health)*, 2007 FCA 209, the Federal Court of Appeal explained the manner in which the onus and burden of proof function in applications under the Regulations:

> [109] Thus, a first person under the Regulations has the overall burden of establishing, on a balance of probabilities, that the

> allegations of invalidity contained in a second person's NOA are not justified. Although the first person has the initial burden, because of the presumption of the validity of a patent set out in section 45 of the pre-1989 Act, it can meet this burden merely by proving the existence of the patent. The second person then has the burden of adducing evidence of invalidity and of putting the allegations of invalidity contained in its NOA "in play". To do so, the second person must adduce evidence which is not clearly incapable of establishing its allegations of invalidity. Hence, not only must the second person's NOA contain a sufficient factual and legal basis for its allegations, but it must also adduce evidence of invalidity at trial.
>
> [110] Once the second person has adduced sufficient evidence, on a balance of probabilities, the first person must, also on a balance of probabilities, disprove the allegations of invalidity set out in the NOA. […]

[40] This statement of law also governs applications under the Regulations respecting patents filed under the post-1989 *Patent Act*, RSC 1985, c P-4, pursuant to which patents continue to enjoy a presumption of validity (*Patent Act*, s 43(2); *Biovail* at para 40).

IX. Claims Construction

A. *Legal Principles*

[41] The first step in a patent suit is to construe the claims to ascertain their meaning and determine their scope (*Whirlpool Corp v Camco Inc*, 2000 SCC 67 at para 43 [*Whirlpool*]). The relevant date for construing the claims is the date of publication of the patent application: December 27, 2001 (*Whirlpool* at paras 54-55). The Court must examine the claims to identify

what the inventor considered to be their “essential elements”, and may be aided by expert evidence regarding the meaning of specific terms (*Whirlpool* at paras 45, 57).

[42] The canons of claims construction are found in the Supreme Court of Canada’s decisions in *Whirlpool* at paragraphs 49 to 55 and *Free World Trust v Électro Santé Inc*, 2000 SCC 66 [*Free World Trust*] at paragraphs 44 to 54. They are the following:

(a) claims are to be read in an informed and purposive way with a mind willing to understand, viewed through the eyes of the person skilled in the art as of the date of publication having regard to the common general knowledge;

(b) adherence to the language of the claims allows them to be read in the manner the inventor is presumed to have intended, and in a way that is sympathetic to accomplishing the inventor’s purpose, which promotes both fairness and predictability; and

(c) the whole of the specification should be considered to ascertain the nature of the invention, and the construction of claims must be neither benevolent nor harsh, but should instead be reasonable and fair to both the patentee and the public.

B. *Person of Ordinary Skill in the Art*

[43] In order to construe the claims in issue, the Court must define the person of ordinary skill in the art [PSA]. This is "the person to whom the patent is said to be addressed, through whose eyes the Court is to read the patent, and who stands as the criterion for determination of obviousness" (*Amgen Canada Inc v Apotex Inc*, 2015 FC 1261 at para 42).

[44] The PSA is unimaginative and uninventive, but reasonably diligent in keeping up with advances (*Pfizer Canada Inc v Teva Canada Ltd*, 2017 FC 777 at para 185). The PSA is not incompetent, and brings background knowledge and experience to the workbench (*AstraZeneca Canada Inc v Apotex Inc*, 2015 FC 322 at para 276). The PSA is not stripped of the ability to pursue reasonable and logical enquiries, and can make deductions based on the information available (*Jay-Lor International Inc v Penta Farms Systems Ltd*, 2007 FC 358 at para 75 [*Jay-Lor*], citing *Beloit Canada Ltd v Valmet Oy* (1986), 8 CPR (3d) 289 at 294 (FCA) [*Beloit*]).

[45] The parties generally agree on the PSA's technical qualifications. According to Drs. Sternson and Sinko, the PSA would have a graduate degree in pharmaceutical sciences or a related field with a few years' experience developing oral dosage forms. Dr. Lee was of the view that a Bachelor's degree in these fields would be sufficient, provided the PSA had sufficient practical experience in the industry.

[46] Valeant objects that Dr. Lee improperly attributed inventive skill to the PSA, because he was prepared to include the inventors of an application cited as prior art within his definition.

Generic Partners responds that by the relevant dates, the body of work described in the prior art was “old”. While the inventors may have exercised ingenuity when arriving at their invention, this does not mean the invention forever remains “inventive” when considering the 671 Patent. I agree with Generic Partners. Dr. Lee was commenting on the common general knowledge available to the PSA respecting the size of dosage forms, which was well-established by the relevant dates.

C. *Common General Knowledge of the PSA*

[47] The patent must be construed taking into account the “common general knowledge” shared by persons skilled in the art (*Free World Trust* at para 44; *Whirlpool* at para 53). This is the knowledge possessed by the PSA at the relevant time, and includes what the PSA would reasonably have been expected to know (*Whirlpool* at para 74). The common general knowledge of the PSA must be established with evidence on a balance of probabilities, and cannot be assumed (*Uponor AB v Heatlink Group Inc*, 2016 FC 320 at para 47). Common general knowledge may include the information presented as background knowledge in the patent itself (*Newco Tank Corp v Canada (Attorney General)*, 2015 FCA 47 at para 10).

[48] The assessment of common general knowledge is governed by the principles found in *Eli Lilly & Co v Apotex Inc*, 2009 FC 991 at paragraph 97 (aff'd, 2010 FCA 240) and *General Tire & Rubber Co v Firestone Tyre & Rubber Co*, [1972] RPC 457 (UKHL) at pages 482 to 483:

(a) the common general knowledge imputed to the PSA must be carefully distinguished from what in patent law is regarded as public knowledge;

(b) common general knowledge is a different concept derived from a common sense approach to the practical question of what would in fact be known to an appropriately skilled addressee – the sort of person, good at his or her job, who could be found in real life;

(c) individual patent specifications and their contents do not normally form part of the relevant common general knowledge, although there may be specifications which are so well known that they do form part of the common general knowledge, particularly in certain industries; and

(d) regarding scientific papers generally:

i. it is not sufficient to prove common general knowledge that a particular disclosure is made in an article, or series of articles, or in a scientific journal, no matter how wide the circulation of that journal may be, in the absence of any evidence that the disclosure is accepted generally by those who are engaged in the art to which the disclosure relates;

ii. a piece of particular knowledge as disclosed in a scientific paper does not become common general knowledge merely because it is widely read, and still less because it is widely circulated;

iii. such a piece of knowledge only becomes general knowledge when it is generally known and accepted without question by the bulk of those who are engaged in the particular art; in other words, when it becomes part of their common stock of knowledge relating to the art; and

iv. it is difficult to appreciate how the use of something which has in fact never been used in a particular art can ever be held to be common general knowledge in the art.

[49] The Court must look at the words of the claims through the eyes of the PSA, not through the eyes of a grammarian or etymologist (*Whirlpool* at para 53). The Court must construe a patent with a judicial anxiety to support a useful invention (*Hospira Healthcare Corporation v Kennedy Trust for Rheumatology Research*, 2018 FC 259 at para 118). If there is more than one construction that can be reasonably reached, the Court must favour the construction that upholds the patent (*Letourneau v Clearbrook Iron Works Ltd*, 2005 FC 1229 at para 38). However, if a patentee has misspoken or created a troublesome limitation, this is a self-inflicted wound. The Court's role is to interpret the claims, not to redraft them (*Free World Trust* at para 51).

D. *Prior Art*

[50] The following prior art is cited by Generic Partners in its NOA, and is relied upon in this proceeding to establish its allegations concerning the invalidity of the 671 Patent.

[51] Hwang, et al, "Gastric Retentive Drug-Delivery Systems", Critical Reviews in Therapeutic Drug Carrier Systems, 1998, 15(3), 243-284 [Hwang Paper]: The Hwang Paper was published in 1998, and is a review article that cites 138 other publications. It provides background information on GI physiology and surveys the state of gastric retentive technologies at the time. The Hwang Paper briefly explains the benefits of developing gastric retentive dosage forms, and discusses some basic GI physiology including gastric emptying times, fed versus fasting states, and the effect of dosage size on gastric retention. The Hwang Paper identifies six different gastric retentive technologies: intragastric floating systems; high-density systems; mucoadhesive systems; magnetic systems; unfoldable, extendible, or swellable systems; and superporous hydrogel systems.

[52] WO 107: WO 107 is titled "Gastric-Retentive Oral Drug Dosage Forms for Controlled Release of Highly Soluble Drugs" and was published in 1998. It disclosed gastric retentive dosage forms of highly soluble drugs, including metformin. The dosage forms comprised a swellable polymer matrix for controlled delivery and improved absorption in the stomach. WO 107 formed the basis for the 624 Patent. Both the 624 Patent and the 671 Patent are owned by Depomed, and licensed to Valeant. Both patents have one inventor in common, Jenny Louie-Helm.

[53] The disclosure of WO 107 included the parameters of various preferred embodiments and outlined the methods of producing them. It also contained eight examples of formulations. WO 107 has 22 claims: independent Claim 1 and 21 dependent claims. Claim 1 teaches a controlled release oral dosage form that, *inter alia*, "swells to at least about twice its volume upon imbibition of water" and releases all of its drug "within about eight hours after" immersion in the stomach's gastric juice. Claim 5 is for dosage forms containing metformin, and Claims 21 and 22 are for dosage forms of particular shapes and sizes. Claim 21 teaches a dosage form consisting of two cylindrical tablets measuring about 9 mm to 12 mm in length and 6.5 mm to 7 mm in diameter. Claim 22 teaches a dosage form consisting of one elongated tablet measuring about 18 mm to 22 mm in length, 6.5 mm to 7.8 mm in width, and 6.2 mm to 7.5 mm in height.

[54] Khosla R, et al, "The Effect of Tablet Size on Gastric Emptying of Non-Disintegrating Tablets". *International Journal of Pharmaceutics*, 1990, 62, R9-R11 [Khosla Paper]: The Khosla Paper was published in 1990, and described an experiment to measure the time that differently-sized dosage forms remain in the stomach. 0.7 cm, 1.1 cm, and 1.3 cm tablets were tested, and 1.3 cm tablets were found to average an additional 30 to 60 minutes of stomach residency compared to the smaller tablets. The Khosla Paper also disclosed the mean resting pyloric diameter [MRPD] as equal to 1.28 ± 7 cm. The MRPD describes the size of the pyloric opening, and was first reported in the 1970s.

[55] WO 99/07342 Application [WO 342]: WO 342 was published in February 1999. It disclosed a dosage form comprising a swellable polymer matrix for controlled delivery and

improved gastric retention. The dosage form was also banded by insoluble material that prevented its banded portion from swelling.

[56] Valeant does not accept that all of the prior art cited by Generic Partners should be considered a part of the common general knowledge of the PSA as of the relevant dates. Valeant points to a statement in the Hwang Paper that "[t]he literature is full of conflicting information".

[57] The Hwang Paper was published in 1998. By June 2000 and December 2001, research was focused on developing dosage forms that were small enough to swallow, but absorbed gastric juice to swell to a size large enough to prevent their exit from the stomach. Furthermore, WO 107, which formed the basis for the 624 Patent, is acknowledged by the 671 Patent to be relevant prior art.

[58] From WO 107, supplemented by the other prior art cited by Generic Partners, I conclude that the common general knowledge of the PSA as of the relevant dates encompassed the following:

(a) There were different methods for attempting to achieve gastric retentive oral dosage forms. The most common and simple method to achieve gastric retention was to use swellable hydrogel polymers.

(b) GI physiology would affect the physical and timing parameters required to achieve retention. The retention of differently-sized particles in the stomach

would depend on the size of the pyloric opening, and the transit time of particles through the stomach under normal physiological conditions (*i.e.*, gastric emptying time).

(c) The MRPD was widely reported as 1.28 ± 0.7 cm. The effect of the size of a dosage form on gastric retention had also been studied. The Khosla Paper reported testing of the gastric retention of three differently-sized tablets. As tablet size increased, residence time in the stomach also increased. Khosla concluded that tablets larger than the "critical value", which was likely similar to the MRPD of 1.28 ± 7 cm, would be retained in the stomach. Similar data were reported in the Hwang Paper.

E. *Construction of Claim 1*

[59] Claim 1 is the only independent claim of the 671 Patent. The expert witnesses were largely in agreement regarding its construction.

[60] Generic Partners identifies nine essential elements of Claim 1:

(a) a controlled-release oral dosage form;

(b) for releasing a drug into at least a portion of a region defined by the stomach and the upper GI tract;

(c) this dosage form comprising a solid monolithic matrix containing the drug;

(d) the matrix is non-circular in shape;

(e) the matrix has first and second orthogonal axes of unequal length;

(f) the matrix swells upon imbibition of water;

(g) the longer axis having a maximum length of 3.0 cm when the matrix is unswollen;

(h) the shorter axis achieves a minimum length of 1.2 cm within one hour of immersion of the dosage form in water; and

(i) the matrix has a shape that, when projected onto a plane, is either an oval or a parallelogram.

[61] Valeant consolidates these nine elements into three, which it describes as follows:

(a) “Size Element” – the minimum length of the swollen, second axis is 1.2 cm;

(b) “Time Element” – the time it takes for the Size Element to be reached is within one hour; and

(c) "Shape Element" – the matrix of the dosage form when projected onto a plane is in the shape of an oval or a parallelogram.

[62] While Valeant's proposed construction is a simplification and omits some nuances from Generic Partners' more comprehensive approach, I am satisfied that it captures the essential elements of Claim 1 in a manner that is helpful in resolving the dispute between the parties. Claim 1 is for a controlled-released, gastric retentive oral dosage form with three essential features:

(a) "Size Element" – the longer axis has a maximum unswollen size of 3.0 cm, and the shorter axis has a minimum swollen size of 1.2 cm;

(b) "Time Element" – the dosage form swells such that the shorter axis achieves the minimum size of 1.2 cm within one hour; and

(c) "Shape Element" – the dosage form is non-circular with a planar projection of an oval or parallelogram with two unequal orthogonal axes.

[63] Given the conclusion reached below regarding the validity of Claim 1 of the 671 Patent, it is unnecessary to construe the multiple variations that are found in dependent Claims 2 to 13, 20 and 25.

X. Anticipation/*Gillette* Defence

A. *Legal Principles*

[64] Pursuant to s 28.2 of the *Patent Act*, a patent claim will be invalid for anticipation if the subject matter defined by the claim was disclosed in such a manner that it became available to the public either more than one year before the filing date of the application, if disclosed directly or indirectly by the patentee (s 28.2(1)(a)), or at any time before the claim date, if disclosed by any other person (s 28.2(1)(b)), and was enabled to a skilled person (*Eli Lilly Canada Inc v Mylan Pharmaceuticals ULC*, 2015 FC 125 at para 145). Disclosure need not reveal an exact description of the subject matter of a claim, but must be sufficient so that, when read by a person skilled in the art and willing to understand the invention, it can be understood without undue burden. The requirement of prior disclosure means that the prior patent must disclose subject matter which, if performed, would necessarily result in infringement of the patent (*Sanofi-Synthelabo Canada Inc v Apotex Inc*, 2008 SCC 61 at para 25[*Sanofi-Synthelabo*]).

[65] If the disclosure requirement is satisfied, the second requirement to prove anticipation is enablement, which is whether the PSA would have been able to perform the invention. Trial and error experimentation is not permitted at the disclosure stage, but is permitted at the enablement stage. For the 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 (*Sanofi-Synthelabo* at para 27).

[66] The *Gillettte* defence is intended to abbreviate the anticipation analysis, and is sometimes described as a "short cut". A patent is not infringed if the behaviour that is alleged to infringe accords with the prior art, because the prior art is either anticipatory or non-infringing (*JK Smit & Sons Inc v McClintock*, [1940] SCR 279 at 286).

B. *Analysis*

[67] Generic Partners says that WO 107 anticipates the 671 Patent. WO 107 formed the basis for the 624 Patent, and shares a common inventor with the 671 Patent. Generic Partners argues that the dosage form claimed in WO 107 is gastric-retentive, because it is said to release all of the drug within eight hours, and an eight-hour stomach residency constitutes gastric retention. Generic Partners then asserts that the PSA would have known that the dosage form must expand to at least the size of the MRPD before gastric emptying occurs within one hour. Thus, Generic Partners argues that the Size Element and Time Element are both present in WO 107.

[68] Generic Partners points to the preferred dimensions in the disclosure and the claimed dimensions in Claims 21 and 22 and says that the Size Element is also present in WO 107. Generic Partners notes that the unswollen starting dimensions in the disclosure and the claims are such that the longer axis is less than 3.0 cm, just as the 671 Patent claims in Claim 1, and the range of lengths of the shorter axes partially overlap the ranges claimed in Claims 5 and 6 of the 671 Patent. According to Dr. Lee, the range of unswollen dimensions claimed and disclosed in WO 107, combined with the claimed doubling of volume of the dosage form, would cause the PSA to conclude that the shorter axes must expand to at least 1.2 cm.

[69] Generic Partners also argues that the Shape Element is present in WO 107. It alleges that the preferred dimensions in the disclosure describe non-circular dosage forms with oval or parallelogram planar projections. Generic Partners bases this allegation on the dimensions themselves and the statement in WO 107 concerning preferred embodiments that "the shapes and sizes can be varied considerably." Generic Partners also argues that WO 107 and the 624 Patent claimed non-circular dosage forms with oval or parallelogram planar projections in Claims 21 and 22.

[70] Valeant maintains that none of the essential elements of Claim 1 of the 671 Patent are present in WO 107. The claim in WO 107 that its dosage form expands to twice its volume does not disclose the dosage form's swollen size or the time it takes to swell to that size. Valeant also contends that the statement that "the shapes and sizes can be varied considerably" does not disclose the Shape Element, as it provides no meaningful guidance to the PSA concerning which shapes improve the gastric retention of dosage forms. In response to Dr. Lee's opinion respecting the preferred dimensions of the swollen dosage form, Valeant notes that WO 107 claims the dosage form doubles in volume, not that its dimensions double in size. When the dosage form doubles in volume, provided the expansion is unrestrained and uniform, the shorter axes are less than 1.2 cm in size.

[71] I agree with Valeant. WO 107 does not disclose the subject matter of the 671 Patent and therefore does not anticipate it. One may argue that the Size Element and Time Element are implicitly disclosed by WO 107, in light of the common general knowledge of the PSA

concerning the MRPD and gastric transit times. However, WO 107 does not disclose the Shape Element.

[72] The statement in WO 107 that dosage forms "can be varied considerably" does not preclude dosage form shapes that are explicitly excluded by the 671 Patent. The shapes described in Claims 21 and 22 of WO 107 are cylindrical or elongated tablets, but the PSA would not have understood them to be non-circular shapes that are either oval or parallelogram when projected onto a plane. Cylinders have two circular sides, while elongated tablets are not necessarily oval or parallelogram when projected onto a plane. Nor are the cylindrical or elongated dosage shapes in WO 107 said to promote gastric retention. The Shape Element of the 671 Patent cannot be ascertained merely by reading WO 107, and there is therefore no disclosure and no anticipation.

[73] Since the 671 Patent is not anticipated, and Generic Partners concedes that its Generic Product will infringe Claim 1, the *Gillettte* defence must also fail (*Bell Helicopter Textron Canada Limitée v Eurocopter*, 2013 FCA 219 at para 115).

XI. Obviousness

A. *Legal Principles*

[74] Pursuant to s 28.3 of the *Patent Act*, a patent cannot be issued for an invention that was obvious on the claim date to a person skilled in the art or science to which the patent pertains. Obviousness is to be assessed as of the priority date: June 20, 2000.

[75] Obviousness is generally considered to be a factual determination, or a question of mixed fact and law (*Wenzel Downhole Tools Ltd v National-Oilwell Canada Ltd*, 2012 FCA 333 at para 44). It must be assessed on a claim-by-claim basis (*Zero Spill Systems (Int'l) Inc v Heide*, 2015 FCA 115 at paras 85, 87-88 [*Zero Spill*]).

[76] When considering obviousness, hindsight is prohibited. To determine whether a claim is obvious, courts generally follow the four-part test found in *Sanofi-Synthelabo* at paragraph 67:

(a) identify the notional "person skilled in the art" and the relevant common general knowledge of that person;

(b) identify the inventive concept of the claim in question or, if that cannot readily be done, construe it;

(c) 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; and

(d) 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?

[77] The fourth step of the inquiry may require consideration of whether the claimed invention was “obvious to try”. This aspect of the test tends to arise in areas of endeavour where advances are often made through experimentation, and where numerous interrelated variables may affect the desired result (*Sanofi-Synthelabo* at paras 68-71). The development of pharmaceutical products is such an endeavour, and it is therefore necessary to ask whether the claimed invention in this case was “obvious to try”. This involves a consideration of the following non-exhaustive factors:

(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?

B. *Analysis*

(1) PSA and Common General Knowledge

[78] The PSA and common general knowledge are discussed under the heading Claims Construction, above. While the relevant dates for claims construction and assessing obviousness differ, neither party suggested that anything turns on this.

(2) Inventive Concept

[79] The parties generally agree on the inventive concept of Claim 1 of the 671 Patent. It is a controlled-release oral dosage form that combines several elements including: a solid, water-swellable monolithic matrix; in the shape of an oval or parallelogram when projected onto a plane; with a long axis having a maximum length of 3.0 cm when the matrix is unswollen; and a short axis that swells to at least 1.2 cm within one hour. When these elements are combined, they create a gastric-retentive dosage form that provides enhanced drug release in the stomach and upper GI tract.

(3) Differences between the State of the Art and the Invention

[80] Generic Partners argues that all of the elements of the inventive concept were present in the state of the art and the PSA's common general knowledge.

[81] Generic Partners says the Hwang Paper disclosed all essential elements of Claim 1 of the 671 Patent. The PSA would have known that in order to achieve gastric retention, an oral dosage form would have to expand to a retentive size before gastric emptying occurred. The Hwang Paper taught that solid food would remain in the stomach for approximately one to three hours. Generic Partners therefore asserts that the Time Element was present in the Hwang Paper.

[82] The Hwang Paper mentioned the Khosla Paper, which determined that 1.3 cm diameter tablets remained in the stomach for a longer period than 0.7 cm and 1.1 cm tablets. Generic Partners therefore asserts that the Size Element was present in the Hwang Paper.

[83] With respect to the Shape Element, Generic Partners points to Figure 14 of the Hwang Paper:

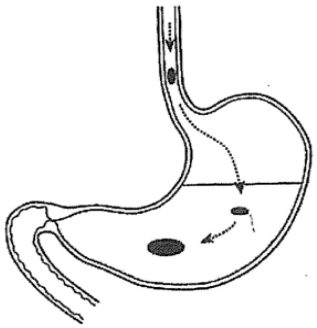

FIGURE 14. The expandable device can swell in the stomach either by absorbing water from the gastric juice or by evaporation of solidified or liquefied gas present in the device.

[84] Generic Partners says this clearly depicts an oval-shaped, water-swellable dosage form similar to the one described in Claim 1 of the 671 Patent.

[85] Generic Partners contends that the Size Element may also be found in Claim 1 of WO 107, which described a dosage form that doubled in size, and disclosed a preferred embodiment with starting dimensions of 0.75 cm for the shorter axis and 2.2 cm for the longer axis. Generic Partners argues that both dimensions fall within the ranges claimed by Claim 1 of the 671 Patent. WO 342 specified a dosage form that expanded to the point that its shorter axis was 1.3 cm or more as a preferred embodiment.

[86] The Khosla paper disclosed an MRPD which could vary up to 2.0 cm. However, Generic Partners asserts that the PSA would not aim for the upper end of the MRPD range. Rather, test results that were published as of the priority date demonstrated that dosage forms of 1.3 cm in

diameter achieved better gastric retention and lower variability than dosage forms of 0.7 cm and 1.1 cm in diameter.

[87] Generic Partners asserts that the Time Element was present in the prior art, and was inextricably linked to the Size Element. The PSA would have known that in order to achieve gastric retention, the dosage form would have to expand to a critical size before gastric emptying occurred. The fact that solid particles took an average of one to three hours to transit the stomach was within the common general knowledge. The PSA would therefore have known it was necessary for dosage forms to expand to the critical size within one hour in order to achieve gastric retention.

[88] Finally, Generic Partners maintains that the Shape Element was disclosed in the prior art and is inherently linked to the Size Element. There was nothing inventive in deciding that the gastric retentive dosage form should be non-circular in shape, oval or parallelogram. WO 107 already taught an elongated tablet dosage form, with preferred dimensions that the PSA would understand to be oval or parallelogram in shape. WO 342 disclosed gastric retentive tablets that were oval or parallelogram in shape, as seen in Figure 1A. As previously noted, Figure 14 of the Hwang paper depicted an oval-shaped, swellable gastric retentive dosage form.

[89] In the alternative, Generic Partners says that if oval and parallelogram shapes for gastric retentive dosage forms were not explicitly disclosed, Dr. Lee's unchallenged opinion is that: (a) these are the most common dosage form shapes; and (b) determining the interplay between the

sizes and shapes useful to enhance gastric retention was simply a matter of routine geometry well within the PSA's ability.

[90] Valeant responds that none of the key elements of the inventive concept of the 671 Patent were present in the prior art.

[91] With respect to the Time Element, Valeant says the Hwang Paper offered a range of gastric emptying times, rather than the precise time of one hour specified in Claim 1, or the even shorter time of 30 minutes found in Claim 2 and other dependent claims. The amount of time it takes for a dosage form to leave the stomach is variable and affected by many factors. Dr. Sternson observed that solid oral dosage forms could pass through the stomach in as few as two minutes in the fasting state. The gastric emptying times of one to three hours reported in the Hwang paper were relative and not absolute, a nuance that Valeant says escaped Dr. Lee.

[92] With respect to the Size Element, Valeant says that the MRPD was understood to encompass a range of pyloric opening diameters from 0.58 cm to 1.98 cm, and there was nothing to teach or suggest the Size Element of the inventive concept. According to Dr. Sternson, if the PSA were to base the preparation of a gastric-retentive dosage form on the information available, the PSA would naturally focus on the top end of the range, namely 2.0 cm. The unimaginative PSA would have chosen the safest route, *i.e.*, the largest pyloric opening, and would not have used inventive skill to select a specific size from within the wide range.

[93] Valeant notes that the Khosla paper found enhanced gastric retention for dosage forms that were 1.3 cm in diameter, not 1.2 cm. Furthermore, the Size Element was not disclosed by WO 342 because it described swellable dosage forms that were banded with insoluble material, which expanded in a different manner than those disclosed by the 671 Patent. In addition, the dosage forms described in WO 342 only expanded to a maximum length of 1.0 cm.

[94] With respect to the Shape Element, Valeant says that nothing in the prior art taught or even suggested a connection between oval and parallelogram dosage shapes and enhanced gastric retention. Figure 14 in the Hwang paper is a schematic which demonstrates the general mechanism of gastric-retentive swellable dosage forms, and cannot be taken to specify a particular dosage shape. The manner in which the shape of the dosage form affects gastric retention is a critical component of the inventive concept, so disclosure of a multitude of shapes in the prior art is insufficient.

[95] I accept that the prior art may have disclosed the Size Element and the Time Element of the inventive concept of Claim 1 of the 671 Patent. However, the Shape Element and the combination of all three elements were notably missing.

[96] The Khosla paper demonstrated that dosage forms with a diameter of 1.1 cm achieved some gastric retention, while 1.3 cm dosage forms achieved better gastric retention. It is conceivable that the PSA would have, without inventive skill, selected a value somewhere in between (*e.g.*, 1.2 cm) as the minimum length of the shorter axis. The range of gastric emptying times was well-established in the prior art, and indeed was acknowledged by the inventors of the

671 Patent in the "Description of the Prior Art". The PSA could have deduced that, in order to enhance gastric retention, the dosage form would have to expand to a particular size to prevent its exit from the stomach. The PSA may well have aimed for the bottom of the gastric emptying time to enhance gastric retention.

[97] But the Shape Element was absent from the prior art. There was no teaching or discussion of a potential correlation between the shape of a dosage form and gastric retention. WO 107 was largely agnostic about the shape of the dosage form, and noted that "the shapes and sizes can be varied considerably." The preferred embodiment of a capsule or elongated tablet does not assist Generic Partners. Indeed, this is described in the 671 Patent as giving rise to the problem of "fortuitous orientation" which the invention is intended to solve.

[98] The fact that the swellable dosage form depicted in Figure 14 of the Hwang Paper appears to be oval was happenstance. Nothing in the diagram or the accompanying text suggested that the Shape Element, specifically an oval or parallelogram, was a relevant factor in improving gastric retention.

(4) Are the Differences Obvious?

[99] Generic Partners argues that the PSA would not have required inventive ingenuity to combine the known elements into the invention claimed by the 671 Patent. All of the elements were known by the PSA to enhance gastric retention, so combining them together to further enhance gastric retention would not require inventive ingenuity.

[100] In the alternative, Generic Partners says the invention would have been obvious to try. All of the elements were disclosed in the prior art. Even if the Shape Element was not, there were only a limited number of shapes a dosage form could adopt. Ovals and parallelograms were common shapes for dosage forms. Generic Partners therefore argues that it was more or less self-evident that the combination would result in enhanced gastric retention, as defined in Claim 1.

[101] Valeant has provided no evidence of the invention's history. Generic Partners asks the Court to draw a negative inference, citing *Sanofi-Synthelabo* at paragraph 71 and *Gilead Science Inc v Canada (Health)*, 2013 FC 1270 at paragraph 83. Finally, Generic Partners says that, in light of the prior art, the PSA clearly had a motive to develop a gastric retentive oral dosage form, as this Court found in *Biovail* at paragraph 107.

[102] Valeant responds that obviousness is difficult to establish. The party who alleges obviousness must show that the PSA would have arrived directly and without difficulty at the invention (*Sanofi-Synthelabo* at para 85; *Beloit* at 294). It is not fair to a person claiming to have invented a combination invention to break the combination down into its parts and find that, because each part is well known, the combination was necessarily obvious (*Zero Spill* at para 95). Valeant says that, even if the 671 Patent discloses a combination of well-known elements, the combination of these elements was inventive because the prior art did not describe the interplay between the elements and gastric retention.

[103] An allegation of obviousness may be weakened if the evidence does not explain directly, or by inference, why the claimed invention was not discovered by others (*Georgetown Rail*

Equipment Company v Rail Radar Inc, 2018 FC 70 at para 149 [*Georgetown*]). Valeant says the absence of any comparable invention in the prior art, particularly respecting the shape of the dosage form, speaks for itself.

[104] Courts frequently caution against employing hindsight in the obviousness analysis (*Georgetown* at para 112; *Meda AB v Canada (Minister of Health)*, 2016 FC 1362 at para 138; *Bridgeview Manufacturing Inc v 931409 Alberta Ltd*, 2010 FCA 188 at para 50). Valeant says that Dr. Lee's interpretation of the prior art is selective and self-serving. He chose the bottom of the range of gastric transit times and the mean of the MRPD to locate the Size and Time Elements in the prior art. Dr. Lee's interpretation of the diagram in Figure 14 of the Hwang paper, which Dr. Sternson described as a "cartoon", is unreasonably literal.

[105] Valeant notes that the apparent simplicity of an invention does not lead inextricably to the conclusion that it was obvious and unworthy of a patent (*Jay-Lor* at para 76). A "mere scintilla of invention" will suffice (*Diversified Products Corp v Tye-Sil Corp* (1991), 35 CPR (3d) 350 (FCA) at 365). The prior art disclosed numerous dosage form shapes, dimensions and timings. No guidance was provided to lead the PSA to the claimed combination without inventive skill. Given the myriad options and combinations available to the PSA, the claimed invention could not have been reached without prolonged and arduous experimentation.

[106] I am persuaded that the invention claimed by the 671 Patent was neither obvious nor obvious to try. The Shape Element was not disclosed in the prior art. While oval and parallelogram shaped dosage forms could be found in the prior art, nowhere was it suggested that

their shapes were a central component of gastric retention. The wide range of options to enhance gastric retention disclosed in the prior art would not have led the PSA inexorably to the invention without inventive ingenuity.

[107] Dr. Lee's observation that determining the interplay between the sizes and shapes useful to enhance gastric retention was a matter of routine geometry or testing is tainted by hindsight. It presupposes that the PSA already understood that gastric retention would be affected by dosage shape. But this is precisely the inventive step claimed by the 671 Patent.

[108] Without the insight that dosage shapes would affect gastric retention, the invention could not be obvious to try. Nothing in the prior art suggested a correlation between dosage shapes and gastric retention. There was therefore no motive in the prior art to find the solution the patent addresses. A multitude of dosage shapes were recognized in the prior art, but none were identified as clearly superior to others in achieving gastric retention. The preferred embodiment of the cylindrical or elongated tablet in WO 107 gave rise to the problem that the 671 Patent claimed to solve.

XII. Double-Patenting

A. *Legal Principles*

[109] There are two types of double-patenting. The first is "same-invention" double-patenting, which occurs when the claims of the second patent are outright "identical or coterminous" to the

first. The second is “obviousness-type” double-patenting, which occurs when the second patent is not identical to the first, but is nonetheless not “patentably distinct”. The prohibition against double patenting involves a comparison of the claims rather than the disclosure (*Mylan Pharmaceuticals ULC v Eli Lilly Canada Inc*, 2016 FCA 119 at paras 27, 37; *Whirlpool* at para 63).

B. *Analysis*

[110] Generic Partners alleges double-patenting with respect to the 624 Patent. WO 107 formed the basis of the 624 Patent, and Generic Partners does not suggest that the two differ in any material way. I have concluded that WO 107 did not anticipate the 671 Patent. It follows that the 624 Patent cannot support an allegation of same-invention double-patenting.

[111] If a consideration of all prior art does not render the 671 Patent obvious, then the more restricted analysis based only on the 624 Patent cannot do so. Generic Partners’ allegation of double patenting must fail.

XIII. Insufficiency

A. *Legal Principles*

[112] Pursuant to s 27(3) of the *Patent Act*, the specification of a patent must correctly and fully describe the invention. The questions the Court must address to determine sufficiency are: (a)

what is the invention? (b) how does it work? and (c) having only the specification, can a PSA successfully produce the invention using only the instructions contained in the disclosure? The possible need for non-inventive trial and error to enable the PSA to use the invention does not render the disclosure of a patent insufficient (*Apotex Inc v Shire LLC*, 2018 FC 637 at para 151; *Teva Canada Limited v Leo Pharma Inc*, 2017 FCA 50 at paras 55-56, 60; *Teva Canada Ltd v Pfizer Canada Inc*, 2012 SCC 60 at paras 50-51).

B. *Analysis*

[113] Generic Partners says the 671 Patent does not provide sufficient information to allow the PSA to know, in advance of testing, if the formulations disclosed will actually enhance gastric retention. Any routine testing the PSA would have to perform to create an enhanced gastric-retentive dosage form in accordance with the 671 Patent could equally be done without the teachings of the 671 Patent.

[114] Valeant responds that there are standard dies and punches that would create dosage forms that fall within the claimed shapes and sizes of the 671 Patent. The 671 Patent also provides detailed descriptions of polymers and their characteristics. Any additional experimentation required to optimize the shapes and sizes of the dosage forms would be a matter of routine. Dr. Sternson described the testing required to determine whether the time and swelling dimensions were achieved as “trivial.”

[115] Dr. Lee criticizes the lack of data and examples provided in the 671 Patent. However, it is not necessary for an inventor to provide a theory of why the invention works (*Bell Helicopter Textron Canada Limitée v Eurocopter*, 2013 FCA 219 at para 150). No allegation is made in Generic Partners' NOA respecting the utility of the 671 Patent, and this is not an issue in the proceeding.

[116] I therefore agree with Valeant that Generic Partners' allegation of insufficiency is without merit.

XIV. Conclusion

[117] Valeant has met its burden of proving, on the balance of probabilities, that Generic Partners' allegations respecting the invalidity of 671 Patent are not justified. The application for an order prohibiting the Minister of Health from issuing an NOC for the Generic Product is therefore granted.

[118] If the parties are unable to agree upon costs, they may make written submissions, not exceeding five (5) pages, within 14 days of the date of these reasons for judgment. Responding submissions, not exceeding three (3) pages, may be made within seven (7) days thereafter.

JUDGMENT

THIS COURT'S JUDGMENT is that:

1. The application by Valeant Canada LP/Valeant Canada SEC for an order prohibiting the Minister of Health from issuing a Notice of Compliance to Generic Partners Canada Inc for its Generic Product, specifically 500 mg extended release tablets of metformin hydrochloride for oral administration, is granted;

2. If the parties are unable to agree upon costs, they may make written submissions, not exceeding five (5) pages, within 14 days of the date of these reasons for judgment. Responding submissions, not exceeding three (3) pages, may be made within seven (7) days thereafter.

"Simon Fothergill"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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