Federal Court Cour fédérale

Date: 20201224

Docket: T-2023-18

Citation: 2020 FC 1189

Ottawa, Ontario, December 24, 2020

PRESENT: THE CHIEF JUSTICE

BETWEEN:

ALLERGAN INC.

Plaintiff

and

SANDOZ CANADA INC.

Defendant

and

KISSEI PHARMACEUTICAL CO., LTD.

Defendant/Patent Owner

AND BETWEEN:

SANDOZ CANADA INC.

Plaintiff by Counterclaim

and

ALLERGAN INC. and KISSEI PHARMACEUTICAL CO., LTD.

Defendants by Counterclaim

JUDGMENT AND REASONS – PUBLIC VERSION
(Identical to the Confidential Judgment and Reasons issued on December 23, 2020)

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I. Introduction

[1] There are three principal issues in this action. The first is whether the Defendant Sandoz Canada Inc. [**Sandoz**] will infringe a patent pertaining to the prescription drug RAPAFLO®, for which the Plaintiff Allergan Inc. [**Allergan**] is the exclusive Canadian licensee. The second is whether representations that were made during the patent application process on behalf of the owner of the patent, the Defendant Kissei Pharmaceutical Co. Ltd. [**Kissei**], can be introduced as evidence in this proceeding pursuant to section 53.1 of the *Patent Act*, R.S.C. 1985, c. P-4 [the **Act**]. The third is whether the patent is invalid on the ground of obviousness.

[2] For the reasons that follow, I have concluded that the generic alternative to RAPAFLO® that Sandoz seeks approval to produce [the **Sandoz Product**] will not infringe the patent at issue, namely, Canadian Patent No. 2,507,002 [the **'002 Patent**]. This is because some of the essential elements of claims 1 to 3 and 6 of that patent are not infringed by the Sandoz Product. Allergan's suggestion to the contrary is based on a reading of the patent that, if upheld, would undermine the certainty and predictability of the patent system, and chill competition.

[3] I have also determined that section 53.1 of the Act cannot be invoked in this proceeding. This is because Allergan is not a "patentee", within the meaning of the Act. Accordingly, the representations made to the Patent Office on behalf of Kissei and the amendments made to the proposed patent during the patent application process are inadmissible extrinsic evidence.

[4] Finally, I have concluded that the '002 Patent in question is not invalid on the ground of obviousness. This is because (i) it was not more or less self-evident that the claimed invention ought to work; (ii) the person skilled in the art of the '002 Patent would not likely have thought that the claimed invention could be achieved relatively quickly, through routine experimentation; (iii) the experimentation actually undertaken to achieve the claimed invention was prolonged and arduous; and (iv) the person skilled in the art would not have had any motivation to pursue the claimed invention.

II. Background

A. *The Parties*

[5] Allergan is a pharmaceutical company incorporated under the laws of Canada. Its principal address is located in Markham, Ontario. Allergan is a "first person" within the meaning of subsections 4(1) and 6(1) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 [the **Regulations**].

[6] Allergan is authorized to manufacture, market, and sell RAPAFLO® capsules in Canada pursuant to a series of Notices of Compliance [**NOC**s] issued by Health Canada dated January 11, 2011, January 29, 2015, April 5, 2017 and March 12, 2018, respectively.

RAPAFLO® capsules contain the active pharmaceutical ingredient [**API**] silodosin and are available in 4mg and 8mg silodosin strengths. RAPAFLO® is indicated for the treatment of benign prostatic hyperplasia [**BPH**].

[7] Kissei is a pharmaceutical company based in Japan. It was joined to this action pursuant to subsection 6(2) the Regulations. Kissei takes no position on whether the Sandoz Product will infringe the ‘002 Patent. However, Kissei denies that any of the claims of the ‘002 Patent are invalid, void or of no force or effect. It adopts and relies on Allergan's submissions in this regard and did not appear during the trial of this proceeding.

[8] Sandoz is a pharmaceutical company incorporated under the laws of Canada. Its principal office is located in Boucherville, Quebec. It is a “second person” within the meaning of subsections 5(1) and 6(1) of the Regulations.

[9] To obtain approval from Health Canada to market the Sandoz Product in Canada, Sandoz filed an Abbreviated New Drug Submission [**ANDS**] for a NOC for 4mg and 8mg silodosin capsules indicated for the treatment of the signs and symptoms of BPH. Given that Sandoz's ANDS relied on Allergan's NOC for RAPAFLO®, Sandoz served Allergan with a Notice of Allegation pursuant to subsection 5(3) of the Regulations on or about October 16, 2018.

[10] Allergan commenced this action pursuant to subsection 6(1) of the Regulations shortly thereafter.

B. *Benign Prostatic Hyperplasia, Dysuria and Silodosin*

[11] BPH is an anatomical change that occurs to a man's prostate. BPH is typically understood to refer to benign prostatic hypertrophy, a condition in which the cells of the prostate increase in size. BPH is also sometimes used to connote benign prostatic hyperplasia, a condition in which the number of cells in the prostate increases.

[12] BPH is the most common benign tumor in men. It is often age-related and occurs more frequently in men over the age of 50. The clinical symptoms associated with BPH include storage disturbances (e.g., the need to urinate more frequently or urgently), voiding disturbances (e.g., various difficulties associated with urinating), and pain during urination. If left untreated, BPH can lead to other symptoms and infections.

[13] Silodosin is a prescribed oral medication indicated for treatment of the signs and symptoms of BPH. Silodosin belongs to a class of drugs known as "alpha-1 blockers". These drugs operate by blocking alpha-1 receptors located in the bladder and prostate that are responsible for the contraction of smooth muscles of the bladder and prostate. By causing the muscles in the bladder and prostate to relax, alpha-1 blockers like silodosin can mitigate BPH symptoms and improve the ability to urinate.

[14] Silodosin is manufactured, marketed and sold in Canada and the United States under the brand name RAPAFLO®. The Drug Identification Numbers assigned by Health Canada to RAPAFLO® are 02361663 (4 mg) and 02361671 (8 mg).

III. The ‘002 Patent

[15] The ‘002 Patent is titled “Solid Drug for Oral Use”. The named inventors are Tsuyoshi Naganuma and Mitsuo Muramatsu [the **Inventors**].

[16] The ‘002 Patent issued from an application filed on December 11, 2003 claiming priority from Japanese Patent JP2002-364238, filed December 16, 2002 [the **Claim Date**]. It was published (“laid open”) on July 1, 2004 [the **Publication Date**] and issued on September 18, 2012.

[17] As a preliminary observation, it is common ground between Allergan and Sandoz that the English translation of the ‘002 Patent is sub-optimal and that this may account for some of the ambiguities in the document. In brief, the translation contains some unclear passages, uses some terms inconsistently and has some grammatical deficiencies. Nevertheless, as Allergan observed during the proceedings, the translation still provides “enough … for us to understand what the patent is talking about”: Public Transcript, at 636.

[18] In a short section entitled “Background Art”, the ‘002 Patent indicates that it was known that silodosin, as an API in a solid dosage form, is useful for treating dysuria without causing strong hypotensive activities or orthostatic hypotension. However, the prior literature identified in that patent did not disclose how to prepare a solid dosage form capsule by conventional formulation methods, or indeed by any other method. The patent notes that preparing such a capsule was extremely difficult to accomplish, due to the potent adhesive properties of silodosin that were disclosed by the patent. Given those properties, the use of a lubricant is required to

formulate silodosin in a capsule form. However, the addition of a lubricant "causes the problem of delaying in *[sic]* dissolution time".

[19] Broadly speaking, the invention claimed in the '002 Patent is a solid oral dosage form capsule for the treatment of dysuria which comprises the API silodosin and specific excipients, manufactured in a manner that achieves a defined rapid dissolution profile. According to the patent disclosure, the invention also "has a high precision for content uniformity, good stabilities, and excellent dissolution properties". It is further noted that an important objective of the Inventors was to achieve "a high content uniformity among formulation batches".

[20] The specific excipients identified in the patent are (i) D-mannitol, (ii) partially pregelatinized starch, (iii) a lubricant selected from the group magnesium stearate, calcium stearate and talc, and (iv) sodium lauryl sulfate [**SLS**]. The rapid distribution profile is described in terms of 85% "in not more than 15 minutes in a dissolution test according to method 2 (paddle method) of the Japanese pharmacopoeia in a condition using water as a test medium and a paddle speed of 50rpm *[sic]*" **[Method 2]**.

[21] Sandoz has admitted, for the purpose of this action, that the Sandoz Product contains silodosin, D-mannitol, partially pregelatinized starch, magnesium stearate and SLS, and that the capsules dissolve by 85% in no more than 15 minutes according to Method 2.

[22] However, the Sandoz Product does not contain "granules" and does not involve "granulating" or a "wet granulation process" [collectively, the **Wet Granulation Elements**], which are elements included in the independent claims that are in dispute in this proceeding,

namely, claims 1 and 6 of the ‘002 Patent. The Sandoz Product is made by a “dry” formulation method.

[23] The disputed claims are reproduced and discussed in Part VI.A.(4) of these reasons below.

IV. Issues

[24] There are three principal issues in this proceeding. They are as follows:

1) Are the Wet Granulation Elements in claims 1 – 3 and 6 essential?
2) Is the prosecution history of the ‘002 Patent admissible against Allergan, pursuant to section 53.1 of the Act? If so, what is the impact, if any, of amendments to the claims and corresponding representations that were made to the Patent Office by a representative of Kissei?
3) Is the ‘002 Patent invalid on the ground of obviousness?

V. Witnesses

[25] Allergan and Sandoz agreed on the qualifications of the four expert witnesses who testified in this case.

A. *Allergan's Witnesses*

(1) Dr. Linda Felton

[26] Dr. Felton is a Professor of Pharmaceutics and Chair of the Department of Pharmaceutical Sciences at the University of New Mexico College of Pharmacy. She is an expert in pharmaceutical formulation, principally of solid oral dosage forms, qualified to opine on formulation methods (including wet granulation, dry granulation, and dry blending), the role of excipients used in formulation, evaluating and assessing dissolution, and the physical and chemical properties of excipients and pharmaceutical compositions.

[27] Dr. Felton testified with respect to the "infringement" and "obviousness" issues in this proceeding. More specifically, she testified with respect to the essential elements of claims 1, 2, 3 and 6 of the '002 Patent, and whether that patent is invalid on the ground of obviousness. She also opined on related issues such as the person of skill in the art to whom the '002 Patent is addressed [the **Skilled Person**], the common general knowledge of the Skilled Person, how the '002 Patent would have been understood by the Skilled Person, the prior art, certain Kissei internal documentation, and the invention contemplated by the patent. In addition, she commented upon experimental tests that were conducted by Dr. MacGregor.

[28] Dr. Felton's testimony was generally straightforward and frank. She readily made certain concessions on cross-examination. Although counsel encountered some difficulty obtaining answers from her on other occasions, it appeared that this was because she was endeavouring to be precise or to identify potentially important nuances. Broadly speaking, her testimony was

better supported and more helpful with respect to the issue of obviousness than it was with respect to the issue of the essential elements of the ‘002 Patent.

(2) Ms. Jenna Wilson

[29] Ms. Wilson is a registered and practicing lawyer and Canadian and United States Patent agent with over 20 years of experience in patent practice. She has expertise in the drafting, filing and prosecution of patent applications before the Canadian Intellectual Property Office [**CIPO**] and the United States Patent and Trademark Office [**USPTO**], and in the analysis and interpretation of communications between the Canadian Patent Office and patent applicant leading to the granting of a patent.

[30] Ms. Wilson testified on behalf of Allergan with respect to the legislative history of section 53.1 of the Act and the prosecution history of the ‘002 Patent. Her testimony in relation to the legislative history of section 53.1 was generally direct, straightforward and helpful. However, given the conclusion that I have reached regarding the interpretation of section 53.1, her evidence concerning the prosecution history of the ‘002 Patent had no bearing on my decision.

(3) Dr. MacGregor

[31] Dr. MacGregor is the President and Dean of Faculty at the Toronto Institute of Pharmaceutical Technology [**TIPT**], an institute for industrial pharmaceutical education. He has taught a variety of courses at TIPT for about 28 years, and has been performing dissolution testing for approximately 30 years.

[32] Dr. MacGregor was a fact witness who testified with respect to dissolution testing experiments he conducted on behalf of Allergan.

[33] Dr. MacGregor's testimony was candid, very forthcoming and to the point.

B. *Sandoz's Witnesses*

(1) Dr. Reza Fassihi

[34] Dr. Fassihi is a Professor of Biopharmaceutics and Industrial Pharmacy at Temple University. He is an expert in: the design of drug delivery systems; preformulation and formulation methodologies for drug delivery systems; excipients/non-medicinal ingredients used in drug delivery systems; the evaluation of drug delivery systems, including bioavailability and dissolution studies; and regulatory requirements relating to drug delivery systems. With respect to each of these five fields, Dr. Fassihi has particular expertise in relation to solid oral dosage forms.

[35] Dr. Fassihi testified with respect to essentially the same issues that were addressed by Dr. Felton. Broadly speaking, his testimony was less straightforward than Dr. Felton's testimony, as he had several memory lapses (while being strikingly clear on other issues), he seemed reluctant to answer what appeared to be straightforward questions and his testimony was not entirely consistent on occasion. Moreover, his evidence with respect to the obviousness issue was not as well supported or persuasive as Dr. Felton's evidence. In addition, his testimony conveyed a sense of advocacy on a significant number of occasions, when he went beyond providing an answer by adding out-of-context commentary to convey his view that something was obvious.

With the foregoing in mind, I generally found Dr. Felton's testimony to merit greater weight, and to be more persuasive, than Dr. Fassihi's on the issue of obviousness.

[36] Nevertheless, I found Dr. Fassihi's evidence to be very helpful and straightforward regarding the experiment conducted by Dr. MacGregor. It was also forthcoming and helpful with respect to certain matters that had a bearing on the issue of the essentiality of the Wet Granulation Elements. I generally found his testimony to be more persuasive than Dr. Felton's on these two matters.

(2) Mr. Michael I. Stewart

[37] Mr. Stewart is a registered Canadian and United States Patent agent with over 40 years of expertise in: 1) the preparation, filing and prosecution of patent applications before the CIPO, the USPTO, and other foreign Patent Offices in areas such as chemistry and pharmacology; and 2) the analysis and interpretation of communications between the Patent Office and the patent applicant leading to the grant of a patent.

[38] Dr. Stewart testified on behalf of Sandoz with respect to the '002 Patent prosecution process, his interpretation of the positions taken by the patent examiner and by Kissei (through its agent Kirby Eades Gayle Baker), and whether certain of Dr. Felton's opinions are consistent with the '002 Patent prosecution history. His testimony was candid, straightforward and forthright. However, given the conclusion that I have reached regarding the interpretation of section 53.1 of the Act, his testimony did not have a bearing on my decision.

VI. Analysis

A. *Claim Construction*

(1) Legal Principles

[39] The claims of a patent must be construed before conducting an assessment of the patent's validity or infringement: *Whirlpool Corp v Camco Inc*, 2000 SCC 67 at para 43 [***Whirlpool***].

[40] In performing this exercise, the language of the claims must be read in an informed and purposive way, from the perspective of a skilled person: *Free World Trust v Électro Santé Inc*, 2000 SCC 66 at para 44 [***Free World***].

[41] The Skilled Person is presumed to have a mind willing to understand the claims, but to be unimaginative and uninventive. This "person" is often a hypothetical individual or combination of individuals with different skills. It is on the basis of the Skilled Person's "common knowledge", sometimes referred to as "common general knowledge", that the claims of the patent must be construed: *Free World*, above, at paras 20, 31(e) and 44; *Bell Helicopter Textron Canada Limitée v Eurocopter, société par actions simplifiée*, 2013 FCA 219 at paras 64-65 [***Bell Helicopter***]; *Hospira Healthcare Corporation v Kennedy Trust for Rheumatology Research*, 2020 FCA 30 at para 79 [***Hospira Healthcare (FCA)***]; *Teva Canada Limited v Janssen Inc*, 2018 FC 754 at paras 64-66, aff'd 2019 FCA 273 [***Teva-Janssen***].

[42] In construing the claims of a patent, the Court may require the assistance of expert evidence, for example, with respect to the technical meaning of the terms and concepts used in

the claims, and how they would have been understood by the Skilled Person: *Free World*, above, at para 51. However, at the end of the day, claims construction is a matter of law for the Court alone: *Whirlpool*, above, at para 61.

[43] Where the wording of the claims in a patent are clear and unambiguous, it is generally improper to have recourse to other parts of the patent in construing those claims: *Mylan Pharmaceuticals ULC v Eli Lilly Canada Inc*, 2016 FCA 119 at paras 39 and 43 [***Mylan Pharmaceuticals***].

[44] However, to ensure a construction that is reasonable and fair to both the patentee and the public, the Court may have regard to the specification as a whole. In brief, this can shed light upon the meaning of terms used in the claims or disclose an ambiguity that is not apparent from a reading of the claims alone: *Whirlpool*, above, at paras 48, 49(g), 52 and 53; *Teva-Janssen*, above, at paras 73-76.

[45] Nevertheless, the focus of the assessment must remain on the language of the claims: *Free World*, above, at paras 39-40 and 66. The public is entitled to rely on that language, so long as is interpreted "fairly and knowledgeably": *Free World*, above, at para 51. Once the wording of the claims is so interpreted, language situated elsewhere in the patent cannot be relied upon to enlarge or contract the scope of the claims as written, or to achieve a desired result: *Whirlpool*, above, at para 52; *Free World*, above, at para 32. This is because "it is the claims, not the rest of the specification, that define the monopoly": *Whirlpool*, above, at para 18. In essence, those claims represent the "fences" and "boundaries" of the patent, which give the "fields" of the monopoly "a comfortable pretence of bright line demarcation": *Free World*, above, at para 14.

For this reason, it is impermissible to have recourse to indications of what may have been the underling "spirit of the invention": *Free World*, above, at para 31(d).

[46] In determining which elements in a claim are essential and which are non-essential, the Court begins with the presumption that all of the elements are essential. The party alleging otherwise therefore bears the onus of establishing non-essentiality: *Free World*, above, at para 57; *Teva-Janssen*, above, at para 70.

[47] That onus can be met by demonstrating either (i) that on a purposive construction of the words of the claim it was clearly not intended that a particular element be essential, or (ii) that at the date of publication of the patent, the skilled person would have appreciated that the element in question could be substituted without affecting the working of the invention. Another way of stating the latter part of the test is to ask whether the skilled person would have considered it to be obvious that the invention would "work in the same way" with the substituted variant, in the sense of "performing essentially the same function in substantially the same way to obtain substantially the same result": *Free World*, above, at para 55.

[48] I am aware that in *Shire Canada Inc v Apotex Inc*, 2016 FC 382 at para 137, the Court suggested that the Supreme Court of Canada likely intended the disjunctive test described in (i) and (ii) of the immediately preceding paragraph to be conjunctive. However, given the findings that I have made in Part VI.A.(4) below with respect to the two prongs of the test for essentiality, nothing in this decision turns on the issue of whether that test is disjunctive or conjunctive.

[49] In ascertaining the inventor's intention, the Court must confine itself to objective manifestations of that intent in the claims of the patent, interpreted through the eyes of the skilled person at the relevant date and without resort to extrinsic evidence (except to the extent now permitted by section 53.1 of the Act): *Free World*, above, at para 66.

[50] In purposively construing the claims, it is incumbent upon the Court to keep in mind that the scope of patent protection must be reasonably predictable and uncertainty must be kept to a minimum. In turn, this requires "that the subjective or discretionary element of claims interpretation be kept to a minimum, consistent with giving 'the inventor protection for that which he has actually in good faith invented'…": *Free World*, above, at para 43, citing *Western Electric Co v Baldwin International Radio of Canada*, [1943] SCR 750 at 574. Among other things, this avoids chilling potential investment and competition: *Free World*, above, at paras 41-42 and 50.

[51] For the purposes of construing the claims of the '002 Patent, the relevant date is the Publication Date, i.e., July 1, 2004. For greater certainty, the claims of a patent must be given the same interpretation for all purposes, regardless as to whether there may be different relevant dates for such purposes: *Whirlpool*, above, at para 49(b).

(2) The Skilled Person

[52] Allergan and Sandoz, together with and their experts (Dr. Felton and Dr. Fassihi, respectively), generally agree regarding the credentials of the Skilled Person in relation to the

‘002 Patent. However, Dr. Fassihi opined that the Skilled Person (to whom he referred as the “skilled formulator”) would have somewhat more experience or relevant education.

[53] For Dr. Felton, nothing turned on this minor disagreement. She maintained that her opinions regarding the issues in dispute would remain unchanged even if the Skilled Person were considered to have the additional experience or education described by Dr. Fassihi.

[54] Dr. Fassihi did not explain why he considered the Skilled Person to have at least two years more experience or additional education, relative to the Skilled Person described by Dr. Felton. By contrast, Dr. Felton supported her description of the Skilled Person as follows:

> Each of the excipients and their general function in formulations is taught to undergraduate students in pharmaceutics or pharmacy programs. The excipient compatibility and dissolution tests described in the 002 Patent would be understood by and be of interest to undergraduate students in the same discipline. The function(s) of different excipients and the desire to achieve a defined dissolution rate are each described in textbooks from which I have taught.

[55] Given the foregoing explanation, I accept Dr. Felton’s position regarding the experience and education of the Skilled Person. In brief, that person would hold a Bachelor’s degree in pharmaceutical sciences, chemistry, or another related scientific discipline and would have one to three years of experience applying his or her education in a laboratory. The laboratory experience would relate to the formulation of drugs and could have been gained through graduate studies or at a job in the pharmaceutical industry.

[56] During the trial of this action, Dr. Felton testified that while the Skilled Person would know how to prepare formulations, he or she may not be responsible for selecting the excipients to be used in a drug, except in relation to "simple drug products with easy formulation, you know, a stable chemical, very water soluble …": Public Transcript, at 62. Sandoz interpreted this as suggesting that the Skilled Person, as defined by Dr. Felton and Allergan, "is incapable of formulating a low-solubility drug without assistance – the very problem that the '002 Patent purportedly addresses". I do not interpret Dr. Felton's testimony in this manner. In my view, Dr. Felton was simply stating that the Skilled Person would not necessarily be responsible for selecting the excipients ultimately used in a drug, before it is finalized for use. Her confirmation that the Skilled Person knows how to formulate drugs implies that the Skilled Person as she defined him/her would have been "sufficiently versed in art to which the patent relates to enable such person on a technical level to appreciate the nature and description of the invention and to put it into practice": Donald H. MacOdrum, *Fox on the Canadian Law of Patents*, 5th ed (Toronto: Thomson Reuters, 2019) (loose-leaf updated 2020-6) at §4.13.

[57] In any event, keeping in mind that "[t]he Court must take a fair and generous view as to what sort of person comprises a person skilled in the art" (*Janssen-Ortho v Novopharm*, 2006 FC 1234 at para 90, aff'd 2007 FCA 217), I consider that the Skilled Person is someone who is familiar with the excipients identified in the '002 Patent, as well as with their functions and the alternative excipients available to perform those functions. For greater certainty, the Skilled Person is also someone who has "the ability to pursue reasonable and logical inquiries": *Apotex Inc v Syntex Pharmaceuticals International Ltd* (1999 CarswellNat 4895, 1 CPR (4th) 22 at para 39 (FCTD), quoting John Bochnovic, "Invention/Inventive Step/Obviousness" in G.F. Henderson, ed., *Patent Law of Canada* (Scarborough, Ontario: Carswell, 1994) at 47-48.

(3) Common General Knowledge

[58] Common general knowledge [**CGK**] refers to the knowledge generally known by the Skilled Person at the relevant time: *Apotex Inc v Sanofi-Synthelabo Canada*, 2008 SCC 61 [***Sanofi***] at para 37. This includes the subset of patents, journal articles and technical information that are generally acknowledged to form part of the CGK in the field to which the patent relates. However, it does not include knowledge of all journal articles or other technical information: *Bell Helicopter*, above, at paras 64-65; *Janssen Inc v Teva Canada Ltd*, 2020 FC 593 at para 109. For the purposes of patent construction, the relevant time is the patent publication date, in this case, July 1, 2004.

[59] Allergan and Sandoz, generally agree regarding the CGK of the Skilled Person. In particular, it is common ground between them and their respective experts (Dr. Felton and Dr. Fassihi) that the CGK of the Skilled Person would have included a general understanding of:

- solid oral dosage forms and the general requirements of dosage forms. This includes tablets, capsules, powders and granules, as well as the fact that powders and granules are often incorporated into capsules for convenience;
- common excipients (inactive ingredients) used in pharmaceutical tablets and capsules, and the reasons why particular excipients may be used, including to aid in manufacturing/processing or product performance, and to improve the drug dissolution rate and/or drug stability – common excipients include diluents/fillers/bulking agents (including lactose and mannitol), binders (including starches and pre-treated starches), lubricants (including magnesium stearate), surfactants (including SLS) and disintegrants (including pre-treated starches);

- the fact that some common excipients can fill multiple roles within a formulation;
- the fact that excipients and the length of mixing time can affect dissolution times;
- the importance of drug dissolution rates, dissolution studies and the methodologies to measure the dissolution profile of a drug;
- common handbooks and guidelines regarding pharmaceutical formulations, such as: Alfonso R. Gennaro, ed, *Remington: The Science and Practice of Pharmacy*, 20th ed (Baltimore: Lippincott Williams & Wilkins, 2000) [***Remington***]; Arthur H. Kibbe, ed, *Handbook of Pharmaceutical Excipients*, 3rd ed (Washington: American Pharmaceutical Association Press, 2000)*; The Pharmacopeia of the United States*, 25th ed (Rockville, MD: United States Pharmacopeial Convention, 2011); the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guidelines; and the Food and Drug Administration's Guidelines regarding active ingredients and finished dosage forms;
- tests performed to assess drug potency and content uniformity, and be able to interpret the results from such tests; and
- various manufacturing methods, including (i) wet granulation – including powder granulation, flued-bed wet granulation and spray-dry granulation; (ii) dry granulation; and (iii) dry blending (which can be used entirely separately, or as simply the first step in both wet and dry granulation).

[60] Allergan and Sandoz, supported by Dr. Felton and Dr. Fassihi, respectively, also appear to agree that the CGK of the Skilled Person would have included:

- the knowledge that, in a wet granulation process, a lubricant is typically added near the end of the formulation process, before tableting or the filling of capsules,

- an understanding of common pre-formulation steps, including optimization procedures, statistical design, the design or experiments or factorial design and tests/processes to determine how an API would interact with common excipients and behave under formulation conditions, such as dry blending and wet granulation;
- an understanding of the potential impact of subjecting an API to compression forces (which are part of the tableting process); and
- an understanding that if there were other products on the market from the same family of drugs (similar chemical structure), those products should be researched to determine what excipients were used with those formulations.

[61] However, despite the representation in the Joint List of Issues that their respective "experts generally agree regarding the [CGK] of the Skilled Person", Allergan and Sandoz disagreed about whether 13 articles addressed in the First Fassihi Report formed part of the relevant CGK or the broader "state of the art". Four of those articles focus on matters relating to light and discolouration that are no longer relevant in this proceeding. The remaining nine articles deal with issues addressed in the immediately preceding paragraphs above. Dr. Felton opined that those articles do not form part of the relevant CGK, as they relate to different therapeutic classes, different biological targets and different chemical structures. For this reason, she added that they would not likely have been found by the Skilled Person on a reasonably diligent search. I do not consider this disagreement between Dr. Felton and Dr. Fassihi in relation to those articles to have a material bearing on the claim construction issue in this proceeding. However, pursuant to the recent decision in *Hospira Health (FCA)*, above, at para 86, those articles must be considered in the obviousness analysis, regardless of whether they may not have been found by the Skilled Person in the course of a reasonably diligent search. This is because

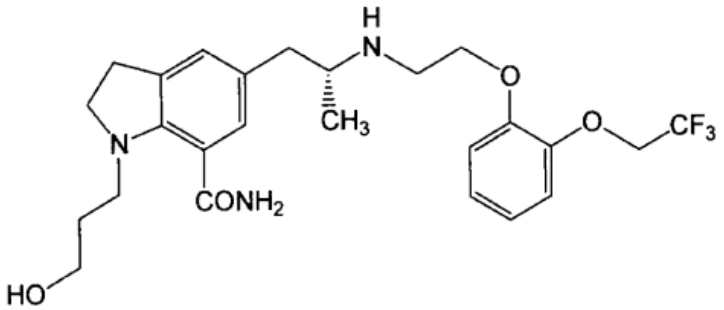
they form part of the body of information "available to the public in Canada or elsewhere", within the meaning of section 28.3 of the Act. The issue of whether the Skilled Person would have found those articles on a reasonably diligent search and then thought to combine their collective teachings with the other CGK and with the other prior art discussed later in these reasons is something that is relevant to the fourth step in the obviousness analysis: *Hospira Health (FCA),* above at para 86; *Biogen Canada Inc v Taro Pharmaceuticals*, 2020 FC 621 at para 153 [***Biogen***].

[62] Allergan and Sandoz, also disagree on certain other aspects of the CGK of the Skilled Person. The principal disagreements in this regard are based on disagreements between Dr. Felton and Dr. Fassihi that will be addressed in Parts VI.A.(4) and VI.B of these reasons, dealing with the essential elements of the '002 Patent and obviousness, respectively.

(4) The Essential Elements of the '002 Patent

[63] The '002 Patent contains six claims. Only four of them are in dispute. Those are claims 1-3 and 6, which state as follows:

> **1.** A capsule which comprises:
>
> (1) a granule prepared by wet granulation of a mixture of a) as the active ingredient, an indoline compound represented by the formula:



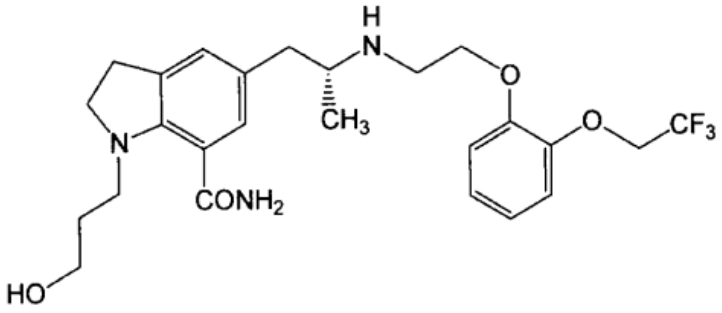
b) D-mannitol and c) partially pregelatinized starch; and (2) d) a lubricant selected from the group consisting of magnesium stearate, calcium stearate and talc, and e) sodium lauryl sulfate, wherein 85% dissolution time of the capsule is not more than 15 minutes in a dissolution test according to method 2 (paddle method) of the Japanese pharmacopoeia in a condition using water as a test medium and a paddle speed of 50rpm.

2. The capsule according to claim 1, wherein the lubricant is magnesium stearate.

3. The capsule according to claim 2, which further comprises 0.1 to 2 parts of sodium lauryl sulfate based on 1 part of magnesium stearate.

…

6. A method for preparing a capsule, comprising the steps of (1) granulating a compound represented by the formula:



b) D-mannitol and c) partially pregelatinized starch by a wet granulation process; and (2) mixing the granule obtained in step (1), d) a lubricant selected from magnesium stearate, calcium stearate and talc, and e) sodium lauryl sulfate.

[64] There is no significant dispute in this proceeding regarding the meaning of the words in the foregoing claims. Instead, Allergan and Sandoz disagree on whether the Wet Granulation Elements are essential. For greater certainty, it is common ground between them that the "compound" described in claims 1 and 6, is silodosin.

[65] For the reasons that follow, I consider that the Wet Granulation Elements are essential in each of Claims 1-3 and 6.

(a) *Claim 1*

[66] Among other things, claim 1 claims a capsule formulation comprising "a granule prepared by wet granulation of a mixture of" silodosin and certain identified excipients. As mentioned above, there is no dispute in this proceeding with respect to the identified excipients and there is no dispute with respect to the words "wherein 85% dissolution time of the capsule is not more than 15 minutes in a dissolution test according to [Method 2]". The sole claims construction dispute is with respect to whether the Wet Granulation Elements are essential.

[67] On a plain reading of claim 1, the terms "granule" and "prepared by wet granulation" are unambiguous. There is nothing in the language of claim 1 itself to suggest that these elements, which have the effect of limiting the scope of the claim, were not intended to be essential. Accordingly, those elements are presumed to be essential. This presumption will hold unless it is established either (i) that on a purposive construction of the patent disclosure and claims as a whole, those elements were not intended to be essential (*Whirlpool*, above at paras 48, at 49(g)), or (ii) that at the Publication Date the Skilled Person would have appreciated that those elements could be substituted without affecting the working of the invention: *Free World*, above, at para 55. (See discussion at paras [46]-[48] above.) I will now address each of those two prongs of this test separately below.

(i) The First Prong of the Test: A Purposive Construction of the Wet Granulation Elements

[68] Allergan and Dr. Felton maintain that there are a number of indicators in the ‘002 Patent that reveal that the Wet Granulation Elements were not intended to be essential. I disagree.

[69] Allergan and Dr. Felton insist that the Skilled Person would have understood that the claims of the ‘002 Patent focus upon, and are directed to, a specific combination of excipients and silodosin in capsule formulations that achieve a well-defined dissolution profile. That profile is 85% dissolution in not more than 15 minutes in a test according to Method 2. Stated differently, the achievement of 85% silodosin dissolution within 15 minutes, as described above, was the purported essence of the invention. This achievement was important because a drug’s dissolution profile and batch-to-batch uniformity can be critical for both efficacy and safety. In addition, the rapid dissolution profile permitted the claimed solid-dose formulation to be expected to behave like a solution, and therefore to generally have no bioavailability problems, e.g., of the type that can sometimes be associated with solid formulations. Allergan maintains that when the ‘002 Patent is understood in this manner, it becomes readily apparent that the Wet Granulation Elements in claim 1 are not essential.

[70] Dr. Felton opined that a Skilled Person would understand that the Wet Granulation Elements in claim 1 are not essential for five reasons.

[71] First, Dr. Felton noted that on page 3 of the Technical Field section of the ‘002 Patent, a capsule comprising “a granule prepared by wet granulation of a mixture of” silodosin and the

identified excipients is described as simply “a particular embodiment of the invention”. This was the first reference to the Wet Granulation Elements, and occurred after “the present invention” was described over the course of the preceding two pages. Dr. Felton stated that the Skilled Person would understand from this that the Inventors made a distinction between “the present invention” and “a particular embodiment” of the invention. I agree that this provides some indication that the Inventors may not have intended the Wet Granulation Elements to be essential. However, as discussed below, a reading of the patent as a whole clearly suggests otherwise.

[72] Second, Dr. Felton opined that the Skilled Person would expect that other manufacturing methods (such as dry granulation and dry mixing) could be substituted without affecting the working of the invention. This will be discussed in the next section below.

[73] Third, Dr. Felton opined that the Skilled Person would understand that the lubricants identified in claim 1 would overcome the disclosed difficulties associated with dry production processes. Once again, this will be addressed in the next section below. For the present purposes, it will suffice to note that this is not something that reflects any intention whatsoever, explicit or implicit, that the Wet Granulation Elements are not essential. In any event, relative to the other indicators of intent discussed below, the presence of lubricants in claim 1 would constitute a weak indicator of the Inventors’ intentions in relation to this issue.

[74] Fourth, Dr. Felton observed that the ‘002 Patent does not set out any details as to how to conduct wet granulation, even though different methods of wet granulation were known. She opined that “[i]f wet granulation were important, the Skilled Person would expect to see details

explaining (i) which binder to select, (ii) how much of the binder to use, (iii) how to select the granulating fluid (solvent), and (iv) desired residual water": Felton First Report, at para 131. Allergan added that the claims in the '002 Patent also do not address the drying conditions that are apparently necessary to make granules by wet granulation, even though those conditions were described whenever wet granulation was clearly used in the tests discussed in the '002 Patent (e.g., Test Example 4 and Examples 1-3). However, as Dr. Felton conceded, the patent also does not set out details with respect to mannitol and pregelatinized starch, which she considers to be essential elements: Public Transcript, at 157-160. (For example, there are different types of mannitol that can be used, and pregelatinized starch can be used as a filler, a binder and sometimes a disintegrant: Public Transcript, at 48.) Moreover, elsewhere in her first report, Dr. Felton explicitly stated that instructions regarding wet granulation were not required for the Skilled Person to know how to formulate using wet granulation. The full import of her view in this regard is captured in the following passage:

> 73. The Skilled Person would have been familiar with wet granulation as it was a well-known formulation approach that had been used in the pharmaceutical industry for decades. No details are provided on the 002 Patent about how to carry out the wet granulation process, although details for drying the granules in the fluid bed apparatus were provided. Regardless, multiple wet granulation techniques were known to the Skilled Person and could have been selected and utilized without difficulty. Instructions from the 002 Patent were not required for the Skilled person to known *[sic]* how to formulate using wet granulation.

[75] Having regard to all of the foregoing, I consider that the absence of details pertaining to wet granulation is at best a weak indication that the Inventors may not have intended the Wet Granulation Elements to be essential.

[76] Fifth, Dr. Felton noted that there are no studies reported in the ‘002 Patent to indicate to the Skilled Person that wet granulation is a necessary manufacturing process. Although the patent notes that “processes for preparing formulations according to conventional procedures” were investigated, no comparison was made between wet granulation and the other conventional processes, i.e., dry granulation and dry blending. Dr. Felton suggested that the Skilled Person would infer from this that wet granulation was not the only method that could be used to produce the claimed formulation. Instead, the Skilled Person would understand that other methods could be used.

[77] I consider the absence of any discussion of the above-described studies in the ‘002 Patent to be a relatively weak indicator of an intention that the Wet Granulation Elements may not have been intended to be essential. As discussed below, there are other, stronger, indications of a contrary intention.

[78] In addition to all of the foregoing, Allergan submitted that that the ‘002 Patent includes other important indications that the Wet Granulation Elements were not intended to be essential. In particular, in its written submissions, Allergan states that the ‘002 Patent only discloses the use of wet granulation in place of a dry process once (‘002 Patent, at page 14), and that discussion pertained to a formulation attempt [the **First Formulation**] which involved a tablet and did not result in a suitable capsule formulation, due to an unexpected fill problem.

[79] I do not read that particular reference to the use of wet granulation in place of a dry process as pertaining solely to the purported First Formulation for two independent reasons. First, the sentence in question specifically refers to the wet granulation process being used to

achieve a "high precision for filling".[1] This implicitly refers to capsules. As Allergan recognized elsewhere, tablets are pressed, rather than filled: Public Transcript, at 640.

[80] Second, it is readily apparent that the discussion of the purported First Formulation is part of a broader disclosure that teaches away from the use of dry processes in connection with the claimed invention. This is so despite the sub-optimal quality of the translation from the original Japanese language.

[81] The teaching away from the use of dry processes begins at page 8 of the patent, in the following passage:

> KMD-3213 [i.e., silodosin] contained as an active ingredient in a solid oral dosage form pharmaceutical of the present invention has potent adhesive and electrostatic properties. Particularly, in cases where formulations are prepared by a dry process, electrostatic charges are generated by physical irritations caused through processes such as pulverization, agitation, blending, granulation and the like, which in turn cause a decrease in fluidity of pulverized, blended or granulated materials, worsen handling properties and decrease precision for content uniformity of an active ingredient. (Emphasis added.)

[82] After then discussing the findings that were made in respect of various additives that were investigated (including binders, lubricants and surfactants), the patent turns to a discussion of the processes for preparing formulations according to conventional procedures that were investigated. Once again, the patent teaches away from the use of a dry process. Specifically, the patent states the following (beginning at the bottom of page 12):

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[1] The full sentence reads: "Then, formulations with good fluidities of blended materials, satisfactory handling properties and high precision for filling can be prepared by granulating through a wet process in place of a dry process, using lubricants in an amount of not more than 1% and mixing for a period of about 3 minutes." (Emphasis added.)

> Firstly, in cases where formulations are prepared by dry processes, pulverized, blended or granulated materials, which are prepared at pulverization, blending or granulation processes, generate electrostatic charges and decrease in fluidities of the materials. As a result, particularly in the case of preparing capsules, handling properties are worsened at the filling processes, and uniformity of the fill volume and precision for filling are worsened. (Emphasis added.)

[83] In the next paragraph (on page 13), the disclosure turns to a discussion of lubricants and once again teaches away from the use of dry processes. In addressing the importance of lubricants and the additional complexity that they introduce (in formulating capsule and tablet dosage forms), the disclosure states as follows:

> KMD-3213 has inherently potent adhesive properties, and particularly in the case of dry processes, electrostatic charges are generated and fluidities of blended or granulated materials are worsened as described above, which result in the use of much more amount of lubricants. However, lubricants have generally water repellant properties and the use of lubricants causes delaying in a dissolution time. (Emphasis added.)

[84] In addition to explicitly teaching away from dry processes, the disclosure of the patent explicitly teaches towards a wet granulation process. It does so in two places, the second of which is the passage on page 14 (discussed at paragraphs [78][80] above). On the first occasion (at page 10), the disclosure states as follows:

> Moreover, the present inventors have studied a variety of processes for preparing formulations, and have found out that formulations, which has *[sic]* satisfactory content uniformity without influenced *[sic]* by electrostatic charges and has *[sic]* good stabilities an excellent dissolution properties, are prepared through granulating by a wet process and regulating the amount of lubricant and a mixing time. (Emphasis added.)

[85] As with the passage on page 14 of the ‘002 Patent, Allergan suggests that this passage refers solely to the purported First Formulation, which was a tablet formulation, because there is no reference to a capsule or to SLS.

[86] I disagree. Read in its context, it is readily apparent that the passage quoted immediately above pertains to the claimed invention, which does not involve tablets. After addressing (in that passage) the issue of the manufacturing process, the paragraph proceeds to disclose two additional findings and then states: “Based on these findings, the present invention has been accomplished.” (Emphasis added.)

[87] The two additional findings were (i) that “in the cases *[sic]* of capsules, formulations with excellent dissolution profiles <u>are prepared</u> by admixing a lubricant in a specific ratio with another additive which is a solid with hydrophilic or surface-active properties”, and (ii) “the photo-degradations of KMD-3213 <u>are well prevented</u> by titanium oxide and photostable formulations can be prepared by using a capsule containing titanium oxide or a coating agent containing titanium oxide”. (Emphasis added.)

[88] In brief, well before the passage on page 14 of the patent that Allergan states is confined to the purported First Formulation (which involved tablets), the ‘002 Patent explicitly teaches away from the use of dry processes and towards a wet granulation process (for capsules). I agree with Dr. Fassihi that in view of this teaching, the Skilled Person would not have read the reference on page 14 to “granulating through a wet process in place of a dry process” as being confined to the purported First Formulation and tablets.

[89] My conclusion in this regard is reinforced by the fact that the disclosure of the ‘002 Patent also teaches towards wet granulation in the following passage (that appears on page 19), which Dr. Felton conceded describes a wet granulation process: Public Transcript, at 136.

> Solid oral dosage form pharmaceuticals of the present invention such as capsules can be prepared as follows. KMD-3213, acceptable salt or pharmaceutically acceptable solvate thereof is admixed with a filler, preferably D-mannitol, if required, an appropriate binder and disintegrator. Then, the mixture is kneaded with the addition of an aqueous solution of binder in an appropriate concentration, and if required, sieved to prepare a granule. Thereafter, a lubricant, preferably magnesium stearate and a solid additive with hydrophilic or surface-active properties, preferably sodium lauryl sulfate are added to the granule, in that case the lubricant being used in an amount of 0.5-2.0%, and the solid additive being used in a ratio of l:10 to 20:10, more preferably 5:10 to l0:l0, evermore preferably 5:10 relatively to magnesium stearate. Then, mixing and filling into an appropriate capsule, preferably a capsule containing titanium oxide in a blending amount of not less than about 3%, more preferably about 3.4 to 3.6% provide capsules.

[90] Moreover, with one exception, the test formulations discussed in the patent all used the wet granulation process. This was acknowledged by Dr. Felton, who also conceded that the one exception was a dry blended formulation that did not include all of the essential excipients – it was missing SLS: Public Transcript, at 176 and 195. She further conceded that there are no examples in the ‘002 Patent of a dry granulation process used to make a capsule: Public Transcript, at 137. Likewise, the only embodiment of the invention discussed in the Technical Field section of the patent was prepared by wet granulation.

[91] In my view, all of the foregoing, taken together, demonstrates a clear indication that the Inventors intended the Wet Granulation Elements to be essential. For greater certainty, this clear

indication overcomes the relatively weak indications of a contrary that are discussed at paragraphs [71], [73], [75] [77] above.

[92] Allergan also maintains that the discussion of what it characterizes as "the second formulation attempt" [the **Second Formulation**], which begins at line 13 on page 14 of the '002 Patent, reflects that the Inventors did not intend the Wet Granulation Elements in claim 1 to be essential. In this regard, Allergan asserts that the disclosure of the purported Second Formulation, which it says resulted in the claimed invention, teaches a solution that not only works for wet granulation but also works for dry blending and dry granulation. Allergan maintains that it does so by disclosing the possibility of using "atypically high amounts of lubricant", together with the surfactant SLS to offset the waterproofing effect of the lubricant. Allergan observes that a Skilled Person would have understood that by permitting the use of an atypically high amount of lubricant, the patent is not requiring the claimed formulation to be produced by a wet granulation process. Allergan explains that this is because an atypical amount of lubricant is not required in a wet granulation process, even for capsules. Allergan insists that there would have been no need to investigate and solve for the use of atypically high amounts of lubricant, if the Inventors had intended the Wet Granulation Elements to be essential. Allergan adds that the absence of any discussion of wet granulation in connection with the Second Formulation would have provided a further reason for the Skilled Person to understand that this formulation was "entirely agnostic" to the manufacturing process.

[93] I disagree with this interpretation of the disclosure in relation to the purported Second Formulation.

[94] Even if one accepts the sequence of events as advanced by Allergan, the reason given for the decision of the Inventors to continue their investigations beyond the purported First Formulation is that there continued to be a high risk for "a filling problem such as sticking". Accordingly, they investigated the use of lubricants in an amount of "not less than 1%" to solve that problem (which relates to capsules), while also achieving the desired dissolution profile.[2]

[95] In my view, the mere fact that the Inventors pursued this investigation does not, as Allergan suggests, necessarily imply that they were "agnostic" to the process by which the capsules were produced: Public Transcript, at 637. Although it was a matter of common general knowledge that increased lubricant is more often used in a dry formulation process, a Skilled Person reading the disclosure would have understood that it was entirely possible that the Inventors wished to solve the filling/sticking problem using the wet granulation process, particularly given the problems that they had discovered with respect to dry processes. The Skilled Person would also have understood that the adverse impact on dissolution caused by an increase in the amount of lubricant could potentially be offset by the use of a surfactant, such as SLS, whether in a wet granulation process or a dry process: Public Transcript, at 471-73; *Remington*, above, at 861.

[96] It follows that the Skilled Person would not necessarily infer from fact that the Inventors decided to investigate the use of a lubricant in amounts of "not less than 1%" that the Inventors had clearly intended to convey that the Wet Granulation Elements in claim 1 were not essential.

[2] I note in passing that Dr. Felton explained that if she wanted to prepare a tablet form of the claimed ingredients, she would not know how they would function under the compression of the tablet press, and she would not know what effect the force applied in tableting would have on the dissolution rate: Public Transcript, at 141.

[97] Indeed, the Skilled Person would have understood from a reading of the tests that pertained to the investigation of what Allergan characterizes as the Second Formulation that several of those tests, as well as Test Example 3, involved the use of the wet granulation process in testing capsule formulations. This was acknowledged by Dr. Felton: Public Transcript, at 155 and 195. The Skilled Person would also have understood that the description of the wet granulation process in several of those examples (which involved an amount of lubricant in excess of 1%) was not matched by any similar description of a dry process anywhere in the patent.

[98] In addition, although it was common general knowledge that "[m]ost lubricants … are used in concentrations below 1%", it was also known that "[t]he quantity of lubricant varies, being as low as 0.1% and, in some cases, as high as 5%": *Remington*, above, at 861. It was not suggested during this proceeding that this particular CGK was confined to dry processes.

[99] In brief, having regard to the foregoing, I do not consider that the disclosure with respect to the purported Second Formulation reflects any intention, clear or otherwise, that the Inventors decided to revisit the possibility of using a dry process, which they had already discovered worsened the fluidities of blended or granulated materials. Stated differently, this disclosure, including in respect of the investigations that were conducted in relation thereto, does not reflect any intention that the Inventors considered the Wet Granulation Elements to be non-essential. I reach the same conclusion with respect to Allergan's suggestion that the absence of any explicit specification regarding content uniformity, flowability and stabilities, in connection with the purported Second Formulation, reflects an intention that the Wet Granulation Elements were not considered essential: Plaintiff's (Allergan) Outline of Oral Argument, at paras 20(g) and (h).

[100] In any event, Allergan's interpretation of this disclosure requires such a subtle reading of the patent that it does not rise to the level of conveying a clear intention that the Wet Granulation Elements are not essential elements of claim 1*: Free World*, above, at para 55. Indeed, permitting such a subtle and unclear indication of intention to displace the unambiguous language in claim 1, as well as the much clearer teachings in the '002 Patent away from dry processes, towards wet granulation, would undermine the important objectives of promoting predictability and reducing uncertainty: *Free World*, above, at paras 41-42. Rather than clearly disclosing an ambiguity in the language of claim 1, it would introduce an ambiguity by suggesting an intention that is not readily apparent on a purposive reading of the claim 1, having regard to the specification as a whole.

[101] For greater certainty, the fact that the Inventors (and the Skilled Person) might have understood that the claimed dissolution profile could also potentially be achieved through dry mixing or dry granulation, as Allergan suggests, does not suffice to provide a clear indication that the Inventors did not intend the Wet Granulation Elements to be essential: *Free World*, above, at para 55. In this regard, I do not agree with Allergan's suggestion that Dr. Fassihi acknowledged that the discussion of the Second Formulation contemplated the possibility of using a dry process. My interpretation of his evidence is that he simply acknowledged that the purported First Formulation, which did not include SLS, had a high risk of a filling problem, as stated at page 14 of the patent. Elsewhere, he was very clear that he read the disclosure pertaining to the purported Second Formulation as contemplating a wet granulation process: see for example, Public Transcript, at 493-494.

[102] I also agree with Sandoz's submission that the use of the limiting terms "granule" and "prepared by wet granulation" in claim 1, when the options of dry mixing and dry granulation were known, suggests that the Inventors intended those terms to be essential elements: *Teva v Janssen*, above, at para 312.

[103] In summary, insofar as the Inventors' intention is concerned, a purposive reading of claim 1 and the patent specification as a whole reflects that the Wet Granulation Elements were intended to be essential. Allergan's assertions to the contrary constitute an attempt to stretch the language of claim 1 to encompass anything that achieves the same desired result as what was actually claimed. This is not permissible: *Free World*, above, at para 32.

(ii) The Second Prong of the Test: Would the Skilled Person Have Appreciated that a Dry Process Could be Substituted Without Affecting the Working of the Claimed Invention?

[104] Allergan and Dr. Felton maintain that at the Publication Date, the Skilled Person reading the '002 Patent would have understood that the method of manufacture would not impact and was not critical to the working of the invention claimed therein. In this regard, they assert that the Skilled Person would have understood that the lubricants identified in claim 1 would overcome the disclosed difficulties associated with dry production processes. They insist that it would have been obvious to the Skilled Person that a dry process could be substituted for the wet granulation process described in the patent, with routine experimentation. Allergan adds that the fact that Sandoz's capsules, which contain the same API and excipients as that invention but were not made using a wet granulation process, nonetheless achieve a similar rapid dissolution as

the invention, serves to affirm the Skilled Person's understanding that the Wet Granulation Elements are not essential to achieve the claimed dissolution rate.

[105] I disagree.

[106] As discussed at paragraphs [80]-[91] above, the patent specification both teaches away from the use of a dry manufacturing process and towards the wet granulation process. In the course of doing so, it makes specific references to the problems associated with dry processes. For the present purposes, the most noteworthy of these passages are as follows:

- Particularly, in cases where formulations are prepared by a dry process, electrostatic charges are generated by physical irritations caused through processes such as pulverization, agitation, blending, granulation and the like, which in turn cause a decrease in fluidity of pulverized, blended or granulated materials, worsen handling properties and decrease precision for content uniformity of an active ingredient. (Page 8, emphasis added.)
- Firstly, in cases where formulations are prepared by dry processes, pulverized, blended or granulated materials, which are prepared at pulverization, blending or granulation processes, generate electrostatic charges and decrease in fluidities of the materials. As a result, particularly in the case of preparing capsules, handling properties are worsened at the filling processes, and uniformity of the fill volume and precision for filling are worsened. (Pages 12-13, emphasis added.)
- KMD-3213 has inherently potent adhesive properties, and particularly in the case of dry processes, electrostatic charges are generated and fluidities of blended or granulated materials are worsened as described above, which result in the use of

> much more amount of lubricants . However, lubricants have generally water repellant properties and the use of lubricants causes delaying in a dissolution time. (Page 13, emphasis added.)

[107] After describing the abovementioned problems, the disclosure specifically explains that "formulations with good fluidities of blended materials, satisfactory handling properties and high precision for filling can be prepared by granulating through a wet process in place of a dry process, using lubricants in an amount of not more than 1% and mixing for a period of about 3 minutes": '002 Patent, at page 14 (emphasis added).

[108] Given the foregoing, I consider that it would not have been obvious to the Skilled Person that a dry process could be substituted for the wet granulation process described in the patent, with routine experimentation. Indeed, to the extent that a dry process would likely require a greater amount of lubricant, as well as a change in the amount of SLS or other surfactant that might be used, Dr. Felton's position on this is somewhat inconsistent with her position that "the selection of excipients and their ratios to achieve a specific dissolution profile was not routine or predictable", and that the Skilled Person would know that "[d]ifferent formulations can impair or enhance the dissolution rate and efficacy of the drug, particularly poor water soluble drugs", such as silodosin: Felton Second Report, at paras 86 and 99(4).

[109] Considering Dr. Felton's caution regarding the potential impact of changes to a formulation, and having regard to the problems with dry processes that were identified in the '002 Patent disclosure, I accept Dr. Fassihi's opinion that the Skilled Person would have understood that the adhesive and electrostatic properties of silodosin "could be problematic in a

dry process and decrease the precision for content uniformity": Fassihi First Report, at para 62. I also accept Dr. Fassihi's related statement that those properties were such that "it would likely be difficult to prepare [a capsule formulation using a method other than wet granulation] with acceptable content uniformity for regulatory approval": Fassihi Second Report, at para 22.

[110] In addition, I accept Dr. Fassihi's testimony regarding another property of silodosin that is problematic when attempting to use the dry granulation process. This is the property that results in silodosin undergoing polymorphic transformation when subjected to the compression used in the dry granulation process: Public Transcript, at 479-481. I note in passing that this testimony is corroborated by Kissei's internal records, which explain that because it was known that the bulk form of silodosin undergoes "polymorphism conversion under strong pressure … dry method granulation examination was not done, and wet granulation (wet method) was adopted": Kissei Production No. 229, at para 5.2.4.

[111] Given the manner in which the '002 Patent taught away from the use of dry processes, and given Dr. Fassihi's evidence regarding the Skilled Person's understanding of silodosin's properties and their implications for a dry process, I consider that the Skilled Person would not have understood that a dry process could be substituted for the wet granulation process without materially affecting the working of the invention. Put differently, the Skilled Person would not have appreciated that the invention "would obviously work in the same way": *Free World*, above, at para 55. The disclosure in the patent suggested otherwise.

[112] For completeness, I will simply add in passing that I do not accept Allergan's submission (at paragraph [104] above) regarding the significance of the Sandoz Product for the purposes of

construing claim 1. In brief, the fact that a third party such as Sandoz might have been able to achieve a similar rapid dissolution as the invention, with the same API and excipients, is not particularly relevant if the allegedly infringing product does not infringe each of the essential elements of the invention: *Free World*, above, at para 32.

(iii) The Prosecution History of the ‘002 Patent

[113] Sandoz submits that its position that the Wet Granulation Elements are not essential elements in claim 1 is supported by the file prosecution history of the ‘002 Patent. It makes a similar argument with respect to the other claims in dispute in this proceeding.

[114] Evidence with respect to the prosecution history of a patent is also known as “file wrapper” evidence. This is because in the United States representations to the Patent Office were historically noted on the file cover or “wrapper”. Pursuant to the doctrine of “file wrapper estoppel”, sometimes called “prosecution history estoppel”, patentees may be precluded from recapturing ground conceded during negotiations with the Patent Office: *Free World*, above, at para 63.

[115] However, in *Free World*, above, at paragraph 66, the Supreme Court of Canada confirmed that there is no doctrine of file wrapper estoppel in Canada and that the prosecution history pertaining to a patent is extrinsic evidence that cannot be considered in construing the patent.

[116] Notwithstanding the foregoing, Sandoz maintains that the representations made by a patent applicant constitute objective facts that can be considered by the Court. In support of this position, Sandoz relies on *Distrimedic Inc v Dispill Inc*, 2013 FC 1043 at para 210 [***Distrimedic***]. There, the Court stated that a "change in the wording of a claim as a result of an objection from the Patent Office is an objective fact from which an inference may be drawn, and is not the same as representations made to the Patent Office".

[117] In *Distrimedic*, the change and the objection in question occurred after a Notice of Allowance that had been granted in respect of a prior version of the Defendant's patent was withdrawn, subsequent to another patent having been brought to the attention of the Patent Office. To overcome the Patent Office's objection and distinguish its invention from the invention covered by the other patent, the Defendant amended the patent.

[118] *Distrimedic* would appear to have been overcome by the enactment of section 53.1 of the Act, which now codifies the limited circumstances in which Parliament intended the prosecution history of a patent to be admissible in an action or proceeding respecting a patent. In any event, the Court made it very clear in *Distrimedic* that "statements or admissions made in the course of patent prosecution should not be used for the purpose of interpreting a claim…": *Distrimedic*, above, at para 210. This is precisely what Sandoz is seeking to do in the present proceeding. Moreover, the facts in *Distrimedic* are distinguishable from the facts in the current proceeding. This is because the representations and amendments upon which Sandoz wishes to rely in the present proceeding were made in the course of prosecuting the '002 Patent, as opposed to in the type of situation that was at issue in *Distrimedic*.

[119] Subsequent to *Free World* and *Distrimedic*, Parliament enacted section 53.1 of the Act. That provision states as follows:

> 53.1 (1) In any action or proceeding respecting a patent, a written communication, or any part of such a communication, may be admitted into evidence to rebut any representation made by the patentee in the action or proceeding as to the construction of a claim in the patent if
>
> (a) it is prepared in respect of
>
> (i) the prosecution of the application for the patent,
>
> (ii) a disclaimer made in respect of the patent, or
>
> (iii) a request for re-examination, or a re-examination proceeding, in respect of the patent; and
>
> (b) it is between
>
> (i) the applicant for the patent or the patentee; and
>
> (ii) the Commissioner, an officer or employee of the Patent Office or a ember of a re-examination board.

[120] The Legislative Summary pertaining to this provision, which appeared in Bill C-86, states as follows:

> Clauses 187, 191, 197 and 201 make written communications between the Patent Office and an individual that occurred during the patent application process admissible as evidence in patent litigation. Previously, any communications between a patent owner and the Patent Office made during a patent application could not be considered as evidence in any later litigation involving that patent. As a result, patent owners were not bound, when enforcing their patent, to what they had said to the Patent Office about its scope, allowing them to assert a larger reach for their patent in court than they had initially asserted in their application. (Emphasis added.)[3]

[3] The relevant clause for the present purposes is clause 191.

[121] Sandoz asserts that the words “an individual” in the second line of the above-quoted summary suggests that Parliament intended section 53.1 to be applicable to permit file prosecution history evidence to be admitted, not just to rebut representations made by a patentee in an action or proceeding, but also by other people who make representations in the course of prosecuting a patent. Sandoz maintains that such an interpretation would be consistent with the following language from the *Budget Implementation Act, 2018, No. 2,* SC 2018, c 27, which states:

> Subdivision A of Division 7 of Part 4 amends the Patent Act in order to
>
> […]
>
> (d) ensure that patent prosecution histories may be admissible into evidence for certain purposes; […]

[122] Sandoz adds that permitting section 53.1 to be applied to representations made by a licensee in the course of prosecuting a patent would be consistent with the definition of “patentee” in s.2 of the Act, which states: “patentee means the person for the time being entitled to the benefit of a patent; (brevet/ ou titulaire d’un brevet)”. Given that Allergan is the exclusive licensee of the ‘002 Patent, Sandoz submits that it is the only company entitled to the benefit of that patent in Canada.

[123] Finally, Sandoz states that it can be inferred from certain representations that were made to the Senate Banking, Trade and Commerce Committee [**BTCC**] that Parliament was “alerted to the prospect that section 53.1 of the Act would introduce ‘American-style’ estoppel doctrine and chose not to amend the legislation, thereby accepting that the section would be applicable to

licensees"[4].The representations in question were made in a written submission by the Intellectual Property Institute of Canada [**IPIC**] to the BTCC. In this regard, IPIC stated that section 53.1 "introduces the American-style estoppel doctrine into Canadian Law": *Intellectual Property Institute of Canada (IPIC) Recommendations on Possible Amendments to Bill C-86, Subdivisions A, B, C, E & H,* Submission to the Senate Standing Committee on Banking, Trade and Commerce, November 27, 2018, at 4 [**IPIC Submission**].

[124] In my view, none of the arguments advanced by Sandoz can overcome the plain wording of subsection 53.1(1), a contextual reading of the Act or the jurisprudence in respect of the definition of the word "patentee" in section 2 of that legislation.

[125] It is trite law that "the words of a statute must be read 'in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act, and the intention of Parliament'": *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 at para 117, quoting *Rizzo & Rizzo Shoes Ltd (Re)*, [1998] 1 SCR 27 at para 21; and *Bell ExpressVu Limited Partnership v Rex*, 2002 SCC 42 at para 26, both quoting E. Driedger, *Construction of Statutes*, 2nd ed. (Toronto: Butterworths, 1983) at 87.

[126] The "chapeau" in subsection 53.1(1) plainly limits the scope of that provision to permitting certain written communications to be admitted into evidence to rebut any representation made by the patentee in an action or proceeding, in respect of the construction of a claim in a patent that is at issue in the action or proceeding. In the present proceeding, it is

[4] Sandoz maintains that licensees are within the scope of the estoppel doctrine in the United States.

admitted that the patentee is the defendant Kissei, which has not made any representation to the Court with respect to the construction of the ‘002 Patent. Accordingly, in the absence of any clear indication elsewhere within the scheme or object of the Act that Parliament intended to word “patentee” to include a licensee of a patent, subsection 53.1(1) cannot be invoked in this proceeding.

[127] I do not agree with Sandoz’s position that a licensee falls within the meaning of the word “patentee”, as defined in section 2 of the Act, namely, “the person for the time being entitled to the benefit of a patent”. This position was specifically considered and rejected in *Electric Chain Co of Canadas Ltd v Art Metal Works Inc*, [1933] SCR 581 at 586-587 [***Electric Chain***]. The effect of that decision was that a licensee had no right to be a party to an infringement action in Canada. As a result, what is subsection 55(1) was added to the Act: *American Cyanamid Co v Novopharm*, [1972] FC 739 at paras 23-24 (FCA) [***American Cyanamid***]. That provision, which has undergone some minor amendments that are not germane for the present purposes, states:

> “A person who infringes a patent is liable to the patentee and to all persons claiming under the patentee for all damage sustained by the patentee or by any such person, after the grant of the patent, by reason of the infringement.”

[128] It has since been confirmed that a person who is a licensee under a patent is a “person claiming under” the patentee within the meaning of subsection 55(1): *Armstrong Cork Canada v Domco Industries Ltd*, [1982] 1 SCR 907 at 914; *American Cyanamid*, above, at paras 31-32.

[129] What is instructive for the present purposes is that while the Act was amended to permit a licensee to sue for infringement, the definition of "patentee" was not amended following the interpretation that it was given in *Electric Chain*, above.

[130] Moreover, given that Parliament included the words "the applicant for a patent" in clause 53.1(1)(b)(i), but not in the "chapeau" of subsection 53.1(1), it can be inferred that (i) Parliament was aware of the distinction between a patentee and a person who is not the patentee, and (ii) Parliament decided to strictly limit the scope of the "chapeau" to a person who is a patentee.

[131] This interpretation of Parliament's intent finds some support in the legislative history. In particular, in the submission that IPIC made to the BTCC, discussed at paragraph [123] above, IPIC noted that the language of section 53.1 created a "loophole" that would permit "a patentee to circumvent the operation of this section by acting through a licensee": IPIC Submission, above, at 12. To address this "loophole", IPIC recommended that subsection 53.1(1) be amended to include "persons claiming under the patentee". The specific amendment proposed by IPIC is the underlined wording in the chapeau of that provision:

> 53.1 (1) In any action or proceeding respecting a patent, a written communication or any part of such a communication, may be admitted into evidence to rebut any representation made by the patentee <u>or a person claiming under the patentee</u> in the action or proceeding as to the construction of a claim in the patent if […]

[132] Ultimately, IPIC's recommendation was not accepted, and Bill C-86 was passed without any change to the language of subsection 53.1(1). This legislative history provides additional support for the view that, at the time Parliament added subsection 53.1(1) to the Act, it was

aware of the distinction between a patentee and a person who is not a patentee, yet it chose to limit the scope of section 53.1 to representations made by patentees.

[133] In summary, the plain and ordinary meaning of the language in subsection 53.1(1), together with a contextual reading of the Act and the jurisprudence discussed above, support the view that the word "patentee" in subsection 53.1(1) does not include a licensee. The legislative history also provides some additional support for this interpretation. Sandoz has not identified any contextual consideration to support the alternative interpretation that it has advanced. Accordingly, given that no representation has been made by the patentee (Kissei) of the '002 Patent in the present action, the file prosecution history is not admissible in evidence in this action. It is barred by the prohibition against extrinsic evidence: *Free World*, above, at para 66.

[134] I have therefore not considered the file prosecution history that Sandoz submits supports its position that the Wet Granulation Elements are essential elements of claims 1, 2, 3 and 6 of the '002 Patent.

[135] I will simply observe in passing that the file prosecution history in question provides a glaring example of the mischief that is implicitly permitted by the current wording of subsection 53.1(1).

(iv) Summary: The Essential Elements of Claim 1

[136] Given the conclusions I have reached in parts VI.A.(4)(a)(i) and (ii) above, the elements of "a granule" and "prepared by wet granulation" are essential elements of claim 1.

[137] It also appears to be common ground between the parties that the excipients and the dissolution rate described in claim 1 are essential elements. Sandoz and Dr. Felton explicitly stated so. There also appears to be no dispute as to the essentiality of the manner in which the dissolution rate is to be tested, the terms “capsule which comprises” and “mixture”, as well as the compound represented by the formula depicted in claim 1 (silodosin).

[138] Accordingly, the essential elements of claim 1 are as follows:

- A capsule which comprises
- a granule
- prepared by wet granulation
- of a mixture of silodosin, D-mannitol and partially pregelatinized starch
- a lubricant selected from the group consisting of magnesium stearate, calcium stearate and talc
- sodium lauryl sulfate
- wherein 85% dissolution time of the capsule is not more than 15 minutes in a dissolution test according to method 2 (paddle method) of the Japanese pharmacopoeia in a condition using water as a test medium and a paddle speed of 50 rpm

(b) *Claims 2 and 3*

[139] The parties agree that claims 2 and 3 are to be construed according to their plain and ordinary meaning. Accordingly, the essential elements of those claims is as follows:

Claim 2:

- The capsule according to claim 1 – this contemplates the essential elements of claim 1, except that it is not possible to choose calcium stearate or talc as the lubricant
- wherein the lubricant is magnesium stearate

Claim 3:

- The capsule according to claim 2 – this contemplates the essential elements of claim 2, except that
- the ratio of SLS to magnesium stearate must be in the range of 0.1 to 2 parts SLS to 1 part magnesium stearate

(c) *Claim 6*

[140] Claim 6 claims a method for preparing a capsule in two steps. There does not appear to be any dispute between the parties with respect to its essential terms, except with respect to whether the elements "granulating" and "wet granulation process" are essential.

[141] In her First Report, Dr. Felton asserted (at para 97) that "Claim 6 introduces no new claim elements not present in claim 1 and removes the dissolution profile limitation claimed in claim 1". However, on cross-examination, she stated that the dissolution rate specified in claim 1 is "inherent" in claim 6 because claim 6 simply addresses "a certain way" of preparing the composition described in claim 1: Public Transcript, at 152.

[142] Later in her First Report (at para 173), Dr. Felton maintained that the essential elements of claim 6 include silodosin, the claimed excipients and a two-step "mixing" of the excipients. On cross-examination, she explained that the first of those steps involves the mixing of silodosin

and the excipients identified in claim 6, and that the second step involves the further mixing of the mixture made in the first step, by adding one of the identified lubricants and SLS: Public Transcript, at 141-142. Later, she stated that "claim 6 is about the order of mixing, specific mixing": Public Transcript, at 148. When pressed regarding the fact that the first of the two steps in claim 6 is described in terms of "granulating", whereas the term "mixing" is only used to describe the second step, she maintained that she reads the term "granulating" to mean "mixing": Confidential Transcript, at 22.

[143] I disagree with this interpretation. The use of the word "granulating" in the first step, and the word "mixing" in the second step, suggests that the Inventors did not intend the word "granulating" to mean "mixing". In the absence of any persuasive indication of a contrary intention elsewhere in the patent, I consider it reasonable to infer that the two words have different meanings and that the word "granulating" connotes the plain and ordinary meaning of that term, rather than "mixing".

[144] Likewise, it can also be presumed that the terms "granulating" and "a wet granulation process" were intended to be essential, unless a contrary intention is clearly indicated on a purposive reading of claim 6 and the specification as a whole: *Teva-Janssen,* above, at para 70.

[145] However, apart from the submissions that I have already rejected above and in discussing claim 1 (in part VI.A.(4)(a) above), neither Allergan nor Dr. Felton has identified any such contrary intention, clear or otherwise. Accordingly, the presumption that the terms "granulating" and "a wet granulation process" are essential elements of claim 6 stands.

[146] For greater certainty, apart from the submissions that I have already rejected above and in discussing claim 1, neither Allergan nor Dr. Felton has identified any basis for concluding that the Skilled Person would have appreciated that the elements "granulating" and "a wet granulation process" could be substituted without affecting the working of the invention contemplated by claim 6. Stated differently, they have not identified any basis for concluding that the Skilled Person would have understood that a dry manufacturing process would obviously work in the same way.

[147] Accordingly, the essential elements of claim 6 are as follows:

- A method for preparing a capsule, comprising the steps of:

  (1) - Granulating silodosin, D-mannitol and partially pregelatinized starch

  - by a wet granulation process; and

  (2) - mixing the granule obtained in step 1 with:

  - a lubricant selected from magnesium stearate, calcium stearate and talc, and

  - SLS.

B. *Is the '002 Patent Invalid on the Ground of Obviousness?*

(1) Introduction

[148] Approximately half way during the trial of this action, the proceedings were adjourned after I was informed that a dispute had arisen regarding a partial settlement offer made by Sandoz. Allergan contended that the offer became a binding contract after it was accepted by Allergan. Allergan then brought a motion to enforce that purported contract. Out of an

abundance of caution, I did not review the materials filed in relation to the motion or adjudicate that dispute. The motion was heard and dismissed by Justice Barnes: *Allergan Inc v Sandoz Canada Inc*, 2020 FC 1047 [***Allergan Motion Decision***].

[149] In brief, according to the *Allergan Motion Decision*, on the afternoon of October 28, 2020, Sandoz offered in writing to withdraw its Counterclaim in this proceeding on a without cost basis. Allergan wrote back a few hours later to communicate its acceptance. The following morning, a dispute arose in respect of Sandoz's position that its invalidity defence remained active. Sandoz took the position that while it had offered to withdraw its Counterclaim, which by that point had been narrowed to alleging a single ground of invalidity – obviousness – it had never intended to abandon its ability to argue invalidity as a defence. It maintained that although it had offered to abandon its claim to *in rem* relief, it had not intended to give up its ability to argue the *Gillette* defence: *Allergan Motion Decision*, above, at 3-4 and 9.

[150] Ultimately, Justice Barnes concluded that no agreement had been reached between Allergan and Sandoz, because there had been no meeting of the minds: *Allergan Motion Decision*, above, at 7 and 10. I understand that Allergan has sought leave to appeal that decision.

[151] In the meantime, Allergan confirmed that Sandoz's Counterclaim based on obviousness remained a live issue in this proceeding. Indeed, after the trial recommenced following the issuance of Justice Barnes' decision, the parties continued to address that issue.

(2) The Legal Test

[152] Pursuant to section 28.3 of the Act, the subject matter defined by a claim in an application for a patent cannot have been obvious to a person skilled in the art or science to which that subject matter pertains, having regard to two types of information. One of those is information that was disclosed before the claim date in a manner that it became available to the public in Canada or elsewhere.

[153] The test for assessing obviousness comprises the following four steps:

> 1. Identify the person skilled in the art and the relevant common general knowledge;
>
> 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; and
>
> 4. Without any knowledge of the alleged invention as claimed, assess whether those differences (i) constitute steps that would have been obvious to the skilled person, or (ii) required a degree of invention.
>
> (*Sanofi*, above, at para 67.)

[154] The foregoing framework contemplates a flexible approach that must be applied contextually to the facts and circumstances of each claim: *Amgen Inc and Amgen Canada Inc v Pfizer Canada ULC*, 2020 FCA 188 at para 7. It also must be applied to the combination of the elements of the invention as a whole, rather than to each of its discrete elements: *Teva-Janssen*, above, at para 86.

[155] This framework contemplates a high bar to clear for alleged infringers, as they must demonstrate that the skilled person would have achieved the invention directly and without difficulty: *Bridgeview Manufacturing Inc v 931409 Alberta Ltd*, 2010 FCA 188 at para 40 [***Bridgeview***], quoting with approval *Beloit Canada Ltd v Valmet Oy* (1986), 8 CPR (3d) 289 at 294 (FCA) [***Beloit***]. Demonstrating that the claimed invention was "worth a try" or that the Skilled Person had good reason to pursue predictable solutions or solutions that provide a fair expectation of success is not sufficient: *Pfizer Canada Inc v Apotex Inc*, 2009 FCA 8 at para 28 [***Pfizer-Apotex***]; *Eli Lilly Canada Inc v Mylan Pharmaceuticals ULC*, 2015 FCA 286 at para 4; *Bristol-Myers Squibb Canada Co v Teva Canada Ltd*, 2016 FC 580 at para 458; *Hospira Healthcare Corporation v Kennedy Trust for Rheumatology Research*, 2018 FC 259 at para 225.

[156] By comparison, the threshold for inventiveness (non-obviousness) is low: *Beloit*, above; *Teva-Janssen*, above, at para 81.

[157] In situations where advances are often won by experimentation, the "obvious to try" test might be appropriate to embrace in connection with the fourth step identified above. An example is inventions in the pharmaceutical industry that involve chemically similar structures that can elicit different biological responses and offer the potential for significant biological advances: *Sanofi*, above, at para 68. It appeared to be common ground between the parties that the invention claimed by the '002 Patent falls into this category and that therefore it is appropriate to apply the "obvious to try" test.

[158] When applying that test, the following factors from *Sanofi* should be considered:

i. Is it more or less self-evident that what is being tried ought to work? Is there a finite number of identified predictable solutions known to skilled persons?

ii. What is the extent, nature and amount of effort required? Are routine trials carried out or is the experimentation prolonged and arduous, such that the trials would not be considered routine?

iii. Is there a motive provided in the prior art to find the solution?

iv. What was the actual course of conduct that culminated in the invention?

[159] Given the close linkage between the second and the fourth of the above-listed factors, they can be considered together: *Bristol Meyers Squibb Canada Co v Teva Canada Ltd*, 2017 FCA 76 at para 44; *Biogen*, above, at para 150; *Teva-Janssen*, above, at para 85.

[160] To satisfy the "obvious to try" test, the evidence must establish on a balance of probabilities that it was more or less self-evident from the prior art and the CGK to try to obtain the invention: *Sanofi*, above, at paras 66 and 85.

[161] Even where the "obvious to try" test is satisfied, it is not necessarily determinative, as this test is simply one factor in the overall obviousness inquiry: *Sanofi*, above, at para 64. Likewise, within the "obvious to try" assessment, a demonstration that it was more or less self-evident from the prior art and the CGK that the claimed invention "ought to work" is simply one factor to consider: *Sanofi*, above, at para 69; *Hospira Healthcare (FCA)*, above, at para 90.

(3) Assessment

(a) *Step One - The Skilled Person and the relevant common general knowledge*

[162] These matters have been addressed at paragraphs [52]-[62] above.

[163] For the purposes of the obviousness analysis, the CGK is assessed as at the Claim Date of the ‘002 Patent. Sandoz has not taken issue with Dr. Felton’s position that there was no material change in the CGK between the Claim Date and the Publication Date: Felton Second Report, at para 15. Accordingly, the CGK for the present purposes is the CGK described at paragraphs 59-60 above.

[164] Allergan and Sandoz are in agreement that the “state of the art” includes a single piece of prior art that was publicly available prior to the Claim Date, namely, Japanese Patent Application No. JP 2000-247998A [**JP998**], which was submitted by Kissei on February 26, 1999 and published on September 12, 2000. As with Allergan, Sandoz and their respective experts, I will refer to the English translation of JP998, which was agreed to be authentic.

[165] It is common ground between Allergan and Sandoz that JP998 represented a prior disclosure of the silodosin compound. The object of the invention described in JP998 was described as being “to provide a therapeutic agent for dysuria associated with prostatic hypertrophy, which the development of resistance resulting from continuous use can be supressed, and the side effects in other organs, such as cardiac hypertrophy, can be avoided”: JP998, at para 0009.

(b) *Step Two - The inventive concept*

[166] Allergan submits that the inventive concept of claims 1-3 and claim 6 is as stated by Dr. Felton. With respect to claims 1-3, Dr. Felton described the inventive concept as being *a capsule formulation containing silodosin and the identified excipients that achieves a specific rapid dissolution rate (85% dissolution within 15 minutes) when measured with the methodology described*. Regarding claim 6, she opined that the inventive concept is "*[a] method for preparing a capsule comprising a silodosin formulation with an improved dissolution rate*". Although there is no mention of a dissolution rate in claim 6, Dr. Felton opined that "the entire patent is about achieving that high dissolution rate", and that if the composition described in claim 1 were made by the process of claim 6, "you would inevitably get that dissolution profile as well because it is the same composition": Public Transcript, at 143-4.

[167] Allergan maintains that this dissolution profile is important because, pursuant to a guideline issued by the United States Food and Drug Administration [**FDA**], entitled *Guidance for Industry – Dissolution Testing of Immediate Release Solid Oral Dosage Forms*, a drug that meets this dissolution profile in simulated gastric juice (0.1 normal hydrochloric acid) "behaves like a solution and generally should not have any bioavailability problems" (page 3). It appears to be common ground between Allergan and Sandoz that a drug that achieves 85% dissolution within 15 minutes in water will also meet that dissolution profile in 0.1 normal hydrochloric acid: Public Transcript, at 103 and 404-407.

[168] Sandoz's expert, Dr. Fassihi, opines that there is no "invention" in claims 1-3 or claim 6 of the '002 Patent, and that therefore there is no inventive concept. More specifically, he and

Sandoz maintain that the silodosin compound, the excipients, their respective functions and the conventional manufacturing processes (including granulating by wet granulation) were all known prior to the Claim Date, and that there is no invention in selecting a dissolution rate. This may well be so, however, it is entirely possible to create an invention by combining known components and manufacturing processes to achieve a new and useful result: *Zero Spill Systems (Int'l) Inc v Heide*, 2015 FCA 115 at para 95; *The King v American Optical Co*, [1950] Ex CR 344 at 355, 1950 CarswellNat 9 (Can Ex Ct).

[169] In the alternative, and relying on *Ciba Specialty Chemicals Water Treatments Limited v SNF Inc*, 2017 FCA 225 at paras 72-77 [***Ciba-SNF***], Sandoz asserts that the inventive concept should be avoided altogether. The inquiry should instead be focused on the essential elements of the claims as construed, rather than "engaging in an unnecessary satellite debate" that draws upon the patent as a whole: *Ciba-SNF*, above, at para 77.

[170] To the extent that the inventive concept of the patent can be discerned from the essential elements of those claims, I agree that this is the appropriate approach to follow where there is a real risk of becoming embroiled in a "satellite debate". However, where it is not possible to fully grasp the nature of the inventive concept solely from those claims, the Court may have regard to the patent specification for that purpose: *Teva Canada Ltd v Pfizer Canada Inc*, 2012 SCC 60 at para 50; *Sanofi*, above, at para 77; *Apotex Inc v Allergan*, 2012 FCA 308 at paras 72-74; *Allergan Inc v Canada (Minister of Health)*, 2014 FC 567 at para 25, aff'd 2015 FCA 137.

[171] That is the situation in the present context. In brief, claim 1 of the '002 Patent describes a capsule comprising a granule prepared by wet granulation of a mixture of silodosin and specific

identified excipients that achieves a specific rapid dissolution rate (85% dissolution within 15 minutes) when measured with the methodology described. Claim 2 refers back to the "capsule according to claim 1" and then specifies magnesium stearate as the sole lubricant. In turn, claim 3 refers back to the "capsule according to claim 2", and then specifies a ratio of SLS to magnesium stearate. Claim 6 then describes a two-step method for preparing a capsule containing the ingredients described in claim 1.

[172] It is readily apparent from the foregoing that the claims alone do not provide sufficient information to properly and fairly understand the innovative concept or to perform the assessments contemplated by the third and fourth steps in the obviousness analysis. Accordingly, I consider it necessary to supplement this information with information from the patent specification that permits those assessments to be conducted.

[173] In my view, there are four additional details in the patent specification that permit the inventive concept to be fully and fairly understood, and then compared with the prior "state of the art" in the third step of the overall analysis. Those are that the invention (i) is a solid oral dosage form pharmaceutical for the treatment of dysuria that has: (ii) a high precision for filling; (iii) a high content uniformity to ensure bioequivalence among batches; and (iv) good stability. I will observe in passing that items (ii) – (iv) are mentioned repeatedly and are characterized alternatively as being "important", "required" and "desired": '002 Patent, at page 6 (lines 3-9), page 8 (lines 12-17 and 26), page 9 (25-27), pat 10 (lines 12-15), page 13 (lines 4-6 and 18-20), page 14 (at lines 3-4), page 21,at lines 22-23), page 41 (lines 2-3).

[174] Drawing upon these additional details and the essential elements in claims 1-3, I consider the inventive concept of those claims to be as follows: *a new solid oral dosage form formulation for the treatment of dysuria that is a capsule comprising a granule prepared by wet granulation of a mixture of silodosin and identified excipients that (i) achieves a specific rapid dissolution rate in water (85% dissolution within 15 minutes) when tested with the methodology described, (ii) has a high precision for filling; (iii) has a high content uniformity to ensure bioequivalence among batches, and (iv) has good stability.*

[175] With respect to claim 6, the inventive concept is *the preparation of the formulation described in claim 1 by (i) granulating the silodosin, d-mannitol and partially pregelatinized starch by a wet granulation process, and then (ii) mixing the granule obtained in step 1 with one of the identified lubricants and SLS.*

(c) *Step Three - The differences between the state-of-the-art and the inventive concept*

[176] Sandoz asserts that there are only small differences between the single prior art, JP998, and the invention claimed in the ‘002 Patent. In brief, those are (i) pre-gelatinized starch has been substituted for cornstarch, (ii) SLS has been added to the formulation in the ‘002 Patent, and (iii) the process of wet granulation has been substituted for the dry method disclosed in the only formulation example provided in JP998.

[177] Allergan insists that the differences between what was disclosed in JP998 and the inventive concept of the ‘002 Patent are more significant than what is stated by Sandoz. To begin, Allergan notes that JP998 is broadly directed to a class of therapeutic agents (alpha-1A

adrenergic receptors that do not exhibit inverse agonist activity) and contemplates "an enormous" list of individual excipients. Allergan adds that, in addition to the differences identified by Sandoz, claim 3 of the '002 Patent specifies a ratio of SLS to magnesium stearate, which is something that was not addressed in JP998. Moreover, whereas JP998 does not mention silodosin's very low solubility in water or its potent adhesive and electrostatic properties, the '002 Patent addresses those properties for the first time and then provides a rapid dissolution solution to the associated capsule filling and content uniformity problems that it identifies.

[178] I agree with Allergan.

[179] The '002 Patent discloses for the first time silodosin's very low solubility in water as well as its potent adhesive and electrostatic properties, together with the filling and content uniformity problems that are associated with those properties. This was not contested by Sandoz or by Dr. Fassihi: Public Transcript, at 460. The '002 Patent then provides a solution to those hitherto unknown problems. That solution is a specific and new capsule formulation, prepared by a two-step wet granulation process. The formulation contains two excipients that were not mentioned in JP998, and is prepared by a specific process that is not mentioned in that patent – which only describes a dry process in the one formulation example that it provides. The '002 Patent discloses that a dry process is associated with decreased fluidity, handling properties and content uniformity.

[180] The solution taught by the '002 Patent, and that forms part of its inventive concept, achieves things that are not mentioned anywhere in JP998. These are (i) a specific rapid dissolution rate in water (85% dissolution within 15 minutes) when tested with the described

methodology; (ii) a high precision for filling; (iii) a high content uniformity to ensure bioequivalence among batches; and (iv) good stability.

(d) *Step Four - Were the differences between the inventive concept and the state of the art obvious?*

[181] As noted at paragraph [157] above, it appears to be common ground between the parties that it is appropriate to apply the "obvious to try" test. I agree and will proceed to address the various aspects of that test below.

(i) Was it more or less self-evident that what is being tried ought to work? Were there a finite number of identified predictable solutions known to the Skilled Person?

[182] Sandoz maintains that it was more-or less self evident to a Skilled Person reading JP998 that the improvements sought and claimed by the Inventors ought to work. Sandoz concedes that the problems of low solubility and potent adhesive/electrostatic properties of silodosin had not been disclosed prior to the Claim Date. However, it asserts that these problems would have been readily identified through routine preformulation testing that was familiar to the Skilled Person. Upon the identification of those problems, the Skilled Person would have known that those problems could be overcome by pursuing straightforward testing involving a small number of known options.

[183] More specifically, Sandoz notes that all of the excipients identified in the '002 Patent, as well as their functions, were known: D-Mannitol was a known filler, pregelatinized starch was a known disintegrant and binder, magnesium stearate was a commonly used lubricant, and SLS

was a well-known surfactant. In addition, Sandoz suggests that the ratio of magnesium stearate to SLS that is specified in the ‘002 Patent is within the typical range in the 2000 edition of the *Handbook of Pharmaceutical Excipients*. Furthermore, the wet granulation process was a well-known process for preparing solid-dose oral drug formulations, it was known that lubricants should be added at the end of the formulation process, and, in any event, the order of mixing is not inventive.

[184] Sandoz adds that Dr. Felton acknowledged that the types of preformulation studies that were conducted in 2002 would have included assessing the solubility of drugs in various solvent systems as well as in water having various pH values. Dr. Felton also conceded that the powder flow of a solid would also have been assessed in such studies, and that the Skilled Person would know that pharmaceutical companies employed skilled people who would know how to conduct compatibility studies of the type identified in the ‘002 Patent: Public Transcript, at 50-53.

[185] Sandoz further notes that Dr. Felton acknowledged that a standard formulation would include a diluent, a lubricant, and a wetting agent (including SLS), and that the Skilled Person would be familiar with running dissolution testing at various biological pH values and with the paddle method at 50 rpm: Public Transcript, at 57-61. She also conceded that the Skilled Person would be aware of various approaches for increasing the rate of dissolution.

[186] Given all of the foregoing, Sandoz maintains, in essence, that it would have been more or less self-evident to the Skilled Person that there ought to be a way of formulating silodosin in a rapid release capsule. The Skilled Person would have known that this could be achieved in a relatively straightforward fashion, through routine experimentation.

[187] In this regard, Dr. Fassihi testified that formulating a drug that meets the FDA standard for immediate release (85 percent in 15 minutes) is "pretty straightforward" and "takes half a day to do – two or three formulations. Two or three days, maybe a week, maybe *[sic]* couple of weeks": Public Transcript, at 381. Later in his testimony, he emphasized that "you can do it in half an hour. Half an hour.": Public Transcript, at 563.

[188] Insofar as the previously undisclosed potent adhesive and electrostatic properties of silodosin are concerned, Dr. Fassihi added that these would have been quickly discovered by the Skilled Person, because "it is just a matter of mixing powders and see *[sic]* what happens": Public Transcript, at 455. Stated differently, Dr. Fassihi stated this can be determined "by simple blending of four or five components of the formulation": Public Transcript, at 458. He added that ascertaining whether an API has electrostatic charges that cause it to stick to the body of equipment "is a very simple exercise" which can be done in "10 minutes": Public Transcript, at 459.

[189] In response, Allergan states that prior to the '002 Patent, the Skilled Person would not have known whether silodosin could be formulated successfully into rapidly dissolving immediate release capsules that provide the claimed dissolution rate in water. This is because the "potent adhesive and electrostatic properties" and the very low solubility of silodosin that were disclosed for the first time in the '002 Patent were previously unknown. The same is true with respect to the capsule filling problems that were identified in the '002 Patent, even when using a wet granulation process. Although the Skilled Person may well have discovered these problems after testing, the fact of the matter is that they were unknown prior to the Claim Date. This was acknowledged by Dr. Fassihi: Public Transcript, at 444, 449, 455, 457, 459-450, 462 and 563-

564 . Consequently, it could not have been more or less self-evident that a rapid release capsule solution to these unknown problems ought to work.

[190] I agree with Allergan's position.

[191] As this Court has recognized, it may be inventive to recognize that a problem to be solved exists in the first place: *Bayer A.G. v Novopharm Ltd*, 2006 FC 379 at para 44; *Glaxosmithkline Inc v Canada (Minister of Health)*, 2003 FC 899 at para 45.

[192] Before becoming aware of the above-mentioned problems that were disclosed for the first time in the '002 Patent, it would not have been more or less self-evident to the Skilled Person that a particular solution to those unknown problems above ought to work. This remains true even if, in theory, there were a small number of known potential solutions to those problems.

[193] Indeed, before knowing of the existence of problems that were solved by the claimed invention, it would not have been more or less self-evident to try to obtain the invention. As was noted in *Sanofi*, above, at para 85: "The fact that there are such known methods … will be of no account if the evidence does not prove that it was more or less self-evident to try them." Similarly, absent the knowledge of silodosin's problematic properties, it would not have been obvious to solve them: *Sanofi-Aventis v Apotex*, 2013 FCA 186, at para 74. In the present proceeding, there is no such evidence, at least none which establishes on a balance of probabilities that, prior to the Claim Date of the '002 Patent, "it was more or less self-evident to try to obtain the invention": *Sanofi*, above, at para 66. Although this is determinative of the

"obvious to try" assessment I will proceed below to assess the remaining parts of the "obvious to try" test.

[194] The foregoing findings weigh in favour of a negative determination in the "obvious to try" assessment.

[195] I will pause to observe that Dr. Fassihi also acknowledged that he was not aware of any prior art reference that addressed the compatibility of silodosin with any of the excipients that were identified in the '002 Patent: Public Transcript, at 559. He also appeared to concede that it was not a foregone conclusion that silodosin could be formulated in a way that met the FDA's rapid dissolution guideline of 85% in less than 15 minutes: Public Transcript, at 563-564. Indeed, Test Example 3 of the '002 Patent reflects that, in attempting to overcome the waterproofing effect of magnesium stearate, only one of the five attempts made by the Inventors worked – the one involving SLS.

(ii) What was the extent, nature and amount of effort required? Were routine trials carried out or is the experimentation prolonged and arduous, such that the trials would not be considered routine?

[196] Sandoz submits that bridging the gap between the prior art (JP998) and the invention claimed in the '002 Patent was part of the routine work of the Skilled Person. It reiterates that the only differences between the lone formulation disclosed in JP998 (at para 0051) and the formulation claimed in the '002 Patent is that (i) SLS, which was known to counteract the hydrophobic properties of magnesium stearate, was added, and (ii) pregelatinized starch, which was a known disintegrant and alternative to cornstarch, was substituted for the latter excipient.

With respect to the process, Sandoz underscores that one of the three conventional approaches (wet granulation) was simply substituted for one of the other conventional processes (dry mixing) that was disclosed in the formulation disclosed in JP998. Moreover, that substituted process (wet granulation) is mentioned in the paragraph of JP998 (0030) that discusses capsule preparations. Furthermore with respect to the mixing sequence, it was known to add a lubricant after wet granulation. Insofar as the dissolution rate is concerned, Sandoz notes that Dr. Felton testified that it necessarily results from using the known excipients.

[197] In addition, Sandoz repeats that the low solubility, adhesion and electrostatic properties of silodosin would have been quickly discovered through the routine preformulation studies and testing described at paragraphs [184]-[186] above. In any event, as explained by Dr. Fassihi (see paragraphs [187]-[188] above), the Skilled Person would have easily and rapidly identified these properties upon starting to work with silodosin and the excipients in question.

[198] Regarding Dr. Felton's opinion that the formulation claimed in the '002 Patent would not have been obvious to the Skilled Person familiar with JP998, Sandoz maintains that Dr. Felton misunderstood the requirements for obviousness. In this regard, Sandoz states that Dr. Felton based her opinion on the fact that the Skilled Person would not know the effect of excipients on dissolution before testing. Sandoz rightly points out that a claimed invention can be found to have been obvious even when routine experimentation and testing is performed. Sandoz adds that the fact that the Skilled Person may have had to assess multiple options or pathways does not preclude a finding of obviousness: *AstraZeneca Canada Inc v Teva Canada Limited*, 2013 FC 245 at para 79; *Gilead Sciences, Inc v Canada (Minister of Health)*, 2013 FC 1270 at para 82.

[199] Sandoz also maintains that the actual course of conduct of the Inventors of the claimed invention provides further support for a finding of obviousness. In particular, it notes that the preformulation work done by the Inventors was the type of work taught in textbooks, and that Dr. Felton described that work as being "the sort of work conducted by large pharmaceutical companies": Felton Second Report, at para 7(9). Sandoz further notes that Dr. Felton did not identify any particular aspect of the Inventors' work or of the claims that would have been considered inventive in 2002.

[200] Finally, Sandoz notes that Allergan did not call either of the Inventors to testify as to whether their actual course of conduct was prolonged or arduous. In any event, it maintains that there is therefore no evidence to support Allergan's position that the Inventors went down several blind alleys, and that this is inconsistent with certain internal documentation produced by Kissei. Sandoz adds that the first time it heard about the "blind alley" argument was during the cross-examination of Dr. Fassihi.

[201] I will pause to note that although the term "blind alleys" may not have been raised in this proceeding before the cross-examination of Dr. Fassihi, Allergan's pleadings allege that "[s]ignificant time, ingenuity, effort and expense were invested in the discovery efforts leading to the 002 Patent": Amended Reply and Defence to Counterclaim, at para 39. Moreover, the Joint List of Issues filed by Allergan and Sandoz identifies "the course of conduct of the inventors" as being one of the issues in dispute, in connection with Sandoz's allegation of invalidity. In addition, the slide presentation summarizing Allergan's opening submissions specifically asserted that "Kissei developed its medicine over a period of years".

[202] In response to Sandoz's positions regarding the obvious and routine nature of the work required to bridge the gap between JP998 and the claimed invention, Allergan states that the Skilled Person would have known that there were multiple potential approaches to modifying the dissolution rate of a drug. These approaches, all of which were identified by Dr. Felton, included:

- Investigating different excipients through a formulation approach;
- Reducing the particle size of the API;
- Using a salt form of the drug substance; and
- Using prodrugs.

[203] As Dr. Felton explained, the formulation approach is the method described in the '002 Patent. However the Skilled Person would have appreciated that that approach would not be obvious or routine. Dr. Felton elaborated as follows:

> … the formulation approach typically required a significant amount of experimentation to determine which excipient or combination of excipients, and amounts, could potentially increase the dissolution of a particular drug substance. These variables depended on the physiochemical properties of the drug substance being considered. For this reason, formulations of different drugs typically do not provide directly useful information for investigating the dissolution of a specific drug substance.
>
> (Felton Second Report, at para 43.)

[204] Dr. Felton's position that the formulation approach typically requires a significant amount of experimentation is corroborated by some of the articles that Dr. Fassihi identified as being part of the "state of the art" at the time of the Claim Date. For example, the article entitled

Selection of Solid Dosage Form Composition through Drug-Excipient Compatibility Testing, which appears at Tab P of Dr. Fassihi's First Report, states the following at page 696:

> Despite the importance of drug-excipient compatibility testing, no generally accepted method is available for this purpose. Most of the methods reported in the literature have poor predictive values. They are labor-intensive and time-consuming, and the number of variables studied are limited.

[205] Indeed, an article co-written by Dr. Fassihi, included at Tab I of his First Report and entitled *Solid state interactions of bromazepam with polyvinylpryrrolidone in the presence of moisture*, states (at page 167): "Difficulties in formulating a new pharmaceutical dosage form have often been experienced because of [solid state] interactions." It adds that "solid state interactions are usually complicated by numerous parallel and consecutive reactions". A third article, entitled Drug-*Excipient Interactions Resulting from Powder Mixing III: Solid State Properties and Their Effect on Drug Dissolution* and included at Tab H of Dr. Fassihi's First Report, states, at the outset of its conclusion: "The results of this study confirm earlier results indicating that drug-excipient interactions are the major factor influencing disintegration time and dissolution rate in hand-filled, uncompacted capsules."

[206] Given the foregoing, I accept Dr. Felton's opinion that in light of the unpredictability associated with formulating a drug with different excipients, "the Skilled Person would not have agreed with Dr. Fassihi that adding a disintegrant (pregelatinized starch) and a surfactant (sodium lauryl sulfate) to any drug substance was a panacea to achieving rapid dissolution": Felton Second Report, at para 163. Stated differently, although the excipients mentioned in the '002 Patent were standard and well-known, "their use in a formulation can significantly impact dissolution and the effects on dissolution are unpredictable": Felton Second Report, at para 84.

Neither Sandoz nor Dr. Fassihi identified any specific prior art or CGK, or combination thereof, which demonstrated otherwise. The fact that some of the prior art identified by Dr. Fassihi may have pointed away from the use of lactose by the inventors, and thereby enabled the inventors to avoid testing lactose, would not have changed the Skill Person's understanding of this basic principle. That principle would have continued to apply to the other steps required to bridge the gap between JP998 and the claimed invention.

[207] I also accept Dr. Felton's opinion that "achieving … a fast dissolution rate would be particularly problematic for a poorly water soluble drug like silodosin", and that therefore "the Skilled Person would understand that with such a low solubility, silodosin would likely not have rapid dissolution and its dissolution would likely be rate-limiting for absorption in the body": Felton Second Report, at paras 82 and 80. Once again, neither Sandoz nor Dr. Fassihi identified any specific prior art or CGK, or combination thereof, which demonstrated that overcoming the problem would not likely be extensive.

[208] Dr. Felton's position regarding the unpredictability of drug formulation and the challenges that the Inventors would have faced in formulating the claimed invention is corroborated by the actual course of conduct of the Inventors, as reflected in both the '002 Patent and internal Kissei documentation. For example, the '002 Patent states the following:

- "… it is extremely difficult to prepare practically usable solid oral dosage form pharmaceuticals comprising, as an active ingredient, [silodosin], its prodrug, pharmaceutically acceptable sale or pharmaceutically acceptable solvate thereof by conventional formulation methods." (Page 5, lines 3-8)

- "The present inventors have intensively investigated the kind, combination or ratio of additives, manufacturing processes and the like, and have found highly practically usable formulations which have suitable handling properties for manufacturing processes, high precision for content uniformity and excellent dissolution properties and are useful for exerting biological activities of [silodosin] effectively." (Page 13, lines 16-23)
- "Regarding [the potent adhesive properties of silodosin], the present inventors have investigated a process for improving the delay in a dissolution time even in the case of using a lubricant in an amount of not less than 1%, and have found out that the delaying in a dissolution time can be prominently improved by blending a solid additive having hydrophilic or surface-active properties and thereby formulations with good dissolution properties can be prepared." (Page 14, lines 8 – 19)

[209] The '002 Patent also describes the investigations and problems that led to the substitution of D-mannitol for lactose, the inclusion of SLS in the formulation and its addition after the granulation process: '002 Patent, at page 10 (lines 1-8) and page 15 (lines 12-16).

[210] Turning to Kissei's internal documentation, Dr. Felton provides the following descriptions:

- "At paragraphs 194-197, Dr. Fassihi says the testing described in sections 4 and 5 of Kissei Production No. 229 were "standard routine tests". Though the tests themselves were not innovative, I disagree that the efforts described would have been routine for the Skilled Person. As I explain above, these tests were conducted by a large pharmaceutical company developing a new chemical entity, and the document itself

cites other individual reports that describe testing on [silodosin]. As indicated by Dr. Fassihi at paragraph 195 of his report, this work canvassed: particle size and physical properties, solubility, hydroscopicity, light stability, melting point and thermal analysis, dissociation constant and distribution coefficient, and crystal form tests (i.e., crystalline transition, solubility of different crystal forms and stability of different crystal forms). The effort required to conduct all this work was extensive." (Felton Second Report, at para 326)

- "As I explain above, it would have taken inventive ingenuity for the Skilled Person to arrive at the inventive concepts of the 002 Patent. In Appendix V, at section 5.2.5, pg. 21 of 32, the document appears to summarize some of Kissei's dissolution and compatibility testing. This section notes that Kissei examined various diluents, disintegrating agents, and lubricants, and ultimately identified D-Mannitol, "partial alpha starch" (PCS)", magnesium stearate and sodium lauryl sulfate as conferring the best dissolution and compatibility characteristics." (Felton Second Report, at para 332)
- "In the case of [silodosin], as I note above, Appendix V indicates that Kissei discovered KMD-3213 in 1993, and the report itself summarizes the development effort to prepare the formulation for a phase III clinical study. It appears that Kissei was conducting phase III trials in 2004. Accordingly, the report appears to summarize a decade-long effort. Over the course of these years, much information was gathered by the inventors and that knowledge was used to develop the final formulation." (Felton Second Report, at para 330)
- "… the testing described in [Kissei Production No. 229] spans nearly 100 pages, and as described in the introduction, covers a variety of testing: final capsule formulation,

> scale-up study, process study on production sale, and stability. The testing cites the work of 38 other Kissei reports, some of which were necessary to guide the testing, which is described in Dr. Fassihi's Appendices W and V. Accordingly, the testing described in these documents is significant, and would have required a significant expenditure of both money and resources." (Felton Second Report, at para 334)

[211] Based on her review of Kissei's internal documentation, Dr. Felton concluded that the testing done by the Inventors of the claimed invention was "extensive" and not "routine or predictable": Felton Second Report, at para 86.

[212] In my view, Dr. Felton's summary of the experimentation done by the Inventors, and her conclusion that it was "extensive" and not "routine or predictable" is fair, corroborated, and more persuasive than Dr. Fassihi's review and conclusion in this regard. For the reason set for in paragraph [35] above, I consider that Dr. Felton's evidence on this issue was also more impartial than Dr. Fassihi's. Indeed, some of the testimony provided by Dr. Fassihi, and described at paragraphs [187]-[188] above, strains credulity.

[213] I will pause to note for the record that, on cross-examination, Dr. Fassihi conceded that the adhesive and filling problems encountered by the Inventors could not have been predicted in advance, and that upon becoming aware of silodosin's properties, the Skilled Person would have been aware that it might be necessary to explore multiple options, including in respect of SLS and magnesium stearate: see, for example, Public Transcript, at 587 and 593-4. Dr. Fassihi also admitted that the Skilled Person would not have expected to encounter filling problems with the wet granulation process: Public Transcript, at 478. In addition, Dr. Fassihi admitted that the

Skilled Person would have known that silodosin is a weak base with a high pH (above 7.0), and that none of the articles that he had identified in connection with SLS referred to the use of SLS with a weak base: Public Transcript, at 592. In this regard, he acknowledged that the Skilled Person would know that a weak base such as silodosin "would dissolve much better in the acidic environment and not so much in the neutral or alkaline pH": Public Transcript, at 389.

[214] In summary, I accept Dr. Felton's opinion that there was "nothing in JP998 or the [CGK] that indicates that it would have been possible to achieve [the claimed] rapid dissolution for a poorly soluble drug substance like silodosin": Felton Second Report, at para 144. I consider it reasonable to infer from this that, upon discovering silodosin's low solubility, the Skilled Person would not likely have thought that the claimed invention could be achieved relatively quickly, through routine experimentation. This is particularly so in light of silodosin's "potent adhesive and electrostatic properties". Neither Sandoz nor Dr. Fassihi identified any particular prior art or CGK that established the contrary.

[215] Moreover, based on the evidence of Dr. Felton and the internal Kissei documentation discussed above, I find that the Inventors likely engaged in a significant amount of difficult, non-routine work and overcame several unexpected obstacles to achieve the claimed invention. Indeed, this is reflected to some extent in the '002 patent. Contrary to Dr. Fassihi's assertions, the Inventors do not appear to have achieved the claimed invention "quickly, easily, directly and relatively inexpensively, in light of the prior art and common general knowledge": *Sanofi*, above, at para 71. On the contrary, their work appears to have "prolonged and arduous" (*Sanofi*, above, at para 69) and involved overcoming multiple obstacles before they finally arrived at the claimed invention.

[216] These findings weigh in favour of a negative finding in the "obvious to try" analysis.

[217] My conclusion in this regard is reinforced by Dr. Felton's evidence that if the Skilled Person were looking to change the formulation disclosed in JP998, he/she would have first looked to other drugs in the class of alpha-1 blockers, namely Flomax and Hytrin, which are very different formulations than what is claimed in the '002 Patent: Public Transcript, at 41-42. I accept Dr. Felton's opinion that following the formulations of those drugs "would have led the Skilled Person away from the inventive concepts of the 002 Patent": Felton Second Report, at para 7(6).

(iii) Was there a motive provided in the prior art to find a solution that the '002 Patent addresses?

[218] Sandoz maintains that the Skilled Person would have been motivated to test the dissolution rate of the formulation disclosed in JP998. Sandoz asserts that if, upon such testing, problems were identified (such as the formulation not dissolving at acceptable rates for immediate release formulations), the Skilled Person would have then been motivated to take steps to improve the dissolution rate. Sandoz states that this motivation would have existed because drug dissolution is an important consideration for drug absorption and therapeutic effect.

[219] I disagree.

[220] Dr. Felton opined that the Skilled Person would not have had any motivation to improve upon the dissolution rate of the formulation disclosed in JP998, because that prior art did not

provide any basis for the Skilled Person to believe that any improvement was necessary. In my view, this is confirmed by a reading of JP998.

[221] This is further confirmed by the testimony of both Dr. Felton and Dr. Fassihi, on cross-examination, that the formulation disclosed in JP998 would be understood to be an immediate release formulation: Public Transcript, at 113, 446-448. Dr. Fassihi conceded that the Skilled Person would understand from this that "there should not be [a] bioavailability issue" and that the Skilled Person would have no motivation to try to improve the dissolution rate of the JP998 formulation: Public Transcript, at 446 and 448-449.

[222] Dr. Fassihi proceeded to add that, if the formulation disclosed in JP998 did not in fact dissolve at a rate of 85% in 15 minutes, the Skilled Person would have been motivated to improve the dissolution rate. However, this begs the question of whether JP998 provided any motivation to the Skilled Person to test the formulation it disclosed, in the first place. I accept Dr. Felton's evidence that there was no such motivation.

[223] I also accept Dr. Felton's opinion that the Skilled Person would have lacked the motivation to pursue the invention claimed in the '002 Patent for an additional reason – the fact that silodosin has low solubility in water. Having regard to that fact, Dr. Felton explained that there was nothing in JP998 or the CGK that would have provided the Skilled Person with a motivation to conduct the necessary work to achieve the claimed invention: Felton Second Report, at para 192.

[224] Sandoz submits that this case is on all fours with this Court's decision in *Eli Lilly Canada Inc v Mylan Pharmaceuticals ULC*, 2015 FC 178 at para 149 [***Eli Lilly v Mylan***], where it was held that "[t]he choice of [the excipients in question] and of their specific amounts was well within the [CGK] of the skilled person". However, that case is distinguishable on the basis that an important factor for the Court was that a standard textbook recommended the "precise" excipients claimed in the disputed patent and that SLS had been specifically disclosed for use with the API in question (tadalafil) in two other patents: *Eli Lilly v Mylan*, above, at para 144.

[225] Based on all of the foregoing, I consider that the Skilled Person would not have had any motivation to pursue the invention claimed in the '002 Patent. The Skilled Person would have had no basis to believe that any improvement in the formulation disclosed in JP998 was necessary or desirable. Moreover, upon discovering the low solubility of silodosin and the fact that the formulation did not meet the rapid dissolution profile of 85% in 15 minutes, the Skilled Person would have had no motivation to conduct the necessary work to achieve the claimed invention. In brief, there was no reason for the Skilled Person to pursue any improved solution; there would have been no predictable solution; and there would have been no "fair expectation of success" in respect of any such solution: *Apotex v Pfizer Canada*, 2009 FCA 8 at para 44; *Amgen Canada Inc v Apotex*, 2015 FC 1261 at para 102. Given the foregoing, the "motivation" factor merits a negative weighting in the "obvious to try" assessment.

(iv) Allergan's experiment

[226] In response to Dr. Fassihi's position that the differences between JP998 and the '002 Patent constitute steps that would have been obvious to the Skilled Person, Allergan retained Dr.

MacGregor to conduct a series of experimental tests. The focus of those tests was to determine the dissolution rate of the formulation disclosed in JP998 and in additional formulations that (i) substituted pregelatinized starch for corn starch, and (ii) added SLS, respectively.

[227] In brief, Dr. MacGregor performed three separate "runs" of different formulations of silodosin and the excipients disclosed in JP998 and the '002 Patent. Each of the three formulations contained 1 milligram of silodosin at the same percentage level, and different levels of the excipients. Six capsules were tested in each run, for a total of 18 capsules overall. Run 1 involved the same ingredients disclosed in JP998, run 2 varied that mix by substituting pregelatinized starch for corn starch, and run 3 added 0.04 mg of SLS to each capsule. The average dissolution rate for each of the three runs was 31.3%, 34.26% and 33.5%, respectively. With one exception, none of the capsules had a dissolution rate in excess of 38%. For the one exception, the dissolution rate was 44.2%.

[228] Among other things, Dr. Fassihi opined that the experimental testing conducted by Dr. MacGregor was not responsive to any scenario presented in the First Fassihi Report, and did not produce meaningful results. I agree.

[229] At paragraph 118 of the First Fassihi Report, Dr. Fassihi suggested that the Skilled Person would have known to test a formulation with (i) pregelatinized starch replacing cornstarch, and (ii) SLS included. This was not done in any of the experimental runs conducted by Dr. MacGregor.

[230] Moreover, the manner in which the testing was conducted did not produce reliable results regarding the dissolution rate of the tested formulations. As reflected in pictures that were taken by Dr. Fassihi, clumps of the mixed formulation stuck to the sides of the test containers, while other clumps were left on the scale or fell out during the capsule filling process. As a result, I accept Dr. Fassihi's opinion that it "is likely that a significant amount of the finer, 'stickier' powders such as silodosin and SLS were lost due to adhesion to the containers and sieves" and that the "loss of this material could significantly affect the dissolution results": Fassihi Third Report, at para 38.

[231] I also accept Dr. Fassihi's opinion that it "is not possible to tell if the target amounts of silodosin were in each capsule": Fassihi Third Report, at para 39. This is in part because enough mixture was prepared for approximately 40 capsules, yet only six capsules of each of the three formulations were tested. Thus, the dissolution rates that were reported by Dr. MacGregor were based on the amount of silodosin that was assumed to be in the capsules. However, given the issues identified above, that assumption was not warranted. Moreover, steps that could have been taken to confirm how much silodosin and other excipients were in each capsule were not taken: Fassihi Third Report, at paras 43-44.

[232] Based on the foregoing, I find that the experimental testing conducted by Dr. MacGregor was not helpful in supporting Allergan's position on obviousness.

(v) Summary of "obvious to try" assessment

[233] It follows from the conclusions reached under the headings (i) to (iii) immediately above that the claimed invention is not something that would have been "obvious to try" for the Skilled Person. In short, (i) it was not more or less self-evident that the steps that were undertaken to achieve the claimed invention ought to work; (ii) the Skilled Person would not likely have thought that the claimed invention could be achieved relatively quickly, through routine experimentation; (iii) the experimentation actually undertaken to achieve the claimed invention was prolonged and arduous; and (iv) the Skilled Person would not have had any motivation to pursue the claimed invention, particularly given the significant uncertainties that existed as to the time and cost associated with the required experimentation, as well as its outcome.

(e) *Conclusion regarding the allegation of obviousness*

[234] Given the conclusions that I have reached in respect of the "obvious to try" test, I conclude that the differences between the "state of the art" and the inventive concept of the '002 Patent do not constitute steps that would have been obvious to the Skilled Person. In my view, the evidence establishes that those steps required a significant degree of invention, as contemplated by the fourth prong of the obviousness inquiry: *Sanofi*, above, at para 67.

[235] Accordingly, Sandoz's Counterclaim that the '002 Patent is invalid on the ground of obviousness is dismissed.

C. *Infringement*

[236] It is common ground between Allergan and Sandoz that the Sandoz Product does not contain granules and is not manufactured with the wet granulation process.

[237] Given my conclusion in Part VI.A.(4) above that the Wet Granulation Elements are essential elements in claims 1-3 and 6 of the ‘002 Patent, the Sandoz Product will not infringe the ‘002 Patent: *Free World*, above, at paras 31(f) and 68(4).

[238] Therefore, I will issue the declaration sought by Sandoz, to the effect that the Sandoz Product will not infringe any of claims 1-3 or 6 of the ‘002 Patent.

D. *The Gillette Defense*

[239] During the trial of this action, Sandoz stated that it would be unnecessary to deal with the Gillette defense that it has asserted, if I find that the Sandoz Product will not infringe the ‘002 Patent. I agree.

VII. Costs

[240] The Court will deal with this issue after receiving submissions from Allergan and Sandoz. To assist the Court, such submissions should address (i) the conclusions that I have reached in respect of the three principal issues in dispute in this action, (ii) the outcome of motions that were brought, and (iii) costs that were incurred in respect of issues that were raised and not ultimately pursued by each of Allergan and Sandoz. Given that we are on the eve of the

end-of-year holiday period, such submissions shall be filed no later than January 15, 2021 and shall not exceed five pages in length for each of those parties.

[241] The Court encourages Allergan and Sandoz to attempt to reach a settlement regarding costs, failing which to identify a lump sum amount that reflects the factors identified above together with any additional relevant factors, including those identified in Rule 400 of the *Federal Courts Rules* and the jurisprudence.

JUDGMENT IN T-2023-18

THIS COURT'S JUDGMENT is that:

1. The declaration sought by the plaintiff Allergan in this proceeding, pursuant to subsection 6(1) of the Regulations, will not be granted.
2. Pursuant to subsection 60(2) of the *Patent Act*, this Court declares that the Sandoz Product, as defined in the attached Reasons for Judgment, will not infringe Canadian Patent No. 2,507,002.
3. Sandoz's Counterclaim that the '002 Patent is invalid on the ground of obviousness is dismissed.
4. Allergan and Sandoz shall have until the noon on December 24, 2020 to provide any submissions that they may have regarding redactions from this confidential version of the Judgment and Reasons in this proceeding, for the purposes of the public version.
5. Allergan and Sandoz shall provide submissions regarding costs that reflect (i) the conclusions that I have reached in respect of the three principal issues in dispute in this action, (ii) the outcome of motions that were brought, except where the Court indicated that there would be no consequences or award associated with the motion, and (iii) costs that were incurred in respect of issues that were raised and not ultimately pursued by each of Allergan and Sandoz.
6. Such submissions shall be provided no later than the close of business on January 15, 2021 and shall not exceed five (5) pages, for each of Allergan and Sandoz.
7. The Court encourages Allergan and Sandoz to attempt to reach a settlement with respect to costs, failing which to identify a lump sum amount that reflects the

factors identified above together with any additional relevant factors, including those identified in Rule 400 of the *Federal Courts Rules* and the jurisprudence.

"Paul S. Crampton"
Chief Justice

APPENDIX 1 — Relevant Legislation

Patent Act, RSC, 1985, c P-4:

Definitions	**Définitions**
2 In this Act, except as otherwise provided,	**2** Sauf disposition contraire, les définitions qui suivent s'appliquent à la présente loi.
…	[…]
patentee means the person for the time being entitled to the benefit of a patent; *(breveté ou titulaire d'un brevet)*	***breveté*** ou titulaire d'un brevet Le titulaire ayant pour le moment droit à l'avantage d'un brevet. *(patentee)*
…	[…]
Invention must not be obvious	**Objet non évident**
28.3 The subject-matter defined by a claim in an application for a patent in Canada must be subject-matter that would not have been obvious on the claim date to a person skilled in the art or science to which it pertains, having regard to	**28.3** L'objet que définit la revendication d'une demande de brevet ne doit pas, à la date de la revendication, être évident pour une personne versée dans l'art ou la science dont relève l'objet, eu égard à toute communication
(a) information disclosed before the one-year period immediately preceding the filing date or, if the claim date is before that period, before the claim date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant in such a manner that the information became available to the public in Canada or elsewhere; and	**a)** qui a été faite, soit plus d'un an avant la date de dépôt de la demande, soit, si la date de la revendication est antérieure au début de cet an, avant la date de la revendication, par le demandeur ou un tiers ayant obtenu de lui l'information à cet égard de façon directe ou autrement, de manière telle qu'elle est devenue accessible au public au Canada ou ailleurs;
(b) information disclosed before the claim date by a	**b)** qui a été faite par toute autre personne avant la date

person not mentioned in paragraph (a) in such a manner that the information became available to the public in Canada or elsewhere.

de la revendication de manière telle qu'elle est devenue accessible au public au Canada ou ailleurs.

…

[…]

Admissible in evidence

Admissibilité en preuve

53.1 (1) In any action or proceeding respecting a patent, a written communication, or any part of such a communication, may be admitted into evidence to rebut any representation made by the patentee in the action or proceeding as to the construction of a claim in the patent if

53.1 (1) Dans toute action ou procédure relative à un brevet, toute communication écrite ou partie de celle-ci peut être admise en preuve pour réfuter une déclaration faite, dans le cadre de l'action ou de la procédure, par le titulaire du brevet relativement à l'interprétation des revendications se rapportant au brevet si les conditions suivantes sont réunies :

(a) it is prepared in respect of

a) elle est produite dans le cadre de la poursuite de la demande du brevet ou, à l'égard de ce brevet, d'une renonciation ou d'une demande ou procédure de réexamen;

(i) the prosecution of the application for the patent,

(ii) a disclaimer made in respect of the patent, or

(iii) a request for re-examination, or a re-examination proceeding, in respect of the patent; and

(b) it is between

b) elle est faite entre, d'une part, le demandeur ou le titulaire du brevet, et d'autre part, le commissaire, un membre du personnel du Bureau des brevets ou un conseiller du conseil de réexamen.

(i) the applicant for the patent or the patentee; and

(ii) the Commissioner, an officer or employee of the Patent Office or a member of a re-examination board.

…

Liability for patent infringement

55 (1) A person who infringes a patent is liable to the patentee and to all persons claiming under the patentee for all damage sustained by the patentee or by any such person, after the grant of the patent, by reason of the infringement.

…

Declaration as to infringement

60 (2) Where any person has reasonable cause to believe that any process used or proposed to be used or any article made, used or sold or proposed to be made, used or sold by him might be alleged by any patentee to constitute an infringement of an exclusive property or privilege granted thereby, he may bring an action in the Federal Court against the patentee for a declaration that the process or article does not or would not constitute an infringement of the exclusive property or privilege.

[…]

Contrefaçon et recours

55 (1) Quiconque contrefait un brevet est responsable envers le breveté et toute personne se réclamant de celui-ci du dommage que cette contrefaçon leur a fait subir après l’octroi du brevet.

[…]

Déclaration relative à la violation

60 (2) Si une personne a un motif raisonnable de croire qu’un procédé employé ou dont l’emploi est projeté, ou qu’un article fabriqué, employé ou vendu ou dont sont projetés la fabrication, l’emploi ou la vente par elle, pourrait, d’après l’allégation d’un breveté, constituer une violation d’un droit de propriété ou privilège exclusif accordé de ce chef, elle peut intenter une action devant la Cour fédérale contre le breveté afin d’obtenir une déclaration que ce procédé ou cet article ne constitue pas ou ne constituerait pas une violation de ce droit de propriété ou de ce privilège exclusif.

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-2023-18
STYLE OF CAUSE:	ALLERGAN INC v SANDOZ CANADA INC and KISSEI PHARMACEUTICAL CO., LTD.
PLACE OF HEARING:	OTTAWA, ONTARIO
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Smart & Biggar LLP	FOR THE DEFENDANT (KISSEI PHARMACEUTICAL CO., LTD.)