Federal Court  Cour fédérale

Date: 20091022

Docket: T-2080-07

Citation: 2009 FC 1077

BETWEEN:

SANOFI-AVENTIS CANADA INC.

Applicant

and

HOSPIRA HEALTHCARE CORPORATION and THE MINISTER OF HEALTH

Respondents

REASONS FOR JUDGMENT

ZINN J.

[1] This is an application brought by Sanofi-Aventis Canada Inc. (Sanofi Canada) under section 6 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, as amended (NOC Regulations) for an order prohibiting the Minister of Health from issuing a Notice of Compliance (NOC) to Hospira Healthcare Corporation (Hospira) until after the expiration of Canadian Patent No. 2,102,778 (the '778 patent).

[2] In its Notice of Allegation (NOA) dated October 15, 2007, Hospira alleged non-infringement and invalidity against the '778 patent, and two other patents marketed by Sanofi Canada: Canadian Patent No. 2,102,777 (the '777 patent) and Canadian Patent No. 2,150,576 (the '576 patent). Hospira accepted that its notice of compliance would not issue until after the expiration of a fourth patent marketed by Sanofi Canada, Canadian Patent No. 1,278,304, which expired December 27, 2007. The alleged non-infringement and invalidity of the '777 patent and '576 patent are not at issue between the parties since Sanofi Canada subsequently limited its Notice of Application to the ‘778 patent.

[3] On November 28, 2007, the patentee filed a notice of disclaimer disclaiming parts of claims 1 to 8 of the ‘778 patent. On the next day Sanofi Canada commenced this proceeding. Claim 8, as disclaimed, is the only claim of the ‘778 patent at issue in these proceedings. Where relevant, I will refer to the patent and claims 1 and 8 after the disclaimer as the Disclaimed ‘778 patent, Disclaimed Claim 1 and Disclaimed Claim 8.

[4] For the reasons that follow the application is dismissed.

THE PARTIES

[5] The Applicant, Sanofi Canada, distributes and sells pharmaceutical products. One such product, the drug at issue, is docetaxel which it markets in Canada under the brand name Taxotere. Sanofi Canada is known as the “first person” under the NOC Regulations.

[6] The Respondent Hospira is a generic drug company, known as the “second person” under the NOC Regulations. Hospira has filed with the Minister a new drug submission (NDS) for docetaxel for injection comprising docetaxel, in a strength of 10 mg/mL, in 2 mL, 8 mL and 16 mL vials (the Hospira Product). Under the NOC Regulations Hospira was obliged to provide an NOA to Sanofi Canada, which had the patents mentioned above listed on the patent register in respect of docetaxel.

[7] The Minister, following receipt of a drug submission and after following the required procedures has the responsibility to issue an NOC to permit the sale and distribution of certain drugs in Canada. The Minister was not represented in these proceedings although she was served with the necessary documents.

THE DRUG

[8] Docetaxel is a drug used to treat various forms of cancer. Sanofi Canada supplies it in a concentrated solution under the trade name Taxotere, which then must be diluted to form an infusion prior to its injection into the body. Docetaxel is synthetically derived from paclitaxel. Both docetaxel and paclitaxel are members of the taxane class of chemotherapy drugs derived from the European yew tree (*Taxus baccata*).

[9] In an ideal world, medical researchers would discover compounds that are non-toxic, highly soluble and physically stable in aqueous solutions. If drugs are toxic then their harmful side effects may outweigh their pharmacological benefits. If drugs have low solubility in water (of which

humans are composed) then other solvents must be used to dissolve the compounds, and various techniques must be employed to ensure continued solubility when the compound is prepared in a water-based infusion for the administration into the human body. Quite frequently these solvents are themselves toxic. Further, low solubility can result in only solutions with a small amount of active drug being able to be made, which can diminish their effectiveness. If drugs are not physically stable, then when they are introduced into the human body, they can quickly precipitate out of their solution (i.e. form solid clumps) and either not be transferred to the place in the body where they need to work, or have their chemical structure changed in such a manner as to render them less than useful or useless at treating the ailment for which they were designed. The world is not ideal. Pharmaceutical companies must address all these issues in bringing their novel compounds from the scientist's bench to the pharmacist's shelf.

[10] While taxanes are known to have significant affects on malignant tumours, they are difficult to formulate because of their poor water solubility. Docetaxel and paclitaxel are no different. This poses problems as described above. The invention in question protected by the '778 patent does not relate to the specific structure of either docetaxel or paclitaxel. Rather, the invention relates to how these drugs can be formulated with other ingredients so as to permit their administration into the human body in an effective form.

[11] Prior to Sanofi Canada's invention, the prior art taught the following formulation: a stock solution was prepared by mixing docetaxel with equal parts of ethanol and Cremophor® EL (Cremophor). This solution was then mixed with an infusion fluid such as saline or dextrose.

Ethanol is a common solvent used in drug formulation. Cremophor is a surfactant. Surfactants, in effect, cling to the surface of other molecules thereby altering their chemical behaviour. One important way that surfactants can alter a molecule's behaviour is by increasing solubility without altering other attributes. It was precisely this modification, increased solubility, that the surfactant Cremophor brought to the solution that made it an essential component.

[12] The problems with this formulation were two-fold. Firstly, both ethanol and Cremophor have side effects. Ethanol results in intoxication. Cremophor can result in anaphylactic shock. Secondly, in order to achieve a formulation that is both physically and chemically stable it was necessary to limit the docetaxel concentration to 0.03-0.6 mg/mL. To be clinically useful, docetaxel concentrations ranging from 0.3-1.0 mg/mL are needed. As a result, the prior art formulation would require large volumes of solution being injected into a patient to administer the desired quantity of the active ingredient, thus increasing the likelihood of the patient becoming intoxicated from the ethanol or experiencing anaphylactic shock caused by the Cremophor.

[13] The Sanofi Canada invention lessened these problems. Sanofi Canada discovered that Cremophor could be replaced with polysorbate 80, an alternative surfactant. With this alteration, Sanofi Canada removed Cremophor from the stock solution, the source of possible anaphylactic shock. Further, it found that with this modification the previously required amount of ethanol could also be reduced and that the concentration of the active ingredient docetaxel could be increased. The Sanofi Canada stock product consists of docetaxel as the active ingredient, mixed with ethanol and polysorbate 80.

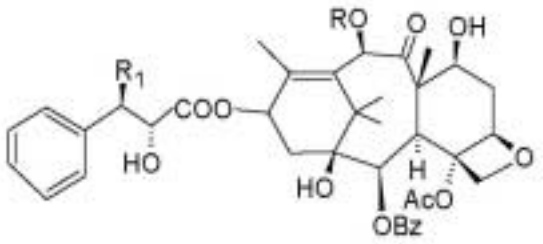
[14] The Hospira stock solution consists of docetaxel as the active ingredient, mixed with ethanol, polysorbate 80 and two other ingredients: Ingredient A and Ingredient B. It is unknown or unclear what value Ingredient A adds to the formulation. However, much but not all of the polysorbate 80 is replaced with Ingredient B, another surfactant, and this permits the concentration of docetaxel to be increased. The Hospira Product permits the stock solution to have docetaxel in a strength of 10 mg/mL whereas the Sanofi Canada product has a strength of 1 mg/mL. Like the Sanofi Canada product, the Hospira Product must be added to an infusion solution prior to injection into the human body.

THE PATENT

[15] As noted above, the only patent remaining at issue is the ‘778 patent. The ‘778 patent entitled *Novel Compositions Based on Taxane Class Derivatives*, was filed in Canada on July 3, 1992, and issued on April 20, 2004. It claims priority to French Patent Application 91 08527 dated July 8, 1991. The ‘778 patent was filed in the French language. The parties relied on the English language translation of the patent that was filed as part of the record in this proceeding.

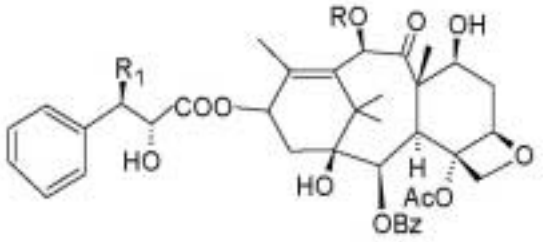
[16] The relevant portion of the description of the ‘778 patent is as follows:

> The present invention concerns a novel pharmaceutical form made from a therapeutic agent with antitumor and antileukemic activity. More specifically, it concerns a novel injectable form containing products from the taxane family, such as, notably, taxol or one of its analogues or derivatives with the following general formula:



[17] Claims 1, 2 and 8 of the ‘778 patent read as follows:

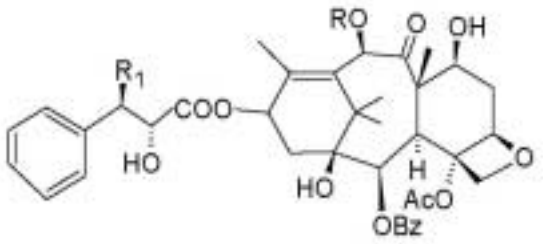
> 1. Compositions made from at least one product in the taxane family or one of its analogues or derivatives in a solution of ethanol and polysorbate.
>
> 2. Composition made from a formula (I) derivative:



> in which R represents a hydrogen atom or an acetyl radical, the symbol R_1 represents a tert-butoxycarbonylamino or benzolotlamino radical in solution in a mixture of ethanol and polysorbate.
>
> 8. Infusion that contains approximately 1 mg/mL or less of formula (I) compounds as defined in claim 2 and that contains less than 35 ml/L of ethanol and less than 35 ml/L of polysorbate.

[18] All of the claims of the ‘778 patent were disclaimed, except that claims 1 and 8 were disclaimed to the following:

> 1. A composition under the form of a solution designed to be formulated for infusion, containing between 6 to 15 mg/mL of a derivative with formula (I)



in which R represents a hydrogen atom and R_1 is a tertiobutoxycarbonylamino radical, in a mixture of ethanol and polysorbate, the ethanol concentration being greater than 5%.

8. An infusion including more than 0.1 mg/mL and less than 1 mg/mL of a compound with formula (I) as defined here above, and which includes more than 5 ml/L and less than 35 ml/L of ethanol and more than 5 ml/L and less than 35 ml/L of polysorbate.

[19] The disclaimer with respect to claim 1 meant that the patentee was claiming only for docetaxel and not paclitaxel or any other taxane as the active ingredient. The disclaimer with respect to claim 8 narrowed the range of docetaxel as well as the ranges of ethanol and polysorbate.

THE NOA AND DISCLAIMER

[20] The NOA, as directed to the ‘778 patent (prior to the disclaimer), alleges (1) no claim for the medicinal ingredient, no claim for the formulation, no claim for the dosage form and no claim for the use of the medicinal ingredient would be infringed or induced to be infringed by the making, constructing, using or selling by Hospira of the Hospira Product, in accordance with the NDS; (2) that the claims of the ‘778 patent are invalid for anticipation, obviousness, claims broader than the invention made and/or disclosed (contrary to section 27(4) of the *Patent Act*), material misstatement

(contrary to section 27(3) of the *Patent Act*), lack of utility, double patenting, the Gillette Defence, and ineligibility for listing on the Patent Register.

[21] After the NOA was served on the applicant and prior to it filing this application, Sanofi Canada disclaimed the claims of the ‘778 patent, as described above. The application proceeded until just prior to hearing on the claims of the ‘778 patent as disclaimed. Hospira reduced its attack on Disclaimed Claim 8 to the following allegations:

a. The Hospira Product does not infringe the Disclaimed ‘778 patent; and
b. Disclaimed Claim 8 is invalid on the following grounds:
    i. claims broader than the invention made or disclosed;
    ii. anticipation;
    iii. obviousness;
    iv. avoidable ambiguity;
    v. sufficiency; and
    vi. method of medical treatment.

[22] With respect to anticipation Hospira submitted that Disclaimed Claim 8 was anticipated by the following prior art references: (1) F. Guéritte-Voegelein et al., “Relationship between the Structure of Taxol Analogues and Their Antimitotic Activity”, *Journal of Medicinal Chemistry*, Vol. 34, No. 3, March 1991, pp. 992-998 (the GV Article), (2) B.D. Tarr et al., “A New Parenteral Vehicle for the Administration of Some Poorly Water Soluble Anti-Cancer Drugs”, *Journal of*

Parenteral Science, 41(1): 31-33 (January-February 1987) (the Tarr Article); and (3) US Patent No. 4,206,221, Miller (the ‘221 patent).

[23] In its Memorandum of Fact and Law filed June 8, 2009, Hospira raised as an issue whether it was required to respond to the ‘778 patent as it read at the date the NOA was served or as it read after having been disclaimed. It took the position that as the NOA was served prior to the disclaimer, this Court’s recent jurisprudence was that the Court must consider only the patent as it read on the date the NOA was served and not as it read after the disclaimer was filed. Hospira also made submissions relating to the validity of the disclaimer, avoidable ambiguity, and method of medical treatment. Hospira submits that the disclaimer is not valid for two reasons. First, it submits that Sanofi Canada has failed to discharge its burden of establishing that the disclaimer meets the requirements of Section 48(6) of the *Patent Act*. Secondly, it submits that it is invalid as it improperly broadens the scope of the claim rather than narrowing it. In this respect, it submits that Disclaimed Claim 8 changed the word “contains” to “includes” in an “attempt to recast the claim to broaden the scope of the claims to cover additional ingredients as is contained in Hospira’s formulation.”

[24] Sanofi Canada responded with a motion to strike the paragraphs from Hospira’s Memorandum of Fact and Law that raised these issues and, in the alternative, sought leave to file reply evidence in response to what it said were new allegations. Hospira countered with its own motion seeking to strike the entirety of Sanofi Canada’s application on the basis that only the patent as it read at the date the NOA was served was relevant and, as Sanofi Canada had failed to lead any

evidence on infringement and validity of the ‘778 patent as construed according to their original claims, its application was an abuse of process and ought to be dismissed.

[25] Prothonotary Tabib dismissed both motions. In her Amended Order dated September 8, 2009, Prothonotary Tabib held that Hospira ought not to have brought its motion so late and that it was not plain and obvious that the application could not succeed. Prothonotary Tabib also held that Sanofi Canada would be allowed to file additional evidence on the validity of the disclaimer and on the issue raised as to whether Hospira was estopped from challenging the disclaimer at this point. The Court subsequently permitted Hospira to file sur-reply evidence.

THE EVIDENCE

[26] Sanofi Canada submitted affidavits in support of its application from Franca Mancino, Dr. Panayiotis P. Constantinides, and Dr. Jean-Christophe Leroux. Hospira submitted affidavits from Dr. David Attwood and Dr. Joseph Bogardus.

[27] After the issues relating to the disclaimer were identified by Hospira and with leave of the Court, Sanofi Canada submitted affidavits from Gerald V. Dahling, Michael Alt, Thierry Orlhac and Robert Kajubi in reply to these new arguments of Hospira.

The Applicant’s Evidence on the Merits of the Application

[28] Franca Mancino is the Senior Director, Regulatory Affairs, Pharmacovigilance and Quality and Compliance at Sanofi Canada. She swore an affidavit on May 22, 2008 describing the

concentrated formulations of docetaxel for which Sanofi Canada had received NOCs. Ms. Mancino provided a copy of the Product Monograph of Taxotere that explained how these concentrated formulations are to be diluted into a perfusion for administration to the patient. She also swore that the '778 patent was listed on the Patent Register, and listed on the Form IV Patent List as part of the original new drug submission for the various NOCs.

[29] Dr. Panayiotis P. Constantinides is the founder and principal of a pharmaceutical consulting company. He obtained his Ph.D. in Biochemistry at Brown University where his thesis work related to the physical chemistry of surfactant micelles. Polysorbate 80, used in the invention of Sanofi Canada, is a surfactant that forms micelles with docetaxel, thereby facilitating the latter's solubility in aqueous solutions. Dr. Constantinides did post-doctoral work at Yale University, and has experience in the pharmaceutical sector on drug solubilisation issues, including the use of taxanes.

[30] Dr. Constantinides swore an affidavit on May 27, 2008 commenting on Hospira's allegations of invalidity relating to the '778 patent. Prior to making his comments, counsel for Sanofi Canada provided him with Hospira's NOA, the references referred to in the NOA, the '778 patent, and the disclaimer dated November 28, 2007.

[31] Dr. Constantinides describes the invention as disclosed by the '778 patent. He asserts that the person skilled in the art (PSIA) would have at least a Bachelor of Science degree in the life sciences, along with relevant scientific or non-scientific work experience in developing intravenous

formulations of poorly soluble drugs. Dr. Constantinides construes the Disclaimed Claim 8 of the ‘778 patent to include the following essential elements:

a. an infusion of docetaxel of more than 0.1 mg/mL and less than 1 mg/mL;

b. more than 5 ml/L and less than 35 ml/L of ethanol; and

c. more than 5 ml/L and less than 35 ml/L of polysorbate.

[32] Dr. Constantinides’ view is that a PSIA would read the Disclaimed Claim 8 to include other components beyond the essential elements listed.

[33] Dr. Constantinides concludes that none of the prior art references would inevitably teach all the components of Disclaimed Claim 8 as construed. He says that the GV Article failed to anticipate because even though it disclosed docetaxel dissolved in ethanol and polysorbate, it did not relate to an infusion, and provided no information on the relative concentrations of the solvent vehicle.

[34] Dr. Constantinides concludes that the Tarr Article did not anticipate because it referred to paclitaxel and not docetaxel as required by the Disclaimed Claim 8. Additionally, he observes that the paclitaxel infusion disclosed was not stable and therefore not useful for administration intravenously.

[35] He says that the ‘221 patent did not anticipate because it implied a bolus injection, as opposed to an intravenous injection, and did not disclose the specific composition of the injectate.

[36] Dr. Constantinides states that it is not possible to predict a drug's solubility in a given solvent mixture, and that solubility has to be determined through experimentation. Dr. Constantinides says that minor variations to a drug's structure could alter its solubility, preventing definitive conclusions from experimentation on one drug to be drawn for another. He describes the various solvent vehicles available to a PSIA in the late 1980s and early 1990s, as well as the other methods available for solubilising poorly soluble drugs and concludes that it would not be obvious to a PSIA which method would be best to solubilise docetaxel in a manner that excluded Cremophor and that it would not be obvious to take what worked with paclitaxel and apply it to docetaxel.

[37] Dr. Jean-Christophe Leroux is a Professor in the Faculty of Pharmacy at the University of Montréal. He completed his Ph.D. in pharmaceutical sciences at the University of Geneva. Prior to becoming a member of the faculty at the University of Montréal, Dr. Leroux was a postdoctoral fellow at the University of Geneva and the University of California, San Francisco. Dr. Leroux's principal areas of research are in surface active molecules and methods to dissolve hydrophobic drugs, including paclitaxel and docetaxel. He has published a number of peer-reviewed articles on micelles and the related solubilisation of hydrophobic drugs.

[38] Dr. Leroux swore an affidavit on May 26, 2008 in which he comments on whether Hospira's Product fell within the range of what was set out in the Disclaimed Claim 8 of the '778 patent. He also comments on Hospira's allegations of invalidity relating to the '778 patent. In making these comments, Dr. Leroux referred to the NOA of Hospira, the references referred to in

the NOA, Hospira's formulation information, the '778 patent, and the disclaimer filed on November 28, 2007. He was asked to focus only on Disclaimed Claim 8 of the '778 patent.

[39] Dr. Leroux describes solubility studies that his research group has conducted on paclitaxel and docetaxel. These studies show that despite structural similarities, the two molecules are characterized by different physicochemical properties. According to Dr. Leroux, these differences would have been apparent to the PSIA in the late 1980s or early 1990s.

[40] Dr. Leroux also describes the challenge this insolubility causes in preparing an intravenous infusion of docetaxel, and the inventive aspect of Sanofi Canada's formulation. He states that the prior art did not sufficiently disclose the invention. Dr. Leroux states that even today formulating such drugs proceeds on the basis of trial and error and that this is particularly so because it is not always possible to apply experience in formulating one drug to the formulation process of a second drug.

[41] After reviewing the legal principles of claim construction provided by counsel for Sanofi Canada, Dr. Leroux construed the Disclaimed Claim 8 of the '778 patent to include the following essential elements: an infusion solution containing the following: (i) 0.1 to 1 mg/mL of docetaxel, (ii) 5 to 35 ml/L of ethanol, and (iii) 5 to 35 ml/L of polysorbate. Dr. Leroux states that the word "includes" in the context of the Disclaimed Claim 8 would be read by the PSIA to be non-exhaustive – it would not mean "includes only".

[42] Dr. Leroux calculated Hospira's Product to include: (i) 0.3 to 0.74 mg/mL of docetaxel, (ii) 6.9 to 17.02 mL/L of ethanol, and (iii) 7.22 to 17.81 mL/L of polysorbate 80. These ranges fall within the ranges stated in Disclaimed Claim 8 of the '778 patent.

[43] Dr. Leroux reviewed the GV Article, concluding that it did not relate to an infusion solution, did not focus on the stability needed for intravenous injection, and did not include the percentage of ethanol and polysorbate present in the final solution. He also reviewed the Tarr Article, concluding that it did not refer to docetaxel, but even to the extent that it discussed paclitaxel, that it did not relate to an infusion. Dr. Leroux also reviewed the '221 patent, concluding that docetaxel was not referred to, and that there was no information on the percentage of ethanol and polysorbate in the solution.

[44] Dr. Leroux describes the various options available in the early 1990s for formulating highly insoluble molecules, such as cosolvents, low molecular weight surfactants, polymeric surfactants, emulsions, complexing agents, and mixtures of excipients when applicable. Dr. Leroux concludes that the prior art would not lead a PSIA directly and without difficulty to the invention taught by the '778 patent because each piece of prior art either did not refer to an infusion and/or did not refer to docetaxel. He notes that one piece of prior art did refer to a docetaxel infusion, but this piece contained emulphor, not polysorbate. Given these various options, and prior art, Dr. Leroux expresses the view that a PSIA would not be led directly and without difficulty to the ethanol and polysorbate combination of Sanofi Canada's '778 patent.

[45] Dr. Leroux states that a PSIA would read the Disclaimed Claim 8 of the ‘778 patent as a non-exhaustive list, including the essential elements of docetaxel, ethanol and polysorbate, but not limited to these elements. Dr. Leroux also says that the Disclaimed ‘778 patent is sufficiently clear to allow the PSIA to work the invention.

The Respondent’s Evidence on the Merits of the Application

[46] Dr. David Attwood was a Professor in the School of Pharmacy and Pharmaceutical Sciences at the University of Manchester prior to his retirement in 2008. He is now Professor Emeritus at the University of Manchester. He obtained his Ph.D. from the School of Pharmacy at the University of London. He has taught courses and supervised graduate research on the formulation of pharmaceutical systems. Dr. Attwood has consulted on formulation issues, particularly involving surfactants, with a number of pharmaceutical companies, and he has also co-authored textbooks on surfactant systems.

[47] Dr. Attwood swore an affidavit on September 12, 2008 commenting on the relevant PSIA, the construction of the Disclaimed ‘778 patent, and Hospira’s allegations of non-infringement and invalidity. Prior to making these comments, Dr. Attwood was provided with copies of the ‘778 patent, the November 28, 2007 disclaimer, the prior art referred to in Hospira’s NOA, the Mancino affidavit, the Leroux affidavit, the Constantinides affidavit, Hospira’s formulation and product monograph, and Hospira’s NOA.

[48] Dr. Attwood characterizes the PSIA as someone with at least a Bachelor of Science in a relevant discipline, two years of post-graduate experience in pharmaceutical formulations or several years in formulations generally, and experience in the development of intravenous formulations of poorly water soluble drugs. The PSIA would have knowledge of the use of surfactants to facilitate solubilisation of drugs in aqueous solutions through the formation of micelles.

[49] Dr. Attwood states that the Disclaimed '778 patent relates to pharmaceutical injectable formulations of four members of the taxane class of drugs. In construing the Disclaimed '778 patent, Dr. Attwood says that the essential elements are an infusion solution containing a taxane, polysorbate and ethanol. Dr. Attwood contends that the ranges of docetaxel, ethanol and polysorbate would not have been essential from the perspective of the PSIA in January 1993. Dr. Attwood says that there is no rationale for the range of concentrations listed in the Disclaimed Claim 8 with respect to docetaxel, ethanol, or polysorbate, and that they appear to be arbitrary in the context of the inventive replacement of Cremophor with polysorbate.

[50] After reviewing and describing the invention disclosed by the '778 patent, Dr. Attwood says that the use of the word "contains" in the original claim 8 would be read by a PSIA to mean an exhaustive list. Dr. Attwood also says that the use of the word "including" in the Disclaimed Claim 8 would also be read to mean an exhaustive list, because ethanol was listed as the only solvent used, polysorbate was listed as the only surfactant used, the examples included no other ingredients, and a PSIA would have known that additional surfactants, stabilizers and/or preservatives could affect the formation and properties of micelles. According to Dr. Attwood, the PSIA would have expected the

inventors to list any additional ingredients in the formulation, particularly given that the inventive step was the removal of Cremophor.

[51] Dr. Attwood determined that the GV Article did disclose the formulation of Disclaimed Claim 8. The GV Article teaches a solvent vehicle for docetaxel of 1:1 ethanol to polysorbate that is identical to the ‘778 patent. According to Dr. Attwood, a PSIA would have understood that this formulation would have to be diluted into an infusion prior to administration in humans. Dr. Attwood states that a stock solution containing 6 mg/mL of paclitaxel would have been known to the PSIA, and that the ideal concentration for an infusion would also have been known. From this knowledge, a PSIA could make the invention described in the Disclaimed Claim 8 of the ‘778 patent. Dr. Attwood concludes that only routine solubility testing would be required to take this information and prepare a stable infusion within the specifications of the ‘778 patent.

[52] Dr. Attwood also concludes that the Tarr Article anticipates the Disclaimed Claim 8 of the ‘778 patent. According to Dr. Attwood, the Tarr Article disclosed the solubilisation of paclitaxel in a mixture of polysorbate and ethanol, along with other ingredients, to form a stock solution of 5 mg/mL, in preparation for the formulation of an infusion, with the final formulation having polysorbate and ethanol concentrations within the range of the Disclaimed Claim 8.

[53] Dr. Attwood maintains that the ‘221 patent disclosed an infusion containing paclitaxel, polysorbate and alcohol. According to Dr. Attwood, a PSIA would know that alcohol in this context means ethanol, and that the polysorbate would be included to function as a surfactant in the

formation of micelles. Dr. Attwood noted that the ‘221 patent did not disclose the concentrations of ethanol and polysorbate in the final infusion, but that this was not important because the concentrations in Disclaimed Claim 8 were not essential to the invention.

[54] Dr. Attwood is of the view that the PSIA desiring to formulate docetaxel for an infusion, would have been aware of the available stock solutions of paclitaxel, would have been aware of the problems with Cremophor, and would have been immediately led to polysorbate as a replacement. The PSIA would have started with a 6 mg/mL stock solution of docetaxel, and would only have had to conduct minor solubilisation studies to make a final formulation according to the clinician’s desired final concentration. While other solvent vehicles were available, Dr. Attwood says that the PSIA would have chosen polysorbate and ethanol as the first and most practical choice.

[55] Dr. Attwood comments on the allegations of over breadth. He repeats his view that the Disclaimed Claim 8 was limited to the delineated ingredients, and argues that otherwise, the claim would be broader than the invention described. Alternatively, if Claim 8 did include other ingredients, Dr. Attwood argues that it insufficiently explained how those ingredients were to be incorporated in the formulation.

[56] Dr. Attwood contrasts his conclusions on these issues to those of Dr. Leroux and Dr. Constantinides, stating where he agreed and disagreed with their analysis; there was very little agreement.

[57] Dr. Bogardus is a consultant for the pharmaceutical industry. He obtained his Ph.D. in pharmaceutical chemistry from the University of Kansas. His thesis focused on solubilising certain drugs. He was a Professor in the College of Pharmacy at the University of Kentucky. Dr. Bogardus also worked for a number of years at Bristol-Myers Squibb where he was responsible for the development of paclitaxel as well as other poorly water soluble anti-cancer drugs. He has authored a number of articles on this subject.

[58] Dr. Bogardus swore an affidavit on September 17, 2008 commenting on the PSIA, the essential elements of Disclaimed Claim 8 of the ‘778 patent, whether Disclaimed Claim 8 was exhaustive, and the allegations of non-infringement and invalidity. Dr. Bogardus was referred to the same materials as Dr. Attwood.

[59] Dr. Bogardus is of the view that the PSIA would have at least a Bachelor of Science in a relevant scientific discipline, with experience in parenteral dosage forms, and some experience in formulations of poorly water soluble drugs. The PSIA would also be expected to have access to relevant texts on solubilisation, as well as access to related scientific professionals.

[60] Dr. Bogardus says that the essential elements of Disclaimed Claim 8 are:

a. an infusion of;

b. a taxane;

c. polysorbate; and

d. ethanol.

[61] After reviewing the Disclaimed ‘778 patent, Dr. Bogardus concludes that the ranges within the Disclaimed Claim 8 appear to be arbitrary, and that there is nothing inventive in the ranges. Dr. Bogardus also says that the Disclaimed Claim 8 was limited to the items listed, and does not include additional ingredients.

[62] Dr. Bogardus reviewed the formulation of Hospira, and determined that the inclusion of Ingredient B in that formulation would have a material affect, and in particular, on the formation of micelles and stability.

[63] Dr. Bogardus states that the PSIA would not normally read the journal containing the GV Article, but that in the early 1990s, a search of the literature would have identified the GV Article, as well as the Tarr Article and the ‘221 patent. Dr. Bogardus argues that regardless, the PSIA would have other professionals who would have informed the PSIA on the information contained in the GV Article. Dr. Bogardus concluded that the GV Article disclosed all the elements of the Disclaimed Claim 8, namely docetaxel, in a 1:1 polysorbate to ethanol infusion. It would have been logical to the PSIA to start with docetaxel stock solution concentrations in line with the already known stock concentrations of paclitaxel, i.e. 6 mg/mL. From this information, the PSIA could make the invention as described in Disclaimed Claim 8.

[64] Dr. Bogardus determines that the Tarr Article disclosed an infusion with paclitaxel, ethanol and polysorbate. Given Dr. Bogardus’s conclusion that docetaxel was not essential to Disclaimed Claim 8, he determined that this information disclosed the invention. Dr. Bogardus also commented

that the PSIA would have been aware that the problems of crystallization described in the Tarr Article would be problematic clinically.

[65] Dr. Bogardus concludes that the ‘221 patent disclosed the infusion characterized by the Disclaimed Claim 8, and that even though the formulation was prepared for administration to mice, the PSIA would be able to apply the same formulating principles to humans.

[66] Dr. Bogardus describes the steps that a PSIA would take in approaching the formulation of a docetaxel infusion to be as follows:

i. consider the formulation of paclitaxel as a starting point due to structural similarities of the two molecules, as well as the problems with Cremophor;

ii. consider polysorbate 80 as an alternative to Cremophor given its similar non-ionic characteristics and the available prior art; and

iii. start with a stock solution of 6 mg/mL given the knowledge that such a stock solution worked with paclitaxel.

[67] Dr. Bogardus says that these steps, combined with clinical instructions on final concentration requirements, and routine stability testing, would lead directly and without difficulty to the invention.

[68] Dr. Bogardus argues that if the Disclaimed Claim 8 was construed to include additional ingredients then the invention is broader than what is described, and does not adequately instruct

how to make it. Dr. Bogardus also argues that if the concentration ranges of the various components are essential then the invention does not describe how to make it.

[69] Dr. Bogardus compared and contrasted his conclusions with those of Dr. Leroux and Dr. Constantinides; there was substantial disagreement on the main issues.

Applicant's Evidence on the Disclaimer

[70] Gerald V. Dahling in an affidavit sworn on September 3, 2009 states that prior to his retirement on June 1, 2008 he was Vice President Group Patent Counsel for the Sanofi Canada group. He was involved in recommending and making the decision to file the disclaimer of the '778 patent. He provides the following as to the reason for filing the disclaimer:

> On October 15, 2007, Hospira sent a Notice of Allegation relating to, among others, the '778 Patent. In the Notice of Allegation, Hospira alleged that the '778 Patent was invalid for Double Patenting in light of Canadian Patent 2,102,777 (the " '777 Patent"). This was the first such allegation of Double Patenting relating to the '778 Patent in view of the '777 Patent that anyone in the sanofi-aventis organization was aware of. Upon review of the issue, we recognize that there was potential overlap in the scope of the claims of these two patents and a decision was made to narrow the scope of Claim 8 of the '778 Patent to limit the active substance to docetaxel (thereby removing paclitaxel from the scope of the claim) and to narrow the range of docetaxel as well as the ranges of ethanol and polysorbate.

[71] Thierry Orlhac swore an affidavit on September 2, 2009. He is a partner at Leger Robic Richard LLP and a registered Patent Agent in both Canada and the United States. He filed the disclaimer. He states that:

> As a result of Hospira's allegation, and to ensure that the Canadian patents were being handled in accordance with then-applicable Canadian law, I was asked to file a disclaimer to remove any possible overlap between the '777 Patent and the '778 Patent. I was also asked to remove paclitaxel from the scope of the claims to address any potential prior art concerns with that compound and to limit the claims to docetaxel.

He further attests that the word "contient" ("contains") in the original patent and the word "comprenant" ("including") in the disclaimer, "in Canadian prosecution … are equivalent and that the disclaimer does not therefore broaden the scope of the original claim."

[72] Dr. Michael Alt, a consultant with partner status at Bird & Bird LLP, Germany, swore an affidavit on August 31, 2009. He was asked to provide an opinion on whether the overlapping subject matter, to the extent that there is any, in the Patent Cooperation Treaty (PCT) applications, would be of concern under the PCT and European patent convention and patent practice at the time they were filed and prosecuted in the International phase. He explains that he is "not aware that the PCT provides any legal basis for raising a double patenting objection ... [and he has] never seen a double protection objection when prosecuting PCT phase applications."

[73] Lastly, Robert Kajubi, the Director, Patent Counsel in the litigation group of Sanofi Canada swore an affidavit asserting that until Hospira had recently filed its Memorandum of Fact and Law in this proceeding it had not asserted that the disclaimer was in any way invalid. He asserts that "to allow Hospira to change its position now to attack the validity of the disclaimer or assert that claims other than the disclaimed claims are in issue is unfair and prejudicial to the Applicant, particularly in

light of the liability that the Applicant has potentially accrued in the meantime under s. 8 of the *Regulations*."

ISSUES

[74] The following are the issues that arise in this proceeding:

1. Whether the justification of Hospira's allegations are determined with reference to the claims of the patent as they read when it served its NOA or as they read as at the date of the hearing which was after the disclaimer had been filed;
2. Whether Hospira is estopped from arguing the invalidity of the disclaimer;
3. Whether the disclaimer is valid; and
4. Whether none of Hospira's allegations are justified.

1. *Whether the Court looks at the claims as they read when the NOA was served or at the date of hearing*

[75] Subsection 6(2) of the NOC Regulations requires the Court to issue a prohibition order if "it finds that none of those allegations is justified." Hospira submits that when making that determination the Court is to examine the claims of the patent as at the date the NOA was served. Sanofi Canada submits that when making that determination the Court is to examine the claims of the patent as at the date of hearing. If Hospira is correct, we look to the claims of the '778 patent as originally filed. If Sanofi Canada is correct we look to the claims of the '778 patent after the disclaimer.

[76] Hospira relies on three recent decisions of this Court which have held that a disclaimer or dedication filed after the NOA was served are ineffective in the context of an application under the NOC Regulations: *Bristol-Myers Squibb Canada Co. v. Apotex Inc.*, 2009 FC 137 [*BMS*]; *Abbott Laboratories v. Sandoz Canada Inc.*, 2009 FC 648; [*Abbott*] and *Janssen-Ortho Inc. v. Apotex Inc.*, 2009 FC 650 aff'd 2009 FC 783 [*Janssen-Ortho*]. Hospira submits that because the disclaimer was ineffective in this proceeding and because Sanofi Canada has failed to lead any evidence on infringement and validity of the '778 patent as first filed, this application is an abuse of process and ought to be dismissed.

[77] For its part, Sanofi Canada submits that insofar as the decisions of this Court have held that the relevant time for considering the claims of a patent in a proceeding under the NOC Regulations is the date the NOA is served, they are manifestly wrong. Sanofi Canada relies on the decision of the Supreme Court of Canada in *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)*, [1998] 2 S.C.R. 193 [*Merck*] and a companion decision made on the same date, *Eli Lilly & Co. v. Novopharm Limited*, [1998] 2 S.C.R. 129, together with an earlier decision of Justice Muldoon of this Court, *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)* (1997), 132 F.T.R. 60 (T.D.) that was relied on by the Supreme Court. Sanofi Canada notes that none of these decisions were before the decision-makers in *BMS*, *Abbott*, or *Janssen-Ortho*. Decisions of the Supreme Court are binding on this Court and Sanofi Canada submits that had they been brought to the attention of the learned Judges and Prothonotary in the decisions relied on by Hospira, the results would have been different.

[78] I turn first to the authorities relied on by Hospira.

[79] In *BMS* this Court held that in context of NOC proceedings, the date to assess the construction of claims within a patent is the date the NOA is filed, even if those claims have since been disclaimed. In *BMS*, as here, the first person, after receiving an NOA, filed a disclaimer the day prior to filing its Notice of Application. The disclaimer was directed to only some of the claims at issue. In construing the patent's claims, Justice Hughes considered the effect, if any, of the disclaimer on the NOC proceeding.

[80] Justice Hughes considered and relied on the reasoning of the Privy Council in *Canadian Celanese Ltd. v. BVD Co.*, [1939] 1 All E.R. 410 (P.C.) [*BVD*]. In *BVD*, the Supreme Court of Canada had ruled that a patent was invalid for over-breadth. The Court's reasons for judgment were delivered before its formal judgment was entered. Before the Court's formal judgment was entered, the patentee filed a disclaimer, disclaiming the patent in accordance with the Court's issued reasons. It then sought to have the matter re-heard by the Court on the basis that the patent as it read at the date of formal judgment was not overly broad, although it had been at the date reasons were given. It was submitted that the relevant date for construing the patent was the date of formal judgment and not an earlier date. The Supreme Court refused to rehear the matter and issued formal judgment. An appeal was made to the Privy Council. The Privy Council held that it was not open to the patentee to change the patent mid-stream in order to overcome the construction of the patent as determined by the Court. It held that the patent was to be construed as at the date of the Supreme Court hearing.

[81] Justice Hughes reviewed the NOC Regulations and the procedure thereunder noting, as have many, that an NOA "is a document beyond the reach of a Court's jurisdiction." The Court has no jurisdiction over the NOA because it is not filed with the Court. However, the NOA "casts a long shadow" over NOC proceedings because "it serves to frame the issues." In contrast to a patent infringement action, where a disclaimer could be met with amended pleadings, the NOC Regulations do not permit the second person to respond with such an amendment.

[82] Taking these facts, jurisprudence, and legislation into consideration Justice Hughes then considered at what date, in the context of NOC proceedings, the claims of the patent at issue are to be assessed by the Court and held that it was as they read on the date the NOA was served.

> 54 Therefore the Court must consider the various possibilities since the Court cannot amend a Notice of Allegation. If the patentee disclaimed certain claims but did not commence proceedings in the court, the generic would get its Notice of Compliance as soon as the 45 day period provide (*sic*) by subsection 7(1)(d) of the *NOC Regulations*. If the patentee commenced proceedings and the generic did not defend, the patentee would get judgment prohibiting the generic from receiving a Notice of Compliance until the patent expired. If a generic wishes to attack the validity of the claims as reformulated by the disclaimer, it cannot revise its Notice of Application since proceedings, as in this case, have already been commenced. [The second person] cannot raise new grounds for invalidity nor allege non-infringement since the proceedings in this Court were initiated immediately after the filing of the Disclaimer thus, in effect, locking in the Notice of Allegation.
>
> 55 The only proper way to approach the matter is to do so in the way that the Privy Council did in *BVD* namely fix a date prior to the disclaimer for the purpose of construing the claims. The Privy Council fixed that date as the date of the Supreme Court decision even though formal judgment had not yet been entered. Here that date must be April 2, 2007, the date that the Notice of Allegation was served. I must add however, that this date for construction relates

> only to claim 2 and only for purposes of this particular NOC proceeding.
>
> 56 Should the Applicants assert the patent subsequent to the date of the disclaimer in an action or other proceeding, then claim 2 may well be considered in the form as disclaimed.
>
> 57 If this were not a proceeding under the *NOC Regulations* but an ordinary patent infringement action, then a disclaimer even if filed during the course of the action, would serve to amend the patent and, therefore, possibly change the issues as to validity and infringement. In an action parties may amend their pleadings and conduct further discovery. This was, for instance, the circumstance in *Cooper & Beatty v. Alpha Graphics Ltd.* (1980), 49 C.P.R. (2d) 145 (FC) per Mahoney J. at pages 162-164. None of this is possible in a proceeding under the *NOC Regulations*.

[83] A similar issue arose before Prothonotary Aalto in *Janssen-Ortho*. Prior to filing its Notice of Application, but subsequent to the second person's NOA, the first person filed a disclaimer in respect of all the original claims in the patent at issue. In filing their Notice of Application, the first person did not address the second person's allegations, and instead argued that the second person's NOA was deficient because it failed to address the claims as disclaimed. I pause to observe that it is hardly surprising that the NOA failed to address the subsequently disclaimed claims as that would have been be impossible unless the second person was blessed with the ability to predict the future. The second person then brought a motion to strike the first person's application. Prothonotary Aalto posed the issue between the parties as follows:

> 1. …[W]hether a generic manufacturer has to respond to claims in a patent which changed as the result of a disclaimer by the innovator subsequent to the generic's notice of allegation and prior to the commencement of a notice of application to prohibit the issuance of a notice of compliance?

[84] Relying on *BMS*, and substantive reasoning of his own, Prothonotary Aalto answered this question in the negative stating:

> 19 It defies logic that [the second person] should have to respond to "claims" that were not in existence at the time of either its NOC or its NOA. [The first person] was required to respond to the NOA by commencing a prohibition application. For whatever tactical reasons, it chose to disclaim the claims and then seek a prohibition order. From a simple policy perspective and a consideration of the way in which the Regulations operate, an innovator should not be able to change the landscape after the patent has been put in play by the NOA.
>
> 20 The allegations in the NOA do not relate to the patent as disclaimed. It is effectively a new patent. It is no answer to say that [the second person] should start the process all over again. The rug has been pulled out from under [the second person] in a tactical move by [the first person] which decided to disclaim all the claims in [its patent].

[85] Prothonotary Aalto held that the rights of the respective parties crystallized upon the receipt by the first person of the second person's NOA and that the filing of an NOA in effect freezes the patent registry at that date. Prothonotary Aalto concluded that disclaimers have prospective and not retrospective effect. He supported his conclusion by an analysis of amendments to the *Patent Act*, the *BVD* decision and the policy objective of certainty and predictability. Prothonotary Aalto asks at paragraph 35: "What would stop any innovator from disclaiming even a minor part of a patent after receiving a NOA in order to make the NOA non-compliant with the Regulations." He expressed the concern that if such conduct were permitted the innovator could inappropriately and unfairly prolong the period in which the generic product would be kept off the market.

[86] Based on these reasons, and the fact that the first person had not filed any submissions rebutting the second person's allegations, Prothonotary Aalto struck the application. The first person appealed. That appeal was heard by Justice Hughes, who dismissed the appeal, and affirmed Prothonotary Aalto's decision: See 2009 FC 783. A further appeal to the Federal Court of Appeal is pending.

[87] Justice Heneghan in *Abbott* considered a similar issue but in the context of a Notice of Dedication rather than in the context of a disclaimer. She reached a conclusion similar to those reached by Justice Hughes and Prothonotary Aalto.

[88] In *Abbott* the second party submitted that the relevant patent was invalid on the basis of double patenting over Canadian Patent No. 2,325,541 (the '541 patent). Abbott, after receiving the NOA that contained this allegation, submitted a Notice of Dedication to the Canadian Patent Office dedicating the '541 patent to the public. The Court in *G.D. Searle & Co. v. Merck & Co.* (2002), 20 C.P.R. (4th) 103 at para. 96 (F.C.T.D.) held that "upon the dedication of the claims, the patent is to be read as if those claims had never issued, subject to any claim for past infringement." Abbott submitted accordingly that there was no basis for the allegation of invalidity on the basis of double patenting as the '541 patent, in effect, had never issued.

[89] Justice Heneghan relying on the *BMS* decision, held at para. 199 that the dedication was without effect in so far as the NOC proceeding was concerned.

> 201 … I am not persuaded by the Applicants' arguments as to the effect of their Notice of Dedication in the context of this proceeding.

> The issue of prejudice to a respondent is not the starting point in dealing with an allegation of invalidity in a prohibition proceeding. Rather, the commencement point is the NOA, the document which frames the grounds upon which a second person advances allegations of invalidity or non-infringement, as the case may be, against one or more patents: *AB Hassle v. Canada (Minister of National Health and Welfare)* (2000), 7 C.P.R. (4th) 272 (F.C.A.) at para. 20. It was upon the content of the NOA that the Applicants decided to commence these proceedings and so it must be upon the date that the NOA was issued that the status of the '541 Patent is considered.
>
> …
>
> 203 …In the context of prohibition proceedings, the NOA is the critical document. According to the NOC Regulations, service of a NOA puts a patentee in the position of deciding whether to commence prohibition proceedings or not.
>
> 204 As noted in *Bristol-Myers* at para. 48, in "proceedings under the *NOC Regulations* all that a Court may do is determine whether the allegations made … in the Notice of Allegation, are justified". [emphasis in original]

[90] Judicial comity provides that a court is bound to follow a previous decision of the same court unless it can be shown that the previous decision was manifestly wrong, or should no longer be followed. Justice Richard of the Federal Court of Canada – Trial Division, as he then was, in *Glaxo Group Ltd. et al. v. Minister of National Health & Welfare* (1995), 64 C.P.R. (3d) 65 (F.C.T.D.), accepted that a decision is manifestly wrong if it fails to consider legislation or binding authority which would have produced a different result. Relying on the principle of judicial comity and the three decisions above, Hospira submits that the '778 patent and its claims are to be construed by the Court as they existed when it served its NOA.

[91] Sanofi Canada submits that *Merck*, a decision of the Supreme Court of Canada, which was not considered in *BMS*, *Janssen-Ortho*, or *Abbott* is a binding authority which, had it been considered, would have produced a different result. *Merck*, it is submitted, stands for the proposition that the date for assessing a patent in an NOC proceeding is the date of the hearing and not the date the NOA was served. In this case, that would require the Court to construe the claims of the Disclaimed '778 patent. It further submits that the Court in the decisions relied on by Hospira also failed to consider relevant legislative provisions, namely subsection 48(6) of the *Patent Act*.

[92] I find no merit in the submission that the Court in the three decisions cited by Hospira failed to consider subsection 48(6) of the *Patent Act*. It is referred to by Justice Hughes in *BMS* which was heavily relied upon in the other decisions.

[93] The Court in *Merck* dealt with NOC proceedings that arose in relation to the compulsory licensing scheme that was then in place. Merck Frosst sought an order prohibiting the Minister from issuing an NOC to Apotex for the drug Norfloxacin until the expiry of a Canadian patent held by Kyorin and for which the applicant was the exclusive holder of a license and sole sublicense. Apotex alleged non-infringement on the basis that it would obtain Norfloxacin from or through Novopharm who held a valid compulsory license for Norfloxacin. Merck Frosst argued "that the NOA was premature because, on the 46th day after its service, the first date on which the NOC theoretically could have been issued in accordance with the Regulations, there was no non-infringing activity possible, owing to the statutory restrictions on Novopharm's compulsory licence": *Merck* at para. 12. Justice Simpson agreed finding that the allegation of non-infringement

was not justified and was premature. She allowed the application and granted the prohibition order. The Federal Court of Appeal rejected an appeal by Apotex but did not deal with this issue. An appeal was then made to the Supreme Court of Canada.

[94] Justice Iacobucci for the Supreme Court phrased the issue before the Court as follows: "What is the relevant date for assessing the justification for a NOA?": *Merck* at para. 17. The Court rejected the conclusions of Justice Simpson that the appropriate date was either the date of serving the NOA or the 46th day thereafter. The Court cited *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare*) (1997), 132 F.T.R. 60 (T.D.) with approval. In that judgment, Justice Muldoon expressly rejected the reasoning of Justice Simpson; he concluded that the appropriate date for assessing the justification of an NOA is the date of the hearing. Justice Muldoon's reasoning was summarized and reproduced by Justice Iacobucci, as follows:

> 26 In *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)* (1997), 132 F.T.R. 60, Muldoon J. specifically rejected the reasoning of Simpson J., holding instead that the appropriate date for assessing the justification of a NOA is the date of hearing. In reaching this conclusion, Muldoon J. disputed the relevancy of the 46th day after the issuance of the NOA, given that, in most cases, no NOC can issue until either the application for a prohibition order is disposed of or the 30-month "statutory stay" occasioned by such an application has elapsed. In his view, at p. 71, such "known and predictable delays" should be considered in assessing the sufficiency of an allegation. Further, he questioned whether, even if no application for prohibition were filed, the Minister would in fact be obliged to issue the requested NOC on the 46th day after the issuance of the NOA, even if it would be unlawful for the applicant to exploit the NOC at that time. In his view, at p. 71, "the Minister is not a robot" and has the discretion, under the Regulations, not to issue the NOC immediately.
>
> 27 Muldoon J. noted at p. 73 that, by s. 6(2) of the Regulations, the court is required to make an order of prohibition "if it finds that none of those allegations [i.e., those contained in the NOA] <u>is</u> justified" (emphasis added). In his words, at p. 73:

> When does or can the court make such a finding? Not earlier than the hearing of the motion for prohibition, is when. It is noteworthy that the regulation does not provide: ". . . it finds that none of those allegations was justified", i.e. "both at the date of the Notice and at the date a NOC could have issued under the Notice". . . . Clearly, if time be the critical consideration, however, the time of the allegations' "prematurity" or "ripeness" is the time at which the court "finds that none of those allegations is justified", which at earliest is the hearing of the prohibition motion and at latest is the date of the court's order and reasons for order, if reasons there be. After all, is that not precisely the time reg. 6(2) provides in so many words, and not some earlier? As above illustrated reg. 6(2) could easily have exacted what the learned judge found about "prematurity", but it does not exact that. [emphasis in original]

[95] Justice Iacobucci states that "the matter comes down to a question of common sense." He agrees that it would be inappropriate "to permit the premature grant of a NOC where the statutory conditions are not met" but finds that where the conditions have been met at the date of hearing, it would be inappropriate to prohibit the Minister from granting an NOC. His conclusion is based, in large part, on the purpose of the NOC Regulations which he says "is simply to prevent infringement by delaying the issuance of NOCs until such time as their implementation would not result in such infringement." (emphasis added) This purpose follows from the fact that the NOC Regulations are made pursuant to section 55.2(4) of the *Patent Act* which permits the Governor in Council to make such regulations as it considers necessary "for preventing the infringement of a patent by any person who makes, constructs, uses or sells a patented invention." As will be discussed below, it is my

view that the answer to the question raised in this application by these parties is also largely determined by examining the issue in light of the purpose of the NOC Regulations.

[96] The Supreme Court in *Merck* was of the view that if the generic can accurately predict the date on which its rights under an NOC would not infringe and is able to time its NOA accordingly, the NOA should not be rejected "solely on the basis that the allegation made in its support was not justified when the NOA was issued, notwithstanding that there was no possibility that the NOC could be granted on that date." The Court notes that this interpretation is "not inconsistent with s. 6(2) of the Regulations, which provides only that the court shall make an order of prohibition 'if it finds that none of those allegations is justified' a finding which can only be made, at the earliest, on the date of hearing." (emphasis added) The Supreme Court holds that the answer to the question "What is the relevant date for assessing the justification for a NOA?" is "As at the date of hearing".

[97] Hospira submits that *Merck* is not a binding authority on the issue before this Court for four reasons: (1) *Merck* dealt with different facts and did not deal with a situation involving a disclaimer; (2) the decision in *Merck* is not inconsistent with the position Hospira is taking; (3) the law in *Merck* is no longer applicable in light of subsequent amendments to the NOC Regulations; and (4) the approach of the Supreme Court in *Merck* was the common sense approach which is the approach taken by Justices Heneghan and Hughes and Prothonotary Aalto. I find none of these arguments to be persuasive.

[98] *Merck* did not deal with a situation where the innovator had filed a disclaimer, and to that extent the factual situations are different. However, the submission that this fact alone is sufficient for this Court to distinguish *Merck* and to not follow it is misguided. The ratio of *Merck* is not as narrow as Hospira suggests. The issue before the Supreme Court was whether Apotex's allegation of non-infringement was justified. Similarly, the issue here is whether Hospira's allegations of non-infringement and invalidity are justified. In *Merck* the court noted that this required that it first determine the relevant date for assessing the justification of an NOA and held that it was the date of hearing. The court then observed, and this is the relevant finding, that it had to determine whether Apotex's allegation of non-infringement was justified as of the relevant date. There was no question that it was not justified if the relevant date was the date of the NOA as there was no possible way that Apotex could obtain Norfloxacin without infringement on that date. Having found that the relevant date is the date of hearing, then the question the Supreme Court in *Merck* says must be asked is whether the allegations of non-infringement are justified as of that date. That is precisely the issue that this Court must always decide in an NOC proceeding, whether or not a disclaimer has been filed: Are none of the allegations justified as of the relevant date?

[99] There is a second difference between the three decisions on which Hospira relies and *Merck*. *BMS, Janssen-Ortho,* and *Abbott* were each cases where the issue was the validity of the patent whereas Merck dealt with infringement. In *BMS, Janssen-Ortho,* and *Abbott* the innovator shifted ground in an attempt to preserve the validity of its patent whereas in *Merck* the generic shifted ground in an attempt to argue non-infringement. Although *Merck* involved a generic attempting to take advantage of the NOC Regulations by filing an "early" NOA, while *BMS, Janssen-Ortho,* and

Abbott involved an innovator who filed a disclaimer or dedication to avoid invalidity, I can see no principled basis to hold that the relevant date should differ depending on whom is taking advantage of the legislative provisions. In the end what is being determined by the Court in these cases, and in every NOC, is whether the allegations, whatever they are, are justified and I can see no persuasive argument to say that a determination of the justification of the allegations should be made as of different dates depending on whether the allegation is one relating to invalidity or one relating to infringement.

[100] Hospira submits that the decision in *Merck* is not inconsistent with the position it is taking, namely, that the proper date for considering the allegation is the date of hearing. What this overlooks is that the Supreme Court then went on to determine whether the allegation is justified as at that date and not, as Hospira submits, as at the date the allegation was made. Accordingly, *Merck* is inconsistent with the position Hospira takes in this proceeding.

[101] Hospira submits that the amendments to sections 5(3) and 5(4) of the NOC Regulations, which it is claimed were in direct response to the *Merck* decision, impact the applicability of that decision. The amendments in question were changes to prevent a generic from serving an NOA before filing its NDS (section 5(3)(a)) and to freeze the patent register so that a generic who had filed an NDS did not need to respond to a new patent filed after the NDS was filed (section 5(4)). Both amendments post-dated *Merck*. However, I agree with the submissions of Sanofi Canada that neither was in response to *Merck* and neither amendment has any impact on the finding in *Merck*. There is no reason to believe that the decision of the Supreme Court in *Merck* would have differed if

these amendments had been in place at that time as neither impacts nor affects the relevant facts the Supreme Court considered.

[102] In my view, the amendment to freeze the patent register supports the position of Sanofi Canada rather than that of Hospira. If Hospira is correct that the date to determine the justification of the allegations is the date of the NOA, then one must ask why subsection 5(4) of the NOC Regulations is required as it deals with events subsequent to the NOA. It has relevance only if the date as at which one determines the justification of the allegations is the date of hearing, a date after the new patents have been added to the register. Without subsection 5(4) of the NOC Regulations it might be thought that the generic would also have to address those more recent patents.

[103] Lastly, Hospira submitted that the Supreme Court applied a common sense approach and it is suggested that if this Court were to do likewise, it would follow the decisions of Justices Heneghan and Hughes, and Prothonotary Aalto. Even if it is accepted that theirs is a common sense approach, that is no answer when there is a higher authority that is to be followed.

[104] I am of the view that *Merck* is binding on this Court on the question as to what the relevant date is for assessing the justification for an NOA – it is to be assessed as of the date of hearing - and that the decisions in *BMS*, *Abbott* and *Janssen-Ortho* ought not to be followed.

[105] Although that finding is sufficient to deal with this issue, I wish to address some other arguments made by the parties as I have no doubt that this issue will be examined by a higher court at some time.

[106] Hospira submitted that if the Court in an NOC proceeding were to focus on the patent as it reads at the date of the hearing, then this will lead innovator companies to use disclaimers as a tactical defence to NOC applications. It submits that once the first person has the NOA of the second person, the former can see how the second person assembled its drug, and narrow the claims at issue in a manner that defeats the allegations. This, it is submitted, could be done again and again, effectively resulting in a perpetual prohibition against the generic. This observation and concern was also noted by Prothonotary Aalto in *Janssen-Ortho*.

[107] In my view, this concern overlooks the obvious, namely, that using a disclaimer in such a manner is an improper use of a disclaimer. A disclaimer is valid only when "by mistake, accident or inadvertence" the original claims were deficient. Furthermore, subsection 48(1) of the *Patent Act*, requires that there be no "wilful intent to defraud or mislead the public" on the part of the person filing the disclaimer. It would appear, at first blush, that a patentee using the disclaimer provisions for the purposes of defeating a generic from entering the market could be said to be engaged in a wilful defrauding of the public.

[108] Prothonotary Aalto suggests that permitting the NOA to be potentially defeated by a disclaimer filed after it has been served is akin to defeating a team from scoring a field goal by

moving the goalposts after the ball is in the air. He uses this example to illustrate the alleged unfairness of the change in the patent claims. With respect, the analogy is not apt. Football has no rule permitting the goal posts to be moved whereas the *Patent Act* specifically permits disclaimers to be filed by a patentee, provided the requirements of section 48 of the *Patent Act* are met.

[109] The apt sport analogy may be to soccer. A striker who kicks the ball into the net of the opposing party scores a goal, unless he is offside. The striker is offside if he is closer to the other team's goal than both the ball and that team's last defender, at the point when his midfielder passes the ball to him. The clever defender, sensing that the midfielder is about to receive the ball and pass it to the striker, will run downfield past the striker, thus placing him in an offside position. Any ball then kicked into the net by the striker will not count as a goal. In soccer the rules permit the moving of the offside line. With that rule in place, it cannot be said that there is any unfairness when the defender runs to place the striker offside – it is simply clever play. The proper use of a disclaimer creates no more unfairness than the clever defender's use of the offside rule. Both are permitted by the rules.

[110] It was suggested by Hospira that the generic suffers some disadvantage because it acts upon the patent as it read at the time the NOA was served. Prothonotary Aalto shared that view.

> 39 … Janssen argues that Apotex will not suffer any "hardship" if the application is allowed to proceed as there is nothing that prevents Apotex from withdrawing its NOA and re-filing in respect of the disclaimed patent. Janssen notes that they are prepared to consent to this relief on a without costs basis. This approach does not reflect the reality of the circumstances nor the law as discussed above.

> 40 Apotex is significantly prejudiced as it has filed its NOA on the basis of the patent register as it found it. It has incurred significant cost in so doing. It is through the tactic of Janssen in delaying its disclaimer until the receipt of the NOA that has precipitated these proceedings. As noted above, the scheme of the Regulations is such that the innovator is given a 45 day window after the receipt of a NOA to determine if it should seek an order of prohibition. That decision is and should be made on the basis of the allegations in the NOA. Obviously, based on Janssen's admission in the disclaimer that the original claims were overbroad, if the decision were made on the basis of the allegations in the NOA this proceeding would not have been brought. Thus, Apotex suffers a hardship if this proceeding is permitted to continue or if it is compelled to effectively restart the clock with a new NOA.

[111] With the greatest of respect for the views of the learned Prothonotary, his explanation presumes that the patentee has been lying in the weeds knowing that its claims were too broadly drafted, perhaps hoping that they would discourage a generic from developing a competing product, and has not filed the disclaimer when first aware of the mistake, accident or inadvertence that resulted in the claim being overly broad. In such a circumstance, as I have previously indicated, the disclaimer is arguably invalid. If the first person is unable to prove the validity of its disclaimer, then the second person will realize a potential advantage as the first person can rely only on the patent as disclaimed. I agree with the comment of counsel for Sanofi Canada that having filed a disclaimer the patentee can not appropriately also rely on the patent as it read before the disclaimer. The filing of the disclaimer is an admission that the patent as filed was over broad and this admission is not effected by a subsequent finding that the disclaimer was not valid.

[112] Hospira also submitted that it relied on the patent as it then read when it filed its NDS and NOA and it will have incurred unnecessary costs that it would not have incurred if the patent read then as it does now. Accordingly, it submits that assessing allegations against a disclaimed patent results in an increase in costs for the generic. In my view, this argument assumes that the generic company that has obtained an NOC on the basis of the pre-disclaimed patent will not subsequently be sued by the patentee for infringement of the disclaimed patent, with all of the costs associated with that action.

[113] In my view, permitting a generic to obtain an NOC when the patent has been disclaimed does not meet the purpose of the NOC Regulations – the Court is not issuing a decision that prevents infringement when it ignores the reality of a disclaimed patent. While in some cases it may be that the generic will have incurred costs that will be thrown away, determining the proceeding on the basis of patent claims that have since been disclaimed and that are ineffective as at the date the generic drug will be produced and marketed is a waste of the Court's and the parties' time and resources, particularly in light of the fact that the innovator can, and likely would, bring a subsequent action for infringement based on the disclaimed claim.

[114] Justice Iacobucci in *Merck* at para. 30 observed that the purpose of the NOC Regulation is "simply to prevent patent infringement by delaying the issuance of NOCs until such time as their implementation would not result in such infringement." The proper interpretation of the NOC Regulations should accomplish and not offend that purpose. How can it be said that this purpose has been met if the Court does not consider the disclaimed patent when assessing whether the

allegations are made out or not? If that requires that the generic company withdraw and refile its NOA, then there is nothing inappropriate with that procedure.

[115] Justice Heneghan and Justice Hughes rely, in part, on the fact that the NOA is a document that cannot be amended by the generic after it has been served and is a document that the Court cannot amend. This, it is said, is relevant because section 6 of the NOC Regulations provides that the Court will prohibit the Minister from issuing an NOC until after the expiry of the patent "if it finds that none of the allegations is justified" and the allegations cannot be amended. This presumes that the "allegations" the Court is required to assess in the proceeding are those set out in the NOA.

[116] I agree with the applicant that the "allegations" referred to in subsection 6(2) of the NOC Regulations - the allegations that the Court is to assess - are those allegations mentioned in subsection 5(1)(b) and 5(2)(b) and are not the "detailed statement of the legal and factual basis for the allegation" described in subsection 5(3) of the NOC Regulations.

[117] Subsection 5(1)(b) of the NOC Regulations provides that if a second person files a submission for a notice of compliance, then in that submission, the second person must:

(*b*) allege that	*b*) soit une allégation portant que, selon le cas :
(i) the statement made by the first person under paragraph 4(4)(*d*) is false,	(i) la déclaration présentée par la première personne aux termes de l'alinéa 4(4)*d*) est fausse,
(ii) the patent has expired,	(ii) le brevet est expiré,
(iii) the patent is not valid, or	(iii) le brevet n'est pas valide,

(iv) no claim for the medicinal ingredient, no claim for the formulation, no claim for the dosage form and no claim for the use of the medicinal ingredient would be infringed by the second person making, constructing, using or selling the drug for which the submission is filed. [emphasis added]	(iv) elle ne contreferait aucune revendication de l'ingrédient médicinal, revendication de la formulation, revendication de la forme posologique ni revendication de l'utilisation de l'ingrédient médicinal en fabriquant, construisant, utilisant ou vendant la drogue pour laquelle la présentation est déposée. [mon soulignement]

[118] The "allegation" the second person makes is limited to one of the four allegations described in the subsection. Indeed, Form V, the form required to be completed by the second person, merely requires the checking of an appropriate box– no detail supporting the allegation is included.

[119] Subsection 5(3) of the NOC Regulations states that "a second person who makes an allegation under paragraph (1)(b) or (2)(b) shall …[serve a notice of allegation and] … include in the notice of allegation… a detailed statement of the legal and factual basis for the allegation…" (emphasis added). Section 6 of the NOC Regulations states that the Court shall issue a prohibition order "in respect of a patent that is the subject of one or more allegations if it finds that none of those allegations is justified." (emphasis added) In my assessment it is clear that the "allegations" that are referenced throughout these provisions are the allegation made by the second party as described in subsections 5(1)(b) and 5(2)(b) – it is not the detailed submissions contained in the NOA.

[120] The NOA merely creates the cause of action and alerts the innovator to the basis on which the generic is alleging that it will not infringe its patent. The innovator has no basis to institute a proceeding against the generic prior to receiving the NOA. The NOA is detailed in order that the innovator can reasonably assess whether or not to challenge the allegations. It binds the generic because the innovator makes its decision as to whether to challenge the generic on the basis of the detail it provides. The first party may decide to launch an application challenging only some of the allegations or it may decide to challenge all of them or none of them. If the generic were permitted to change its allegations or add new allegations after the innovator had commenced its application that would render an injustice to the innovator who has relied on the NOA in making an assessment as to whether or not to bring a prohibition application and if so, the scope thereof.

[121] However, it is the Notice of Application not the NOA that closely defines the issues in dispute. The Notice of Application deals with the allegations against the patent as it reads on the date when the application is filed with the Court. If the patent has been disclaimed prior to the application then it is the disclaimed patent that is under consideration against the allegations made under subsections 5(1) and (2) of the NOC Regulations. In that application, if the generic challenges the *bona fides* of the disclaimer, the burden of proof is on the innovator to establish that the disclaimer is valid and proper as will be explained below.

[122] In summary, and with the greatest of respect for the contrary findings of Justice Heneghan, Justice Hughes and Prothonotary Aalto, I can see no basis on which to find that the date to assess the allegations of the second party is other than the date of hearing as was held by the Supreme

Court of Canada in *Merck*. Accordingly, I find that the three previous decisions of this Court relied on by Hospira were wrongly decided and would have been decided differently had the *Merck* decision been brought to the attention of the Court.

[123] The justification of the allegations of Hospira in its submission for a notice of compliance is to be assessed on the basis of the Disclaimed '778 patent. If I am in error in this finding, then this application must be dismissed as Sanofi Canada has led no evidence related to the '778 patent as filed on which the Court could find that none of the allegations of Hospira are justified.

2. *Whether Hospira is estopped from arguing invalidity of the disclaimer*

[124] Sanofi Canada argues that Hospira is estopped from arguing that the disclaimer is invalid. Sanofi Canada relies on the dicta of Lord Denning in *Amalgamated Investment & Property Co. (In Liquidation) v. Texas Commerce International Bank Ltd.*, [1982] 1 Q.B. 84 (C.A.), which was cited by the Supreme Court of Canada in *Ryan v. Moore*, 2005 SCC 38 [*Ryan*] at para. 51. Lord Denning summarizes estoppel as follows:

> When the parties to a transaction proceed on the basis of an underlying assumption -- either of fact or of law -- whether due to misrepresentation or mistake makes no difference -- on which they have conducted the dealings between them -- neither of them will be allowed to go back on that assumption when it would be unfair or unjust to allow him to do so. If one of them does seek to go back on it, the courts will give the other such remedy as the equity of the case demands.

[125] In *Ryan* at para. 59, the Supreme Court held that the following three factors form the basis of estoppel by convention:

1. The parties' dealings must have been based on a shared assumption of fact or law: estoppel requires manifest representation by statement or conduct creating a mutual assumption. Nevertheless, estoppel can arise out of silence (impliedly).

2. A party must have conducted itself, i.e. acted, in reliance on such shared assumption, its actions resulting in a change of its legal position.

3. It must also be unjust or unfair to allow one of the parties to resile or depart from the common assumption. The party seeking to establish estoppel therefore has to prove that detriment will be suffered if the other party is allowed to resile from the assumption since there has been a change from the presumed position.

[126] Sanofi Canada and Hospira both appear to have assumed that the disclaimer was valid and effective, until very recently. Both parties led evidence only on the claims as disclaimed. Hospira did not challenge the validity of the disclaimer until well after the completion of the submission and cross-examination of expert evidence. Hence, step 1 of the estoppel by convention test is met.

[127] The same cannot be said for the second step. The Supreme Court states that there must be reliance on the shared assumption for estoppel by convention to arise. In these proceedings, Sanofi Canada has not relied on the shared assumption of the parties. These proceedings were instigated because Hospira served an NOA on Sanofi Canada. The NOA addressed the original claims of the patents in question. It was Sanofi Canada who then filed a Notice of Application, limiting its argument to the disclaimed claims of the ‘778 patent. Sanofi Canada was first to raise the issue of the disclaimed patent. It was also Sanofi Canada that filed evidence first; Hospira filed its evidence

subsequently. Although Hospira's evidence addressed the claims as disclaimed, this was in response to both Sanofi Canada's Notice of Application, as well as its expert evidence. There is no evidence in the record that Sanofi Canada changed its legal position in reliance on the shared assumption.

[128] The party relying on estoppel by convention has the burden of proving detriment. Sanofi Canada's evidence on this point is scant. Sanofi Canada argues that it decided what evidence to file based on the silence of Hospira at a case conference between the parties. This seems untenable given that Sanofi Canada had already filed its Notice of Application, which limited the issues in play to the Disclaimed '778 patent. Further, Sanofi Canada disclaimed the '778 patent on its own accord and, as its counsel admitted at the hearing:

> [H]ow can I argue the original claims when my client has put in an unconditional disclaimer. That would be misleading the court. That would be asking the court to rule on something that doesn't exist. That would be inappropriate, in my view, to ask the court to do that.

[129] Sanofi Canada submits that the possibility of a claim for costs under section 8 of the NOC Regulations is also a detriment. This argument presumes that had Hospira challenged the validity of the disclaimer immediately following the filing of the Notice of Application, Sanofi Canada would have withdrawn its application so as to limit any such possible costs. There is no evidence to support that assumption. In any event, it was acknowledged at the hearing that Hospira does not yet have regulatory approval for its NDS, so no damages yet arise.

[130] I am of the opinion that Sanofi Canada has not lead sufficient evidence to prove detriment. Consequently, the third step of estoppel by convention is also not satisfied.

[131] For these reasons, I hold that Hospira may challenge the validity of the disclaimer.

3. *Whether the disclaimer is valid*

[132] The *Patent Act* specifically provides that a patentee may disclaim all or part of its patent, subject to the conditions set out in section 48 of the *Patent Act* which provides as follows:

48. (1) Whenever, by any mistake, accident or inadvertence, and without any wilful intent to defraud or mislead the public, a patentee has	48. (1) Le breveté peut, en acquittant la taxe réglementaire, renoncer à tel des éléments qu'il ne prétend pas retenir au titre du brevet, ou d'une cession de celui-ci, si, par erreur, accident ou inadvertance, et sans intention de frauder ou tromper le public, dans l'un ou l'autre des cas suivants :
(*a*) made a specification too broad, claiming more than that of which the patentee or the person through whom the patentee claims was the inventor, or	*a*) il a donné trop d'étendue à son mémoire descriptif, en revendiquant plus que la chose dont lui-même, ou son mandataire, est l'inventeur;
(*b*) in the specification, claimed that the patentee or the person through whom the patentee claims was the inventor of any material or substantial part of the invention patented of which the patentee was not the inventor, and to which the patentee had no lawful right,	*b*) il s'est représenté dans le mémoire descriptif, ou a représenté son mandataire, comme étant l'inventeur d'un élément matériel ou substantiel de l'invention brevetée, alors qu'il n'en était pas l'inventeur et qu'il n'y avait aucun droit.

the patentee may, on payment of a prescribed fee, make a disclaimer of such parts as the patentee does not claim to hold by virtue of the patent or the assignment thereof.

(2) A disclaimer shall be filed in the prescribed form and manner.

(3) [Repealed, 1993, c. 15, s. 44]

(4) No disclaimer affects any action pending at the time when it is made, unless there is unreasonable neglect or delay in making it.

(5) In case of the death of an original patentee or of his having assigned the patent, a like right to disclaim vests in his legal representatives, any of whom may exercise it.

(6) A patent shall, after disclaimer as provided in this section, be deemed to be valid for such material and substantial part of the invention, definitely distinguished from other parts thereof claimed without right, as is not disclaimed and is truly the invention of the disclaimant, and the disclaimant is entitled to maintain an action or suit in respect of that part accordingly.

(2) L'acte de renonciation est déposé selon les modalités réglementaires, notamment de forme.

(3) [Abrogé, 1993, ch. 15, art. 44]

(4) Dans toute action pendante au moment où elle est faite, aucune renonciation n'a d'effet, sauf à l'égard de la négligence ou du retard inexcusable à la faire.

(5) Si le breveté original meurt, ou s'il cède son brevet, la faculté qu'il avait de faire une renonciation passe à ses représentants légaux, et chacun d'eux peut exercer cette faculté.

(6) Après la renonciation, le brevet est considéré comme valide quant à tel élément matériel et substantiel de l'invention, nettement distinct des autres éléments de l'invention qui avaient été indûment revendiqués, auquel il n'a pas été renoncé et qui constitue véritablement l'invention de l'auteur de la renonciation, et celui-ci est admis à soutenir en conséquence une action ou poursuite à l'égard de cet élément.

[133] Hospira attacks the validity of the disclaimer. First, it submits that the disclaimer as it relates to Disclaimed Claim 8 is improper as it broadened rather than narrowed claim 8. Second, it submits that Sanofi Canada has presented no evidence to establish that there was a mistake, accident or inadvertence at the time the '778 patent was filed. It takes the position that the burden of proof is on Sanofi Canada to prove on a balance of probabilities that it meets the essential conditions of section 48. It must prove: (i) that the original specification was too broad; (ii) that this was done by mistake, accident or inadvertence on the part of the patentee; and (iii) there was no wilful intent to defraud or mislead the public.

[134] Sanofi Canada submits that its disclaimer is valid and further submits that Hospira should not be permitted to raise any objection to its validity as it was raised for the first time in its memorandum filed shortly before the hearing. Sanofi Canada submits that it ought to have been raised by Hospira at the case management conference on February 15, 2008, when the parties discussed the order of filing evidence.

[135] Sanofi Canada suggests that if Hospira wanted to argue invalidity of the disclaimer, the proper process would have been to withdraw their NOA, and file a new NOA raising this issue. Sanofi Canada asserts that to allow Hospira to plead these new allegations so late in the game would cause significant prejudice to Sanofi Canada, in part because of the continuing exposure to section 8 costs.

[136] First, as noted earlier there is no issue of section 8 costs arising because Hospira has not yet received regulatory approval of its submission. Further, the Prothonotary permitted Sanofi Canada to file reply evidence on the issues relating to the disclaimer as well as an additional memorandum; it did both.

[137] There can be no serious question that Hospira was late in raising the argument on the invalidity of the disclaimer. Even though the case law on which Hospira relies as support for its position that the disclaimed patent is irrelevant did not emerge until recently, there was nothing to stop Hospira from making the argument that the disclaimer was invalid. Hospira was silent at the February 15, 2008 case management conference, and did not raise the issue until after the completion of the evidence.

[138] Effective and fair civil litigation systems must eschew trial by ambush. However, Sanofi Canada cites no law to support its submission that it is too late to permit these arguments by Hospira, and states only that it will be prejudiced. I have found that it is not prejudiced. In *Canderel Ltd. v. Canada*, [1994] 1 F.C. 3 (C.A.), at para. 9, the Federal Court of Appeal described the test for determining whether a party should be allowed to amend its pleadings at a late stage:

> ... [A]mendment should be allowed at any stage of an action for the purpose of determining the real questions in controversy between the parties, provided, notably, that the allowance would not result in an injustice to the other party not capable of being compensated by an award of costs and that it would serve the interests of justice.

[139] In my view, similar reasoning ought to apply in the circumstances before us. Given the absence of prejudice and the fact that it was Sanofi Canada that is partially responsible in that Sanofi Canada disclaimed that relevant patent after the NOA was served, it is appropriate to consider Hospira's submissions on the validity of the disclaimer.

[140] The *Patent Act* provides the Commissioner of Patents with no discretion to refuse a disclaimer, consequently, when issues arise as to the validity of a disclaimer, the proper place for them to be addressed is before a judge in an infringement action or other proceeding: *Richards Packaging Inc. v. Canada (Attorney General)*, 2007 FC 11, at para. 10, aff'd 2008 FCA 4.

[141] Justice Martineau in *Hershkovitz v. Tyco Safety Products Canada Ltd.*, 2009 FC 256, at para. 79, held that when the propriety of the disclaimer is contested and litigated, "the onus of showing that there was 'mistake, accident or inadvertence' is on the patentee." Sanofi Canada submits that this is in error as it fails to consider the import of subsection 48(6) of the *Patent Act* which provides that "a patent shall, after disclaimer as provided in this section, be deemed to be valid…" In my view, the submission of Sanofi Canada is misguided as it confuses the validity of the disclaimer with the validity of the disclaimed patent.

[142] All that subsection 48(6) of the *Patent Act* provides is that the presumption of validity that every patent enjoys is not adversely affected by the disclaimer. The patent as disclaimed remains entitled to that presumption of validity. However, the section does not directly address whether the disclaimer itself is entitled to any presumption of validity and, in my view, there is no such

presumption. If the validity of the disclaimer is not put in issue, then the patentee will have the benefit of subsection 48(6) as a defence to allegations of invalidity of the patent as disclaimed. However, if the validity of the disclaimer is raised, then the patentee must establish on the balance of probabilities that it is a valid disclaimer.

[143] Hospira submits that the disclaimer filed with respect to the ‘778 patent was not because of a legitimate mistake, accident or inadvertence but was a deliberate litigation tactic “to preserve an NOC proceeding that was doomed to failure from the start” and it submits that it was not Sanofi Canada who made any mistake or had any accident or was inadvertent in the original filing as the evidence is that Sanofi Canada had no involvement in the disclaimer – it was directed to be filed and was drafted by its counsel in these proceedings.

[144] Sanofi Canada submits that it has established that there was a mistake in the filing of the ‘778 patent in that the Canadian patent examiner failed to cite the ‘777 patent against the ‘778 patent and, as a result, there was a potential for a double patenting attack on its validity. It submits that the law with respect to double patenting in Canada was not developed at the time of filing as the decision in *Whirlpool Corp. v. Camco Inc.* (2000), 9 C.P.R. (4th) 168 (S.C.C.) [*Whirlpool*] had yet to be issued. Further it has filed affidavit evidence that indicates that different patent agents in Canada were prosecuting the two patents and neither had both patents at hand. It also filed evidence as to the European patent practice to indicate that the potential double patenting was not an issue that would arise there.

[145] The substantive evidence for Sanofi Canada is in the affidavit of Thierry Orlhac, sworn September 2, 2009, and the affidavit of Gerald V. Dahling sworn on September 3, 2009.

[146] Mr. Orlhac is a patent agent. He was responsible for the filing of the disclaimer at issue. He swears that the disclaimer was filed "to avoid any overlap between the '777 Patent and the '778 Patent as well as to address prior art concerns regarding paclitaxel." It is evident from his affidavit and cross-examination that he has no knowledge of any prior art concerns. He does not attest as to what prior art was of concern and, most critically, does not attest that the failure to previously consider this prior art was due to mistake, accident or inadvertence. Accordingly, there is simply insufficient evidence to establish that Sanofi Canada was unaware of the prior art raised by Hospira. If the disclaimer was filed, as Mr. Orlhac swears that it was in part, to address prior art concerns, then Sanofi Canada has failed to meet its burden of proof to establish any mistake, accident or inadvertence on its part related to the prior art allegation.

[147] Mr. Orlhac also swears that part of the reason for the filing of the disclaimer was the alleged double patenting. However, he has no direct knowledge of how it was as a result of mistake, accident or inadvertence on the part of Sanofi Canada. His evidence at pages 8-9 of his cross-examination was that Sanofi Canada's counsel "sent me information explaining why it should be done and what kind of Disclaimer should be done." As to why it should be done, we are left in the dark as Sanofi Canada objected to producing the exchanges between Mr. Orlhac and Mr. Creber, Sanofi Canada's counsel, on the grounds of privilege.

[148] In summary, Mr. Orlhac offers no evidence to support that the conditions set out in subsection 48(1) of the *Patent Act* have been met.

[149] The other evidence offered by Sanofi Canada is that of Mr. Dahling. He retired from the Sanofi-Aventis Group on June 1, 2008. He had been employed prior to his retirement as in-house patent attorney and he instructed external counsel in this application for Sanofi Canada. He swears that one of his responsibilities prior to his retirement was in recommending and making the decision to file the disclaimer at issue. Although noted previously, his evidence as to the reason for the disclaimer is repeated for ease of reference.

> On October 15, 2007, Hospira sent a Notice of Allegation relating to, among others, the '778 Patent. In the Notice of Allegation, Hospira alleged that the '778 Patent was invalid for Double Patenting in light of Canadian Patent 2,102,777 (the " '777 Patent"). This was the first such allegation of Double Patenting relating to the '778 Patent in view of the '777 Patent that anyone in the sanofi-aventis organization was aware of. Upon review of the issue, we recognize that there was potential overlap in the scope of the claims of these two patents and a decision was made to narrow the scope of Claim 8 of the '778 Patent to limit the active substance to docetaxel (thereby removing paclitaxel from the scope of the claim) and to narrow the range of docetaxel as well as the ranges of ethanol and polysorbate.

[150] Mr. Dahling attests that the allegation of double patenting in the NOA was the first such allegation Sanofi Canada had received. The claim of double patenting in the NOA was as follows:

> The '778 Patent is invalid for double patenting in view of the '777 Patent. Both patents claim a stock solution, and an infusion solution having polysorbate and a taxane (in particular paclitaxel or docetaxel), and ethanol.

> Aventis has therefore claimed the benefit of the identical monopoly twice (for example: the infusion solution of claim 16 ('777 Patent) is not patentably distinct from claim 8 ('778 Patent); the composition of claims 1-11 ('777 Patent) are not patentable (*sic*) distinct from the composition claims 1-7 ('778 Patent).

[151] Mr. Dahling attests that as a consequence of this allegation, the disclaimer was made to limit the active substance to docetaxel by removing paclitaxel from the scope of the claim. He further attests that Sanofi Canada decided to narrow the range of docetaxel as well as the ranges of ethanol and polysorbate.

[152] Mr. Dahling admits on cross-examination that he has no recollection of a disclaimer being required as a result of any prior art concerns. His evidence as to why the disclaimer was necessary, was filed in the form it was, and what caused the original patent claims to be too broad is found in the following excerpts from his cross-examination:

> Q. So did you read the Notice of Allegation and determine there were validity issues with respect to the 778 Patent or were those identified to you by outside counsel?
>
> A. I am not a Canadian lawyer, so I certainly would not opine about validity issues in relation to Canadian patents. So I, if my recollection is correct, I turned the matter over to Tony Creber.
>
> Q. And at some point Mr. Creber indicated to you that there were issues of validity that were raised in the Notice of Allegation?
>
> A. That is correct.
>
> Q. And can you recollect what the nature of the discussion was or the advice that was given?
>
> A. Yes, I do, in general terms, remember that there was some kind of a conflict between two, two patents and it was Mr. Creber's

view that it was a double patenting issue and that something should be done. And, again, I followed his recommendation.

Q. Did you give any advice as to how the claims should be amended in the disclaimed claims?

A. No.

Q. Did anyone at Sanofi verify what Mr. Creber was proposing was the proper course of action?

A. I don't believe so. I am not 100 per cent sure, but I don't believe so. Tony Creber was the expert. His team in Canada understands Canadian patent law and it's a matter of delegating to the people with the right expertise and that was what was done.

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Q. What was your involvement in recommending and making the decision to file this disclaimer?

A. I called a meeting with outside Canadian counsel, and that was Tony Creber and his team, along with – I don't quite remember everyone who attended the meeting, but I was there and I believe the general counsel of Canada was there and perhaps one or two others. And we heard Tony Creber's assessment of the various patents at issue. And there came a time when Tony Creber recommended and pointed out that there was an issue concerning a possible double patenting situation involving the two patents that are the subject of paragraph 4 and Tony's recommendation was that certain of those claims be disclaimed, and I was the one who had to authorize that and that was my involvement. And I made the decision, and I followed Tony's advice and recommendation.

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Q. And what was, what Mr. Creber's proposal? Did you get into specifics in terms of what amendments he proposed to the claims?

A. Not the specifics of the precise amendments, but he recommended as a disclaimer to file to alleviate the potential issue, and I authorized that.

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> Q. Well any other issues in terms of the allegations that were raised in the Notice of Allegation and how to address them vis-à-vis the disclaimer?
>
> A. Well I asked Tony Creber to look at all of the Sanofi patents that related to docetaxel and the Notice of Allegation and come up with a plan for defending our product in Canada. And he followed that instruction. Then I called the meeting to hear the results of his analysis and so he went over the Notice of Allegation, he described the various patents which had been granted in Canada, and the two patents which are the subject of my affidavit, paragraph 4, came up and probably some others did too. But do I remember specifically? No. But it would have been a very strange and short meeting if the entire time would have been focussed only on 777 and 778 from my paragraph 4. [emphasis added]

[153] There are a number of difficulties with this evidence. The first and arguably the most significant is that the affiant never swears or provides any basis on which to conclude that there was a mistake, accident or inadvertence on the part of Sanofi Canada in filing the original specifications of the '778 patent that made them too broad. He says that the NOA alerted Sanofi Canada to a "potential overlap". He does not say that the claims of the two patents did overlap and that therefore the '778 patent claims were too broad; he merely says that there was a potential for an overlap. In order to be a valid disclaimer under the *Patent Act*, the patentee must, at a minimum, unequivocally admit that the original specification is too broad. Admittedly, Sanofi Canada did that when it filed the disclaimer because the statutory form specifically contains an admission by the patentee that it has "by mistake, accident or inadvertence, and without any wilful intent to defraud or mislead the public, made the specification too broad…" However, that statement is precisely what is under attack by Hospira and Sanofi Canada must do more to support the validity of that

statement and its disclaimer than have someone swear an affidavit that it was “potentially” too broad. At a minimum, there must be an admission by the relevant witness that the claim was too broad and then set out how this happened, to prove that it was by mistake, accident or inadvertence and with no wilful intent to defraud the public. In this case, Sanofi Canada has failed to prove on a balance of probabilities that through mistake, accident or inadvertence its patent as filed was overly broad. In short, it has failed to meet its burden of proof establishing that the disclaimer meets the prerequisites of subsection 48(1) of the *Patent Act*. Accordingly, I find that for the purposes of this application, the disclaimer is invalid and the Disclaimed ‘778 patent cannot be relied upon by Sanofi Canada.

[154] Hospira also submits that the disclaimer is invalid as it broadens the previous claim. The purpose of the disclaimer is to narrow what was previously claimed and it is therefore invalid if it broadens what was claimed or recasts the invention.

[155] Hospira asserts that the change of the word “contains” in the original patent to “including” and “includes” in the disclaimed patent results in a broader claim than the original. Hospira relies on the admission of Dr. Constantinides in cross-examination that “contains” or “containing” would be more limited than “includes” or “including”.

[156] The claims within a patent are made so that the public can understand them. However, the public, in the context of reading a patent, is not the ordinary lay person, but rather the person skilled in the art. This is why when construing the claims, it is necessary to have expert evidence to inform

the decision-maker of how a PSIA would read the claims. However, determining whether a patentee correctly employed the disclaimer provisions within the *Act* is a factual and legal question for the trier-of-fact. The opinions of the experts are relevant, but not determinative.

[157] I am of the opinion that "contains" or "containing" and "includes" or "including" are synonymous in the context of this patent. The '778 patent has many passages using the word "contains" and "containing" where it is clear that it is meant to refer to an open list of ingredients in that it refers to one of many ingredients in the composition. The following are examples:

1. "…a first, so-called 'stock', solution is prepared that contains approximately 6 mg/mL of taxol in a solvent mixture composed of [50% ethanol and 50% Cremophor by volume]"
2. "..it is necessary to inject solutions containing, in addition to the active ingredient, concentrations of each of the following compounds, ethanol and Cremophor…"
3. "According to a preferred embodiment, the composition contains 6 to 15 mg/mL of formula (I) compounds."
4. "Infusions prepared from the previous stock solutions and containing an active ingredient concentration of …"
5. "After mixing with a 5% glucose solution to obtain a final concentration of 1 mg/mL, this solution contained approximately 33 mg/mL of polysorbate 80 and 33 mg/mL of ethanol."

[158] Therefore, as read within the patent as a whole, I find that the disclaimer does not broaden the claim from the original, as alleged by Hospira, and it is not invalid on that basis.

[159] Having found that the justification of the allegations of Hospira are to be determined based on the Disclaimed '778 patent and having found that the disclaimer is invalid, this application must be dismissed; however, in the event that there is an appeal of this decision, I shall deal with the remaining issues that were raised by the parties. I shall do so with reference to the Disclaimed '778 patent and the Disclaimed Claim 8, as Sanofi Canada has admitted that it is not relying on the patent as it read prior to the disclaimer.

4. *Whether none of Hospira's allegations are justified*

[160] The parties are in agreement on the legal burden of proof in NOC proceedings. Hospira's allegations are presumed to be true. Therefore, Sanofi Canada has the burden of proving, on a balance of probabilities, that the allegations are not justified: *Eli Lilly Canada Inc. v. Apotex Inc.*, 2009 FC 320 at para. 41. There is a statutory presumption in section 43 of the *Patent Act* that the patent is valid. Where the second person alleges invalidity, the first person can rely on the statutory presumption; this shifts the onus to the second person to provide sufficient evidence that, on a balance of probabilities, displaces the statutory presumption: *Procter & Gamble Pharmaceuticals Canada Inc. v. Canada (Minister of Health)*, 2004 FCA 393 at paras. 15-16, leave to appeal to S.C.C. denied, [2005] S.C.C.A. No. 9 (QL). Therefore, the burden of proving invalidity, on a balance of probabilities, rests with Hospira.

Person Skilled in the Art

[161] Patents are not directed to the general public, but rather to the mythical PSIA. The Supreme Court, in *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66 at para. 44 [*Free World Trust*], endorsed the following definition of the PSIA provided by Dr. Fox:

> [A Person Skilled in the Art is] a hypothetical person possessing the ordinary skill and knowledge of the particular art to which the invention relates, and a mind willing to understand a specification that is addressed to him. This hypothetical person has sometimes been equated with the "reasonable man" used as a standard in negligence cases. He is assumed to be a man who is going to try to achieve success and not one who is looking for difficulties or seeking failure.

[162] The first step in any infringement or invalidity analysis is to determine who this mythical person, this PSIA, is in the circumstances of the particular patent at issue.

[163] The parties agree that the PSIA would have at least a Bachelor of Science degree in a related scientific discipline. Sanofi Canada asserts that the PSIA would have experience in developing intravenous formulations of poorly water soluble drugs. Hospira asserts that the PSIA would have *some* experience in developing parenteral formulations of poorly water soluble drugs. Beyond the word “some”, there is very little to separate the parties’ positions on this aspect. The word “some” is congruent with the position that the PSIA had only a first degree in the sciences. If the PSIA had an advanced degree, at a minimum, then it would be expected that he or she had more experience, not just some. I find, therefore that the PSIA is someone with at least a Bachelor of Science Degree

in a related scientific discipline with some experience developing parenteral formulations of poorly soluble drugs.

Claims Construction

[164] The parties agree on the general legal principles that govern claims construction. Claims construction is a question of law for the Court: *Whirlpool Corp.* at para. 61 and the relevant date is the date of publication, i.e. January 21, 1993. The Court must determine, as of this date, how a PSIA would read the patent and interpret the claims.

[165] "A patent specification should be given a purposive rather than a purely literal" construction: *Catnic Components Ltd. v. Hill and Smith Ltd*, [1982] R.P.C. 183 at 243 (H.L.). "We must look to the whole of the disclosure and the claims to ascertain the nature of the invention and methods of its performance, …being neither benevolent nor harsh, but rather seeking a construction which is reasonable and fair to both patentee and public": *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] 1 S.C.R. 504 at 520 [*Consolboard*]. If the patent can be read to support a really useful invention then it should be so read: *Consolboard* at 521.

[166] The key task in claims construction is determining which elements of the claims are essential, and which are non-essential. According to *Free World Trust* at para. 31 that determination is made:

> a. on the basis of the common knowledge of the worker skilled in the art to which the patent relates;
>
> b. as of the date the patent is published;

c. having regard to whether or not it was obvious to the skilled reader at the time the patent was published that a variant of a particular element would not make a difference to the way in which the invention works; or

d. according to the intent of the inventor, expressed or inferred from the claims, that a particular element is essential irrespective of its practical effect;

e. without, however, resort to extrinsic evidence of the inventor's intention.

[167] The parties agree on the general aspects of what is essential to Disclaimed Claim 8, i.e. that it is an infusion with polysorbate and ethanol. The parties disagree on whether the Disclaimed Claim 8 claims docetaxel only or the broader class of taxanes. The parties disagree on whether the concentration ranges listed are essential. The parties disagree on whether the items listed in Disclaimed Claim 8 are exhaustive of what comprises the formulation. I have already found that it is not an exhaustive list, but that does not mean that additional ingredients are essential.

[168] Sanofi Canada submits that the essential elements of Disclaimed Claim 8 are:

a. An infusion containing the following:

b. 0.1 mg/mL to 1 mg/mL of docetaxel;

c. 5 mg/mL to 35 mg/mL of ethanol; and

d. 5 mg/mL to 35 mg/mL of polysorbate.

[169] Hospira submits that the essential elements of Disclaimed Claim 8 are:

a. An infusion containing the following:

b. A taxane;

c. Ethanol; and

d. Polysorbate.

[170] Hospira argues that if you read Disclaimed Claim 8 in the context of the disclosure, the use of the word docetaxel should be taken to mean any taxane. I cannot agree with this submission. The whole purpose of the disclaimer was to limit a claim that was previously overly broad to a more discrete claim. The original claim 8 did claim a broad class of taxanes, but this was disclaimed by the patentee to include only docetaxel. The word choice of the patentee was very specific, and this, taken together with the whole reason for the disclaimer, leads to the conclusion that Disclaimed Claim 8 claims docetaxel only.

[171] I have addressed the issue of whether the language in Disclaimed Claim 8 is exhaustive and concluded that the wording of Disclaimed Claim 8 is non-exhaustive. This is not to say that there are essential ingredients that are not listed, only that the Disclaimed Claim 8 does contemplate the possible inclusion of other, non-essential ingredients.

[172] Hospira argues that the ranges included in Disclaimed Claim 8 are arbitrary and that the patent does not explain the inventive aspect of the range, citing *BMS, supra* and *Shire Biochem Inc. et al. v. Apotex Inc. et al.*, 2008 FC 538. Sanofi Canada argues that there is no obligation to explain the reason for the narrow range.

[173] The inventive step is not the identification of the range of each element in the infusion, but rather is the replacement of Cremophor with polysorbate. In my view, the cases cited by Hospira do not assist its position. In *BMS* Justice Hughes held that a range of water within a given formulation was non-essential because it related to the presence of other crystalline forms of the molecule that were not important to what was being claimed. In *Shire* the specification called for an "effective amount" of the active ingredient so as to produce a specific physiological response. On this basis, Justice Hughes concluded that a listed dosage range of active ingredient was not inventive and was non-essential, since what was important was whether the amount was effective, and this was related to particle size not dosage range.

[174] I have reservations about the approach argued by the respondent in this case. Hospira correctly noted that when determining the essential elements of the claim one must do so with an eye to the inventive concept, as Justice Hughes did in the cases cited above. However, a component of a formulation can be essential in that it cannot be substituted without affecting the working of the invention and at the same time, in itself, not be inventive. Hospira has submitted that the ranges are not inventive but merely flow from the demands of clinicians as to the necessary amount of docetaxel that a patient should receive.

[175] In my view, the specified ranges are essential, even though they may not be inventive. The desired concentration of active ingredient flows from clinical demands. If the concentration is too low, then it will take too long to administer the formulation, all the while exposing the patient to an increased amount of solvent, and the associated side effects. If the concentration is too high, then it

can be toxic to the patient and physically or chemically unstable in the infusion solution. In short, the concentrations matter, and a PSIA would read Disclaimed Claim 8 that the ranges are essential to the formulation.

[176] I conclude that Disclaimed Claim 8 has the following essential elements:

a. an infusion containing the following:

b. 0.1 mg/ml to 1 mg/ml of docetaxel;

c. 5 ml/L to 35 mL/L of ethanol; and

d. 5 ml/L to 35 ml/L of polysorbate.

Infringement

[177] Infringement is a question of mixed fact and law. The first person need only show infringement in one claim to be successful. There is no infringement if an essential element is different or omitted, but there may still be infringement if non-essential elements are substituted or omitted: *Free World Trust*.

[178] The Hospira formulation uses all of the essential elements of Disclaimed Claim 8 as construed above and omits none. Hospira argues that the addition of Ingredient B varies their formulation in such a way so as to bring them outside the Disclaimed Claim 8 of the ‘778 patent. It submits that Ingredient B is a variant and that the principles set out by the Supreme Court of Canada in *Free World Trust* at para. 55 bring its formulation outside the Sanofi Canada invention.

[179] Justice Binnie in *Free World Trust* at para. 55 described the situation of a variant in an infringement claim, as follows:

> It would be unfair to allow a patent monopoly to be breached with impunity by a copycat device that simply switched bells and whistles, to escape the literal claims of the patent. Thus the elements of the invention are identified as either essential elements (where substitution of another element or omission takes the device outside the monopoly), or non-essential elements (where substitution or omission is not necessarily fatal to an allegation of infringement). For an element to be considered non-essential and thus substitutable, it must be shown either (i) that on a purposive construction of the words of the claim it was clearly not intended to be essential, or (ii) that at the date of publication of the patent, the skilled addressees would have appreciated that a particular element could be substituted without affecting the working of the invention, i.e., had the skilled worker at that time been told of both the element specified in the claim and the variant and "asked whether the variant would obviously work in the same way", the answer would be yes: Improver Corp. v. Remington, supra, at p. 192. In this context, I think "work in the same way" should be taken for our purposes as meaning that the variant (or component) would perform substantially the same function in substantially the same way to obtain substantially the same result. (emphasis added)

[180] One must ask what element of the Sanofi Canada formulation is being varied by Hospira. Hospira varies the amounts of ethanol and polysorbate by replacing *some* of it with Ingredient B; however, Hospira's variation does not bring it outside the ranges in the Disclaimed ‘778 patent nor indeed the original ‘778 patent. Ethanol and polysorbate have been construed to be essential elements of the patent; accordingly, Hospira cannot non-infringe as a result of (i) in the above test.

[181] The Court characterizes the only other way non-infringement can be shown as whether the PSIA would read the patent in such a way "that a particular element could be substituted without

affecting the working of the invention" (emphasis added). In this case, there is no substitution, only an addition, thus, it is not possible to show non-infringement through (ii) in the test above.

[182] Hospira has not substituted Ingredient B for any of the essential ingredients. Further, Hospira has not substituted Ingredient B for part of an essential ingredient such that its formulation is now outside the range claimed by the patentee. In short, there is no variation of an essential element. There is complete infringement of the invention, with what Justice Binnie characterizes as the addition of "bells and whistles". Even if the "bells and whistles" materially affected how the invention worked, and there is no evidence to support this conclusion, Hospira would still be utilizing the invention of Sanofi in a manner that infringes.

[183] Therefore, I find that Hospira's formulation is within Disclaimed Claim 8 and infringes the applicant's patent.

Validity

[184] The Court heard challenges to the validity of the Disclaimed '778 patent based on submissions relating to the claims being overly broad, anticipation, obviousness, material misstatement, and non-patentable subject matter.

Claims Broader

[185] An invention that claims more than what the inventor actually did, or more than what the disclosure says, is invalid for being overly broad: *Pfizer Canada Inc. et al. v. The Minister of Health et al.*, 2008 FC 11 at paras. 45-46.

[186] Hospira submits that if the claims of the ‘778 patent are construed to include additional ingredients then the invention is invalid for being overly broad. I have concluded that a PSIA would not read Disclaimed Claim 8 to exclude other non-essential ingredients.

[187] I have found that the patent sets out all of the essential elements – additional elements that may be read into Disclaimed Claim 8 are nonessential to the invention. A failure to list every additional non-essential ingredient doe not make the claim overly broad.

[188] Accordingly, I find that the Disclaimed Claim 8 covers the invention of the inventors and is not overly broad.

Anticipation

[189] Anticipation is concerned with whether a single disclosure completely enables the PSIA to produce the invention; this is different from obviousness, where the question is how the PSIA would behave given the availability of various pieces of prior art.

[190] Subsection 28.2(1) of the *Patent Act* states:

28.2 (1) The subject-matter defined by a claim in an	28.2 (1) L’objet que définit la revendication d’une demande de

application for a patent in Canada (the "pending application") must not have been disclosed

brevet ne doit pas :

(*a*) more than one year before the filing date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant, in such a manner that the subject-matter became available to the public in Canada or elsewhere;

a) plus d’un an avant la date de dépôt de celle-ci, avoir fait, de la part du demandeur ou d’un tiers ayant obtenu de lui l’information à cet égard de façon directe ou autrement, l’objet d’une communication qui l’a rendu accessible au public au Canada ou ailleurs;

(*b*) before the claim date by a person not mentioned in paragraph (*a*) in such a manner that the subject-matter became available to the public in Canada or elsewhere;

b) avant la date de la revendication, avoir fait, de la part d’une autre personne, l’objet d’une communication qui l’a rendu accessible au public au Canada ou ailleurs;

(*c*) in an application for a patent that is filed in Canada by a person other than the applicant, and has a filing date that is before the claim date; or

c) avoir été divulgué dans une demande de brevet qui a été déposée au Canada par une personne autre que le demandeur et dont la date de dépôt est antérieure à la date de la revendication de la demande visée à l’alinéa (1)*a*);

(*d*) in an application (the "co-pending application") for a patent that is filed in Canada by a person other than the applicant and has a filing date that is on or after the claim date if

d) avoir été divulgué dans une demande de brevet qui a été déposée au Canada par une personne autre que le demandeur et dont la date de dépôt correspond ou est postérieure à la date de la revendication de la demande visée à l’alinéa (1)*a*) si :

(i) the co-pending application is filed by

(i) cette personne, son agent, son représentant

	légal ou son prédécesseur en droit, selon le cas :
(A) a person who has, or whose agent, legal representative or predecessor in title has, previously regularly filed in or for Canada an application for a patent disclosing the subject-matter defined by the claim, or	(A) a antérieurement déposé de façon régulière, au Canada ou pour le Canada, une demande de brevet divulguant l'objet que définit la revendication de la demande visée à l'alinéa (1)*a*),
(B) a person who is entitled to protection under the terms of any treaty or convention relating to patents to which Canada is a party and who has, or whose agent, legal representative or predecessor in title has, previously regularly filed in or for any other country that by treaty, convention or law affords similar protection to citizens of Canada an application for a patent disclosing the subject-matter defined by the claim,	(B) a antérieurement déposé de façon régulière, dans un autre pays ou pour un autre pays, une demande de brevet divulguant l'objet que définit la revendication de la demande visée à l'alinéa (1)*a*), dans le cas où ce pays protège les droits de cette personne par traité ou convention, relatif aux brevets, auquel le Canada est partie, et accorde par traité, convention ou loi une protection similaire aux citoyens du Canada,
(ii) the filing date of the previously regularly filed application is before the claim date of the pending application,	(ii) la date de dépôt de la demande déposée antérieurement est antérieure à la date de la revendication de la

	demande visée à l'alinéa *a*),
(iii) the filing date of the co-pending application is within twelve months after the filing date of the previously regularly filed application, and	(iii) à la date de dépôt de la demande, il s'est écoulé, depuis la date de dépôt de la demande déposée antérieurement, au plus douze mois,
(iv) the applicant has, in respect of the co-pending application, made a request for priority on the basis of the previously regularly filed application.	(iv) cette personne a présenté, à l'égard de sa demande, une demande de priorité fondée sur la demande déposée antérieurement.

[191] The three pieces of prior art raised in Hospira's Memorandum of Fact and Law fall on dates that meet the requirements of the *Patent Act* and consequently they would anticipate the '778 patent if the appropriate legal test is met.

[192] In *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61 [*Sanofi-Synthelabo*], the Supreme Court recasts the test for anticipation. The Court described a two-step test: Does the single piece of prior art disclose the full subject matter claimed by the patent in question? If yes, does the disclosure enable the PSIA to work the invention?

[193] At the first step, no trial and error or experimentation is permitted. The PSIA is "simply reading the prior patent for the purposes of understanding it": *Sanofi-Synthelabo* at para. 25. If the single piece of prior art discloses the full subject matter claimed by the patent in question then one proceeds to the second step.

[194] At the second step, the PSIA is allowed to conduct some trial and error experimentation, but it must not result in "undue burden", i.e. it cannot involve too much work. The Court in *Sanofi-Synthelabo* at para. 37 stated that the following non-exhaustive factors may be considered:

> 1. Enablement is to be assessed having regard to the prior patent as a whole including the specification and the claims. There is no reason to limit what the skilled person may consider in the prior patent in order to discover how to perform or make the invention of the subsequent patent. The entire prior patent constitutes prior art.
>
> 2. The skilled person may use his or her common general knowledge to supplement information contained in the prior patent. Common general knowledge means knowledge generally known by persons skilled in the relevant art at the relevant time.
>
> 3. The prior patent must provide enough information to allow the subsequently claimed invention to be performed without undue burden. When considering whether there is undue burden, the nature of the invention must be taken into account. For example, if the invention takes place in a field of technology in which trials and experiments are generally carried out, the threshold for undue burden will tend to be higher than in circumstances in which less effort is normal. If inventive steps are required, the prior art will not be considered as enabling. However, routine trials are acceptable and would not be considered undue burden. But experiments or trials and errors are not to be prolonged even in fields of technology in which trials and experiments are generally carried out. No time limits on exercises of energy can be laid down; however, prolonged or arduous trial and error would not be considered routine.
>
> 4. Obvious errors or omissions in the prior patent will not prevent enablement if reasonable skill and knowledge in the art could readily correct the error or find what was omitted.

[195] With these principles in mind, I turn to examine the prior art cited by the respondent.

The GV Article

[196] The GV Article discloses a formulation of docetaxel containing a 1:1 solvent vehicle of polysorbate to ethanol. The disclosure relates to a stock solution, and not an infusion.

[197] Sanofi Canada argues that the GV Article does not anticipate Disclaimed Claim 8 because it did not relate to an infusion, did not address stability, and did not teach the relevant percentage of polysorbate and ethanol in the final infusion. Hospira argues that GV Article does anticipate Disclaimed Claim 8 because it discloses all the essential ingredients in Disclaimed Claim 8, and would enable a PSIA to produce all the essential elements of the Disclaimed Claim 8.

[198] The GV Article does disclose all the elements of Disclaimed Claim 8, thus satisfying the first step of the *Sanofi-Synthelabo* test. The real question is whether it would enable the PSIA to produce the invention. The GV Article discloses a formulation of docetaxel solubilised in ethanol and polysorbate. The first question is whether the PSIA would have the requisite general knowledge to know that the stock solution had to be prepared in an infusion prior to administration in humans? In my view, that answer to this question would be an affirmative. The next question would be whether the PSIA would have the general knowledge that the desired clinical concentration of docetaxel within a range of 0.1-1 mg/mL. This knowledge was cited by the patentee in its disclosure, stemming from the Rowinsky Article discussed in that disclosure. It does not seem likely, based on the evidence before the Court, that the PSIA being a scientist and not a doctor would have knowledge of this desired range even though it would be readily discoverable. I am not convinced that the PSIA would know they needed to prepare a final infusion with 0.1-1

mg/mL of docetaxel. As a result, the GV Article does not lead to enablement, and does not anticipate the ‘778 patent.

[199] If I am wrong, the next question would be whether the PSIA would produce the requisite concentration of polysorbate and ethanol? The answer to this question has to be affirmative. The concentrations of polysorbate and ethanol in Sanofi Canada’s formulation appear to be nothing more than the by-product of diluting the stock solution of 0.1-1 mg/mL of docetaxel in the infusion solution.

[200] The last question to ask would be whether the PSIA could, without undue burden, determine that the final infusion would be stable? This question must also be answered in the affirmative. Stability testing is a relatively routine exercise. It would not take the PSIA much effort to determine the physical and chemical stability of infusions within the ranges as described by the disclaimed ‘778 patent.

[201] However, since I have found that the PSIA would not have the common knowledge to select a starting docetaxel concentration of between 0.1 and 1 mg/mL, the GV Article does not anticipate the Disclaimed ‘778 patent.

The Tarr Article

[202] The Tarr Article refers to paclitaxel, but it does not refer to docetaxel. It discloses a solvent vehicle of ethanol and polysorbate in a 3:1 ratio, not a ratio of 1:1. It discloses an infusion, but the infusion has poor physical stability, and crystallizes in the infusion solution within two hours.

[203] The Tarr Article does not refer to docetaxel and therefore fails the first step of the *Sanofi-Synthelabo* test.

The '221 Patent

[204] The '221 patent discloses a formulation of paclitaxel with polysorbate and alcohol, and saline. Sanofi Canada argues that it does not disclose an infusion for humans since the testing was on mice. Hospira argues that a PSIA would interpret alcohol to mean ethanol, and that the same formulating principles for administration to mice would apply for administration to humans.

[205] Since the '221 patent does not disclose a formulation including docetaxel, it cannot anticipate the disclaimed '778 patent.

Obviousness

[206] The test for obviousness was recently reiterated in *Sanofi-Synthelabo* at para. 67:

> a. (a) Identify the notional "person skilled in the art"; (b) Identify the relevant common general knowledge of that person;
>
> b. Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;

> c. Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;
>
> d. Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

[207] The Court instructs that at the fourth step, the “obvious to try” test can be applied, but it is to be applied with caution. The relevant factors to consider under “obvious to try” are set out at para. 69, as follows:

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

[208] I have already identified the PSIA. The parties disagree on what general common knowledge the PSIA would possess. Both parties attempt to characterize the relevant general common knowledge of the PSIA along the lines of their ensuing legal arguments. I find that the PSIA had general common knowledge of the following:

a. taxanes, and in particular paclitaxel and docetaxel;

b. solubility issues relating to taxanes;

c. potential chemical differences between drugs that are members of a common class;
d. a formulation of some unknown but easily determinable amount of paclitaxel in a 1:1 solvent of ethanol and Cremophor;
e. how to conduct stability testing for physical and chemical stability in infusions; and
f. various solvent and/or other options available for solubilising poorly water soluble drugs.

[209] The inventive concept has already been discussed, but to reiterate, it is the replacement of Cremophor with polysorbate so as to formulate an infusion containing docetaxel, ethanol and polysorbate.

[210] Hospira submits that there is no difference between the state of the art and the inventive concept. Sanofi argues that there were relevant differences, namely, not referring to docetaxel, not referring to an infusion, not referring to the relevant concentrations, and not referring to a stable infusion.

[211] The GV Article alone discloses a formulation of docetaxel in polysorbate and ethanol. It does not disclose an infusion or whether such an infusion would be stable. The PSIA would not have had general knowledge of the stock concentration of paclitaxel in that formulation. The PSIA would have been aware of the GV Article that disclosed the polysorbate/ethanol solvent vehicle. Would it be obvious to the PSIA to try this solvent vehicle first in place of Cremophor/ethanol? I think the answer is yes, both based on the prior art, and based on the fact that Cremophor and

polysorbate are similar surfactants. Would it have been obvious that the polysorbate/ethanol vehicle would work in a manner that could replace the Cremophor in the Rowinsky prior art? I do not think so, but it would have been obvious to try. Had the PSIA tried this combination, they would have been led directly, and without difficulty to all the essential elements of Disclaimed Claim 8. All that would be left would be the routine experiments necessary to achieve stability, which I think would not raise the level of effort to an undue burden. I conclude that the Disclaimed '778 patent is invalid for obviousness.

Material Misstatement

[212] Hospira argues that Sanofi Canada made a material misstatement because they failed to correctly describe the reduction in anaphylaxis achieved by their invention. As evidence of this failure, Hospira cites the Taxotere product monograph, which requires pre-treatment of patients prior to drug administration so as to reduce the incidence and severity of anaphylaxis. Sanofi Canada argues that Hospira has provided insufficient evidence to meet their evidential burden, and consequently, this issue ought not to be in play. I agree.

[213] The '778 patent makes no claim to a complete alleviation of anaphylaxis or to alleviation of the need for pre-treatment. The '778 patent claims an improvement of toxicity through the removal of Cremophor, which will result in less anaphylaxis. Hospira's allegation of the remaining need for pre-treatment does not rebut this statement.

[214] Hospira also argues that the ‘778 patent is insufficient because it does not list the potential additional ingredients necessary to work the invention. The test for insufficiency is “whether the specification adequately describes the invention for a person skilled in the art” so that when the monopoly expires, the PSIA can work the invention: *Consolboard* at 524-525. The specification does describe the invention, and how to make it. The fact that Disclaimed Claim 8 may be non-exhaustive does not mean that the patent is insufficient. Consequently, the patent is not invalid for insufficiency.

Non-patentable Subject Matter

[215] Hospira argues that because professional skill is required in determining the appropriate active ingredient dose to be administered, the patent is invalid as a method of medical treatment. I disagree. The invention is for the replacement of Cremophor with polysorbate. There is no inventiveness in the range of docetaxel selected, even though this range is essential to the invention. Consequently, the patent is not non-patentable subject matter.

SUMMARY OF FINDINGS

[216] The Court finds as follows:

a. In an application for an order of prohibition under the NOC Regulations, where the patentee has filed a disclaimer after the NOA was served, the Court is to assess the allegations of the second party against the claims of the patent as at the date of hearing and not as at the date of the NOA. In this case, the allegations of Hospira are to be assessed against the ‘778 patent as disclaimed.

b. Hospira is not estopped from arguing the validity of the disclaimer of the ‘778 patent that was filed by Sanofi Canada on November 28, 2007.

c. Sanofi Canada has failed to prove on a balance of probabilities that the disclaimer it filed on November 28, 2007, meets the requirements of section 48(6) of the *Patent Act* and the disclaimer is therefore invalid.

d. If the disclaimer had been valid then Hospira’s formulation would have infringed on the Disclaimed Claim 8.

e. If the disclaimer had been valid then the Disclaimed ‘778 patent would not have been invalid on the basis of being over broad, anticipation, material misrepresentation, or non-patentable subject matter; but would have been invalid on the basis of obviousness.

[217] Hospira shall have its costs as against Sanofi Canada. The parties know this Court’s recent jurisprudence which sets out reasonable cost parameters in NOC applications. If the parties are unable to agree on costs, then directions or an Order on any issues preventing agreement may be sought.

POSTSCRIPT

[1] The Reasons for Judgment are un-redacted from confidential Reasons for Judgment which were issued on October 22, 2009 pursuant to Direction dated October 22, 2009.

[2] The Court canvassed counsel for the parties whether they had concerns if the reasons were issued to the public without redactions. The parties were advised that in the absence of comments to be received no later than November 2, 2009, the Reasons for Judgment would be unsealed in their entirety. On October 30, 2009, Hospira advised that there are no portions of the confidential Reasons for Judgment that should be redacted. Sanofi Canada provided no response.

"Russel W. Zinn"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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