Federal Court  Cour fédérale

Date: 20090707

Docket: T-1129-07

Citation: 2009 FC 648

Toronto, Ontario, July 7, 2009

PRESENT: The Honourable Madam Justice Heneghan

BETWEEN:

ABBOTT LABORATORIES and
ABBOTT LABORATORIES LIMITED

Applicants

and

THE MINISTER OF HEALTH
and SANDOZ CANADA INC.

Respondents

REASONS FOR JUDGMENT
(Confidential Reasons for Judgment issued on June 19, 2009)

I. Introduction

[1] Abbott Laboratories and Abbott Laboratories Limited (the "Applicants" or "Abbott") apply pursuant to the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the "NOC

Regulations") for an order prohibiting the Minister of Health from issuing a Notice of Compliance ("NOC") to Sandoz Canada Inc. (the "Respondent" or "Sandoz"), pursuant to section C.08.004 of the *Food and Drug Regulations*, C.R.C. c. 870 until the expiry of the Canadian letters patent 2,285,266 (the " '266 Patent"), 2,358,395 (the " '395 Patent") 2,325,541 (the " '541 Patent") and 2,209,714 (the " '714 Patent").

[2] This application was commenced in response to a Notice of Allegation ("NOA") dated May 7, 2007 and served by the Respondent on that day. The Respondent alleged that the Abbott patents are invalid on several grounds including obviousness, lack of actual utility, lack of sound prediction utility and double patenting.

[3] On June 19, 2007, the Applicants filed their application, pursuant to the NOC Regulations, claiming that the allegations are not justified and requesting the issuance of a Prohibition Order.

A. The Parties

[4] The Applicant Abbott Laboratories is a Canadian company that distributes and sells pharmaceutical products.

[5] The Applicant Abbott Laboratories Limited, a company incorporated under the laws of the United States of America, is the parent of Abbott Laboratories and is the owner of the patents at issue in this proceeding. The Applicants are engaged in the development and manufacture of innovative pharmaceutical products.

[6] Sandoz is the Canadian subsidiary of a multinational generic pharmaceutical manufacturer. It has applied for an NOC to permit it to market its version of clarithromycin extended-release 500 mg tablets.

[7] The Minister of Health (the "Minister"), although a party to this proceeding, is not actively participating in it.

B. The Drug

[8] Clarithromycin, or 6-0-methoxy erythromycin is an erythromycin derivative and an antibiotic. It is administered to humans in a composition or formulation. Abbott sells this product in an extended release ("ER") 1000 mg formulation under the trade name BIAXIN®XL ("BIAXIN").

[9] Clarithromycin is the active pharmaceutical ingredient ("API") in Abbott's BIAXIN tablets. BIAXIN is administered for the treatment of mild to moderate bacterial infections.

[10] In order to work, the clarithromycin is released from the formulation, dissolved, absorbed through the bloodstream, distributed to various tissues, metabolized, and ultimately eliminated from the body. The path that the drug takes from the formulation through the body depends on the biological characteristics of the drug in the body, specifically its absorption, distribution, metabolism and excretion ("ADME").

[11] Prior to the ‘266 Patent, these clarithromycin tablets were sold only in an immediate release (“IR”) formulation. This required a patient to take multiple daily doses of the tablets. Multiple daily doses can lead to poor patient compliance and affect the efficiency of treatment. A second problem with the IR composition was the phenomenon of taste perversion, an adverse effect which can lead to non-compliance by a patient with the treatment regime.

[12] Abbott tried to resolve the issues related to multiple dosing by creating an extended release (“ER”) formulation. This allows patients to take only one 1000 mg tablet daily, rather than taking a 500 mg tablet twice a day, that is in the morning and at night.

[13] An important aspect of the ER formulation is that it maintains adequate drug levels in the blood over the extended period of time. This advantage is known as the demonstration of favourable pharmacokinetics (“p-kinetics”), that is the study of the movement of drugs, especially the rates of absorption and excretion of drugs.

[14] In terms of p-kinetics, the area under the plasma concentration time curve (“AUC”) describes the measure or quantity of the total amount of a drug that is delivered in 24 hours. The C-maximum (“C-max”) is the maximum drug concentration in the blood that is attained over the period. The C-minimum (“C-min”) is the minimum drug concentration in the blood reached over the period. The T-maximum (“T-max”) is the time at which the C-max is reached. Bioavailability is the measurement of the amount of the drug available in the blood upon reaching the body’s systemic circulation. The Degree of Fluctuation (“DFL”) is the measure of the difference between

the C-max and the C-min. In particular, it measures the variation in the drug levels between the lowest and highest levels during the steady state, the steady state being the point at which the rate of drug supply to the body equals the rate of drug removal from the body.

[15] Abbott first attempted to address the issue of multiple dosing with a once-daily formulation by combining clarithromycin with alginate in a matrix (the "Alginate Formulation") and obtained a patent in respect of this product, that is the 2,209,714 (the "'714 Patent"). The Alginate Formulation is sold in the United Kingdom under the name KLARICID® . However, the '714 Patent does not address the phenomenon of taste perversion. Abbott wanted to meet the need for a composition that would allow once-daily dosing and which would also address the issue of taste perversion, as compared with the IR formulation.

C. The Patents

[16] Although the NOA referred to four patents, only two patents are the subject of this proceeding, that is the '266 Patent and the '395 Patent.

i) The 266 Patent

[17] The '266 Patent is entitled "Extended Release Formulations of Erythromycin Derivatives". The invention in the patent relates to "pharmaceutical compositions of erythromycin derivatives with an extended release of an active compound in the gastrointestinal environment." The invention relates to a pharmaceutical composition that is taken daily as a single dose.

[18] The ‘266 Patent contains 12 claims. Only Claims 11 and 12 are in issue.

[19] The ‘266 Patent was filed in the Canadian Patent Office on March 6, 1998 and claimed priority from U.S. Patent 08/838,900. The priority date is April 11, 1997. Pursuant to sections 28.1 and 28.2 of the *Patent Act*, R.S.C., 1985, c. P-4 (the “*Patent Act*”) the claim date is the earliest of the date the application was regularly filed with the Canadian patent office; the date a previous application was regularly filed with the Canadian Patent Office that reveals the subject matter defined by the claim in the new application; or the convention priority date, if applicable. In the present case, the earliest of the three dates is the convention priority date. The claims will therefore be assessed as of April 11, 1997.

[20] The ‘266 Patent contains an ER composition that is comprised of a pharmaceutically active compound and a pharmaceutically acceptable polymer. The pharmaceutically active compound is an erythromycin derivative, in particular, clarithromycin, which varies from about 45 – 60 percent by weight of the composition with the preferred amount being 50 percent.

[21] The pharmaceutically acceptable polymer may be a water soluble hydrophilic polymer, most preferably being a low viscosity hydroxypropyl methylcellulose (“HPMC”), with viscosity ranging from about 50 centipoise (“cps”) to 200 cps, the most specific amount being 100 cps, and commercially available under the trade-mark METHOCEL K 100 LV from the Dow Chemical Company. The amount of the polymer can range from 5 to 50 percent, the most specific variance being from 10 – 30 percent by weight of this composition.

[22] The remainder of the composition is made up of pharmaceutically acceptable excipients and/or fillers such as lactose, starches, glucose and the like. The amount of lubricant within the composition will generally vary from about 0.5 to about 10 percent by weight of the composition.

[23] The ‘266 Patent provides p-kinetics that are suitable for once-daily dosing but that are superior to those of the Alginate Composition of the ‘714 Patent.

[24] The ‘266 Patent describes the ER composition by comparing its p-kinetics to those of the IR composition. These are measured in a comparative p-kinetic study between the two compositions.

[25] It was discovered that the C-max of clarithromycin in the ER formulation is statistically significantly lower than that in the IR composition when the IR composition is given twice daily, while the AUC and C-min levels were maintained throughout the 24 hour period. The ER composition is advantageous because the patient is exposed to a lower spike of the drug concentration at the peak of the cycle, while maintaining whatever minimum concentration that is necessary for good effect and still maintaining the overall delivery as measured by the AUC.

[26] As stated, the claims of the ‘266 Patent relevant to this proceeding are Claims 11 and 12. Claim 11 relates to an ER composition made according to Claims 1 through 10, where the erythromycin derivative is clarithromycin. Claim 12 relates to the composition in Claim 11, where clarithromycin comprises 50 percent of the weight of that composition.

ii) The ‘395 Patent

[27] As previously noted, the ‘714 Patent does not address the issue of taste perversion. Originally Abbott had filed one patent application for its invention of the formulation, their favourable p-kinetics and the improved taste profile. However, during the prosecution of the ‘266 Patent, the Commissioner of Patents required Abbott to divide out any claim relating to improved taste profile into a separate application. This led to the ‘541 application from which the ‘395 Patent ultimately issued. In light of this background, the make-up of the ER clarithromycin composition in the ‘395 Patent is the same as that described relative to the ‘266 Patent.

[28] The ‘395 Patent also is entitled “Extended Release Formulations of Erythromycin Derivatives”. It was filed on March 6, 1998 and claims priority from U.S. Patent 08/838,900. The priority date is April 11, 1997. For the reasons referred to above, this claim will be assessed as of April 11, 1997.

[29] The invention described in the ‘395 Patent shows that when the active compound and the polymer are combined, they yield an improved taste profile and a reduction in adverse effects related to the digestive system.

[30] Abbott is relying on and asserting Claim 22 of the ‘395 Patent. This claim relates to an ER composition described in Claims 12 through 21, where the composition formed has an improved taste profile as compared to the IR composition.

iii) The ‘541 Patent

[31] The ‘541 Patent likewise is entitled “Extended Release Formulations of Erythromycin Derivatives”. The ‘541 Patent is in issue in this proceeding only insofar as Sandoz alleges that the ‘395 Patent is invalid for double patenting over it. The ‘541 Patent was dedicated to the public by a Notice of Dedication dated January 20, 2009 which Notice was filed with the Canadian Patent Office on January 20, 2009.

[32] The ‘541 Patent was filed in the Canadian Patent Office on March 6, 1998 and claims priority to U.S. Patent 08/838,900. The priority date is April 11, 1997.

D. The NOA

[33] By letter dated May 7, 2007 Sandoz served its NOA upon the Applicants, pursuant to subsection 5(3) of the NOC Regulations, respecting the Abbreviated New Drug Submission (“ANDS”). The ANDS was filed in respect of Sandoz’s version of clarithromycin extended-release 500 mg tablets for oral administration for the treatment of mild to moderate infections caused by susceptible strains of the designated microorganism of specified diseases of the upper respiratory tract and of the lower respiratory tract.

[34] The NOA was lengthy and raised allegations of non-infringement, improper listing on the Patent Register and invalidity in respect of four patents, that is the ‘714 Patent, the ‘266 Patent, the ‘541 Patent and the ‘395 Patent. Not all of these issues were addressed in the parties’ written Memoranda of Law.

E. The Evidence

[35] Both parties filed affidavits from factual and expert witnesses. The qualifications of the experts is not challenged although each party challenged the credibility and reliability of some of the opinion evidence that was submitted.

i) The Applicants' Witnesses

[36] Abbott filed the affidavits of Ms. Sonia Atwell, Ms. Claire Nachbauer, Dr. Cynthia Holas, Dr. Daniel Weiner and Dr. Gilbert Banker.

[37] Ms. Atwell is a law clerk with the law firm of McCarthy Tétrault LLP, solicitors for the Applicants. In her affidavit, she referenced a letter dated March 28, 2000 from the Canadian Intellectual Property Office requesting the amendment of the '266 Patent.

[38] Ms. Nachbauer is a Senior Paralegal in the Intellectual Property Litigation Department at Abbott Laboratories. She was asked to obtain copies of the study reports on adverse effects data for Abbott Studies M96-454, M97-667, M97-756, M97-734 and M02-472. In her affidavit, she deposed that Studies M95-454, M97-667, M97-756 and M97-734 were catalogued and entered into Abbott's Global Pharmaceutical Regulatory Affairs Department's Research Information Center ("RIC") RIC/Webcat database as of November 17, 1997, March 30, 1999, April 2, 1999 and April 21, 1999, respectively. This means that the study reports and adverse effect data for each of these studies was available to the inventors of Abbott's patents before October 2001.

[39] Dr. Holas is the Assistant Director of Trial Specialty in Clinical Operations at Abbott Laboratories. She had formerly been a Clinical Project Manager with the Anti-Infective Clinical Project Team at Abbott Laboratories from July 2002 to December 2005. In that capacity, she managed Abbott's internal databases. The Clarithromycin Master Inventory List ("CMIL"), which is found on the database, is a complete listing of every study involving clarithromycin that was sponsored or managed by Abbott. Dr. Holas deposed that the M02-472 study was the last Abbott study that was undertaken since 2002.

[40] Dr. Weiner is a statistician at Pharsight Corporation. He holds a Ph.D. in statistics from the University of Kentucky and has worked for more than 25 years in the pharmaceutical industry. He was asked to provide an opinion on the issue of whether certain ER clarithromycin formulations exhibit an improved taste profile and a statistically significant reduction in the severity of adverse effects to the digestive system when compared against IR formulations.

[41] Dr. Weiner dealt with the '395 Patent and in that regard, he conducted a meta-analysis of all relevant Abbott studies to determine whether the ER formulation of the '395 Patent showed an improved taste profile. A meta-analysis involves the pooling of all relevant data, including that from multiple studies, in order to assess the differences in safety results to determine statistical significance. He referred to the CMIL which contains all of Abbott's studies on clarithromycin and selected those studies, for the purpose of his meta-analysis, which showed the following criteria:

(a) The ER formulations had to be 10-30 percent by weight of HPMC;

(b) The studies had to have been head-to-head, in that the ER formulation must have been administered in the same study as the IR formulation to control against variability arising from test differences;

(c) The ER formulations must have been administered in dosages of 1,000 mg once-daily, while the IR formulations had to have been administered in 500 mg twice-daily doses; and

(d) The AUC for the ER clarithromycin formulation had to be bioequivalent to that of the IR formulation, because a requirement under the '395 Patent is that the ER formulation must deliver an equivalent amount of total drug as the IR formulation, although over a longer period.

[42] Applying these parameters, Dr. Weiner concluded that the only relevant studies for use in his meta-analysis were M96-454, M97-667, M97-756, M97-734 and M02-472. Using the Cochran-Mantel-Haenszel ("CMH") method to analyze the pooled data, which compares the ER and IR groups against each other, Dr. Weiner found that the incidence of taste perversion for the ER formulation in the '395 Patent were statistically significantly lower than those under the IR formulation and that there was less than a one in twenty chance that this difference in the incidence of taste perversion between the formulations could have been due to chance alone.

[43] Dr. Banker is Dean Emeritus and the John L. Lach Distinguished Professor of Drug Delivery Emeritus at the University of Iowa College of Pharmacy. He obtained his Ph.D. in 1957

from Purdue University. He was asked to provide an opinion on the allegation of non-infringement and invalidity set out in the NOA.

[44] Dr. Banker addressed a number of issues, beginning with a definition of the person skilled in the art. In his opinion, this person would have experience in the art of pharmaceutical formulation and an understanding of p-kinetics. He would hold a Bachelor of Sciences degree in Chemistry, Pharmacy or something similar, with at least two years experience in the pharmaceutical industry and experience in designing and evaluating formulations.

[45] Dr. Banker commented on the allegations of obviousness and said that a person skilled in the art and reading the six prior art references cited by Sandoz in its NOA would have believed that an attempt to create an ER formulation with clarithromycin and an HPMC polymer would likely result in reduced bioavailability, which is the least desirable outcome for a drug like clarithromycin.

[46] He offered the opinion that even if by experimentation a person skilled in the art reached a bioavailable ER composition using HPMC, it still would not have been obvious how to do so in a way that provides the comparator p-kinetic advantages of the ‘266 and ‘395 Patents, or in a way that achieves an improved taste profile. He said that in the absence of intensive experimentation, a person skilled in the art would not be able to obtain the claimed compositions and accordingly, the subject matter of these patents is not obvious.

[47] Dr. Banker also commented on the actual utility of the ‘395 Patent. He said that the data contained in Table VI of the ‘395 Patent demonstrates that there was indeed an observed improvement in taste profile for the claimed ER composition as compared to the IR composition. Further, while Sandoz alleges that the M97-667 and M97-756 studies show that the claimed compositions do not have an improved taste profile, Dr. Banker disagreed with that allegation. He said that these studies show an observed decrease in the incidence of taste perversion in the formulation claimed by the ‘395 Patent.

[48] Dr. Banker also said that Sandoz’s reference to taste panels and super tasters demonstrates its misconception of the nature of “taste profile”. Taste panels and super tasters relate to the assessment of the taste of a compound on the tongue or in the mouth. This is different from taste perversion as discussed in the ‘395 Patent. There it is defined as an adverse event and occurs after ingestion. According to Dr. Banker, it is inappropriate to use taste panels or super tasters to evaluate taste perversion.

[49] Dr. Banker also addressed the issue of double patenting in relation to the ‘266, ‘541 and ‘395 Patents. He said that there are three specific inventions identified in these three patents and that none of the inventions are invalid for double patenting. He said that the ‘266 Patent claims clarithromycin and HPMC compositions for ER release and as having certain p-kinetics. The ‘541 Patent claims compositions with the added limitation that these compositions have an improved taste profile. Dr. Banker said that there is no double patenting over the ‘266 Patent, since the improved taste profile in the ‘541 Patent is not the same invention as that claimed in the ‘266 Patent,

and because improved p-kinetics and taste profile do not necessarily co-exist with the claims under the ‘266 Patent.

[50] Further, Dr. Banker observed that there is no double patenting over the ‘541 Patent by the ‘395 Patent, since the ‘395 Patent has the additional limitation of a statistically significant reduction in the severity of adverse effects to the digestive system which does not arise from the ‘541 Patent formulations. He noted that a reduction in the severity of effects on the digestive system do not go hand in hand with improved p-kinetics or with an improved taste profile. Accordingly, in Dr. Banker’s opinion, the reduction in the severity of the effects on the digestive system is not obvious from the claims of the ‘266 or ‘541 Patents.

ii) The Respondent’s Witnesses

[51] The Respondent filed the affidavits of Ms. Pamela Christoforakis, Dr. Metin Celik, Dr. Walter G. Chambliss, Dr. Thomas R. Einarson and Dr. Jake J. Thiessen.

[52] Ms. Christoforakis is a law clerk with Hazzard & Hore LLP, solicitors for Sandoz. She attached a copy of the NOA as an exhibit to her affidavit, as well as the 147 prior art references upon which Sandoz relies.

[53] Dr. Celik is a Research Professor of Pharmaceutical Processing at the Department of Industrial and Systems Engineering, Rutgers, The State University of New Jersey and President of Pharmaceutical Technologies International Inc. He obtained a Ph.D. in Pharmaceutical Technology

from De Montfort University in 1984. He was retained to opine on the allegations relating to non-infringement, obviousness, anticipation and double patenting.

[54] With respect to the issue of obviousness relative to the ‘266 Patent, he said that it was known that formulations like those disclosed in the ‘266 Patent would generally reveal the same p-kinetics as those disclosed in the ‘266 patent. As well, he said that the WO 95/30422 patent (the “‘422 patent”) sets out the necessary parameters required of the ‘266 Patent, but uses azithromycin.

[55] Dr. Celik noted that azithromycin, erythromycin and clarithromycin were all known to be similar in their make-up and that if the skilled person would have formulated one of these in a certain way, he would have formulated the others in the same way. In his opinion, it would have been obvious for the skilled person to substitute clarithromycin to arrive at the claimed composition.

[56] Dr. Celik also said that the ‘395 Patent is obvious, since it was known by the 1990’s that macrolide antibiotics like clarithromycin exhibited concentration-dependent side effects and that these side effects could be reduced by limiting the concentration of the dose.

[57] Dr. Chambliss is a Professor of Pharmaceutics at the University of Mississippi and a Research Professor in the National Center for Natural Products Research in the Research Institute of Pharmaceutical Sciences at the University of Mississippi. He obtained his Ph.D. in Pharmaceutics in 1982 from the University of Mississippi. He was asked to give an opinion on Sandoz’s allegations of invalidity in respect of the ‘266 and ‘395 Patents.

[58] Dr. Chambliss also addressed the notion of the person skilled in the art, on behalf of Sandoz, and said that such person would be one with a Ph.D. in pharmaceutical science or a similar field, with at least two years experience in either pharmaceutical formulations or in an equivalent field. He offered an alternative definition, that is a person holding a Bachelor's or Master's degree in the said field but with significantly more experience in formulating pharmaceutical products.

[59] Dr. Chambliss addressed the allegation of obviousness in relation to the '266 and '395 Patents. He tendered the opinion that these patents are obvious in light of the prior art, as of the claim date of April 11, 1997. He said that it was well known at this date that hydrophilic polymers like HPMC could be used to make the ER formulation claimed.

[60] Dr. Chambliss also said that as of the relevant date, the prior art showed how to make ER formulations using HPMC, teaching in particular that low viscosity grades were appropriate for poorly water soluble drugs like clarithromycin.

[61] Dr. Chambliss also said that clarithromycin could easily be substituted for known formulations consisting of a similar drug called azithromycin such that a skilled person would have been led easily to the claimed patents. He also said that the p-kinetics claimed in the '266 Patent were well-known and previously disclosed.

[62] Dr. Chambliss addressed the allegation of lack of sound prediction utility in relation to the '395 Patent. He used a broader interpretation of taste perversion than was used by Dr. Banker and

said that a skilled person would understand the term as referring to both the initial taste of the drug in the mouth of a patient and any undesirable taste resulting from the systemic effects of ingestion. He said that the prior art reveals a broader definition of taste perversion than that offered by Dr. Banker.

[63] Dr. Chambliss also said that the Abbott studies that allegedly show an improved taste profile used an inadequate number of subjects such that the results cannot be considered statistically significant. He said that it was not known if the comparative IR tablets had an aqueous coating. This coating has been previously found to enhance taste profile. If the ER tablets were coated and the IR tablets were not, this might explain any noted improvement in taste profile, as between the ER and IR compositions.

[64] Finally, Dr. Chambliss commented on the allegation of invalidity on the basis of double patenting, in reference to the ‘266, ‘541 and ‘395 Patents. He expressed the opinion that these three patents each disclose and claim the same formulation. The claims of the ‘266 Patent cover p-kinetics, the claims of the ‘541 Patent cover improved taste profile and the claims of the ‘395 Patent cover p-kinetics and improved taste profile. In Dr. Chambliss’ opinion, the claims overlap and so the ‘395 Patent is invalid for double patenting.

[65] Dr. Einarson is an Associate Professor of Pharmacy Administration at the Leslie Dan Faculty of Pharmacy at the University of Toronto and an Associate Professor of Health Policy, Management and Evaluation at the Faculty of Medicine, also at the University of Toronto. He

obtained his Ph.D. in Pharmacy in 1987 from the University of Arizona. He was asked to provide an opinion on the meta-analysis that was conducted by Dr. Weiner.

[66] Dr. Einarson addressed the issue of lack of actual utility of the ‘395 Patent. He reviewed the meta-analysis that was conducted by Dr. Weiner and concluded that it was flawed. He said that the five studies that Dr. Weiner considered differ in design and patient population and that Dr. Weiner used a method of analysis, that is the fixed effects model that is customarily used only when study protocols are the same. Dr. Einarson said that the proper method was the random effects model, which accounts for differences in the study protocols.

[67] Dr. Einarson also criticized Dr. Weiner for having failed to conduct a proper literature search. He said that he himself had conducted a search and had located thirty-five studies regarding adverse effects of clarithromycin between ER and IR formulations. After combining these studies with those chosen by Dr. Weiner, he concluded that there was not a statistically significant difference in taste profile between the ER and IR compositions.

[68] Dr. Thiessen is the Hallman Director of the School of Pharmacy and the Director of the Health Sciences Campus at the University of Waterloo. He was asked to give an opinion on the issues of the lack of actual utility and the lack of sound prediction utility.

[69] He reviewed the product monographs for Abbott’s various forms of clarithromycin and found that there was no difference in taste profile between the IR and ER compositions. He also

concluded that two articles, one by John Murray et al. and the other by Jay Adler et al., each of which was co-authored by an employee of Abbott, did not show any difference in taste profile between the two compositions. He concluded that the ER composition lacked utility.

[70] Dr. Thiessen considered the M96-454 study done by Abbott. He expressed the opinion that this study, which is the only one available as of the Canadian filing date of March 6, 1998, provides a sample group that is too small to give any meaningful result relative to the issue of taste profile. He said that the conclusions in this study concerning the incidences of taste perversion were also inconclusive because the amount of lactose used in the ER versus the IR formulation could have impacted on the taste results. He concluded that the improved taste profile of the ER composition was not soundly predicted.

II. Issues

[71] The following issues arise from this application:

1. Should the Court permit the admission of new evidence from Sandoz relative to the ‘395 Patent?
2. How should Claims 11 and 12 of the ‘266 Patent and Claim 22 of the ‘395 Patent be construed?
3. Are Sandoz’s allegations of invalidity respecting the ‘266 and ‘395 Patents valid in relation to:
    (a) Obviousness of the ‘266 and ‘395 Patents;
    (b) Actual utility of the ‘395 Patent;

(c) Sound prediction utility of the ‘395 Patent; and

(d) Double Patenting in relation to the ‘395 Patent over the ‘266 and ‘541 Patents.

III. Discussion and Disposition

[72] The parties filed a considerable amount of evidence in relation to this proceeding. I will not refer to all of the evidence contained within the record but instead will base my conclusions upon that evidence which I found to be most relevant, credible and reliable. I have not ignored evidence to which I do not explicitly refer.

A. Nature of This Proceeding

[73] This application seeks to prohibit the issuance of a NOC to the Respondent for its product which contains clarithromycin. The Applicants challenge the Respondent’s NOA on the grounds that the allegations of invalidity of the ‘266, and ‘395 Patents are not justified.

[74] A NOC grants marketing approval for drugs in Canada. It is issued by the Federal Government, indicating that all requirements have been met pursuant to the Food and Drug Regulations for the protection of public health and safety. The NOC Regulations authorize owners of existing patents for pharmaceutical products to file a “patent list” relative to those products for which they hold a NOC. The NOC Regulations refer to the person filing such a list as the “first person”. In this case, the Applicants are the “first person”.

[75] The framework of the NOC Regulations allows generic drug manufacturers to rely on prior approval of related pharmaceutical products in applying for marketing approval of their generic form of the products. Manufacturers who produce the same drug may file an application for a NOC that refers to and relies on the fact that prior approval has been granted for the brand-name version of the drug. Such a manufacturer is known as the “second person” and that is the Respondent’s status.

[76] The NOC Regulations prohibit the Minister of Health from issuing a NOC until all relevant product and use patents in the earlier approved medicine, as described in the patent list, have expired. Consequently, a second person must either wait until patent expiry before receiving a NOC or it may submit a NOA to the Minister with its new drug submission.

[77] The NOC Regulations require service of the NOA upon the first person. Section 5 sets out the grounds upon which a NOA is to be based. Briefly, the NOA must assert either that the first person is not the patentee, that the patent is expired or invalid, or that it would not be infringed if a NOC were issued.

[78] Following service of the NOA, the Minister may issue a NOC to the second person, unless the first person avails of its right, pursuant to section 6(1) of the NOC Regulations, to seek an order from the Federal Court prohibiting the Minister from issuing the NOC. Any such step must be taken by the first person within 45 days after receipt of the NOA and once such a proceeding is

commenced, the issuance of a NOC to the second person is stayed for a maximum period of twenty-four months.

B. Burden of Proof

[79] Before addressing the specific aspects of this case, I will briefly address the jurisprudence applicable to the burden of proof and the question that must be answered in a NOC proceeding. It is well-established that the burden of proving that the second person's, that is, Sandoz's, allegations are not justified is on the person seeking the Prohibition Order, Abbott. Abbott must establish, on a balance of probabilities, that Sandoz's allegations are not justified. Sandoz must put its allegations "in play" through its NOA. However, once that has been done, Abbott bears the burden of proving that such allegations are not justified, on a balance of probabilities: see *Eli Lilly Co. v. Nu-Pharm Inc.* (1996), 69 C.P.R. (3d) 1 (F.C.A.), *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)* (1994), 55 C.P.R. (3d) 302 (F.C.A.) and *SmithKline Beecham Pharma Inc. v. Apotex Inc.*, [2001] 4 F.C. 518 (T.D.), aff'd (2002), 291 N.R. 168 (F.C.A.).

[80] Second, the Court must determine whether Sandoz's allegations of invalidity are justified or not. In *Pharmacia Inc. v. Canada (Minister of National Health and Welfare)* (1994), 58 C.P.R. (3d) 209 (F.C.A.) ("*Pharmacia*") the Federal Court of Appeal commented upon the standard to be applied to this type of proceeding, at page 216:

> ...these proceedings are not actions for determining validity or infringement: rather they are proceedings to determine whether the Minister may issue a notice of compliance. That decision must turn on whether there are allegations by the generic company sufficiently substantiated to support a conclusion for administrative purposes (the

> issue of a notice of compliance) that the applicant's patent would not be infringed if the generic's product is put on the market…

[81] In *Smith Kline,* Justice Gibson considered the evidentiary burden in proceedings under the NOC Regulations where invalidity of a patent is alleged. At pages 533 to 534 he wrote the following:

> Against the foregoing, I conclude that while an evidential burden lies on Apotex to put each of the issues raised in its Notice of Allegation in play, if it is successful in doing so, the persuasive burden or legal burden then lies with SmithKline. Assuming Apotex to be successful in putting the issue of validity of the '637 Patent in play, SmithKline is entitled to rely on the presumption of validity of the patent created by subsection 43(2) of the Act.
>
> The persuasive burden or legal burden that lies with SmithKline in the circumstances described in the preceding paragraph is, however, impacted by the nature of the proceeding here before the Court. In *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)*, [(1994), 55 C.P.R. (3d) 302 (F.C.A.)] Mr. Justice Hugessen, for the Court, wrote at pages 319-20:
>
> > As I understand the scheme of the regulations, it is the party moving under s. 6, in this case Merck, which, as the initiator of the proceedings, has the carriage of the litigation and bears the initial burden of proof. That burden, as it seems to me, is a difficult one since it must be to disprove some or all of the allegations in the notice of allegation which, if left unchallenged, would allow the Minister to issue a notice of compliance.
> >
> > …
> >
> > In this connection, it may be noted that, while s. 7(2)(b) [of the Regulations] seems to envisage the court making a declaration of invalidity or non-infringement, it is clear to me that such declaration could not be given in the course of the s. 6 proceedings themselves. Those proceedings, after all, are instituted by the patentee and seek a prohibition against the Minister; since they take the form of a summary application for judicial review, it is impossible to conceive of them

> giving rise to a counterclaim by the respondent seeking such a declaration. Patent invalidity, like patent infringement, cannot be litigated in this kind of proceeding.
>
> Thus, the burden on SmithKline is only to disprove the allegations in the notice of allegation, not to justify declaration of validity and infringement or conversely to negative claims for declarations of invalidity and non-infringement.

[82] The burden lies on Abbott, as the Applicants, to refute the allegations set forth by Sandoz in its NOA dated May 7, 2007. Therefore, like any plaintiff or applicant, Abbott has the overall legal burden of proof. Sandoz, as the Respondent, has an obligation to put the allegations set out in its NOA in play.

[83] The present proceeding is a summary proceeding pursuant to the NOC Regulations and the *Federal Court Rules, 1998*, SOR/98-106 (the "Rules") governing applications for judicial review. A finding of invalidity or infringement in the context of this type of proceeding is not determinative of that issue in any subsequent action: *Pharmacia* at page 216.

Issue 1: Admission of Sandoz's Additional Evidence

[84] Prior to the hearing, Abbott brought a motion seeking to strike paragraphs 88 to 93 and 96 of Dr. Thiessen's affidavit on the basis that these paragraphs address matters that exceed the scope of the NOA. The Respondent defended the inclusion of these paragraphs on the grounds that the evidence was proper reply to the evidence submitted by the Applicants. Prothonotary Aalto ruled that the Applications Judge would be better placed to deal with the status of the challenged paragraphs.

[85] Paragraphs 88 to 93 and paragraph 96 address the contents of Abbott's product monographs for BIAXIN, BIAXIN BID and BIAXIN XL contained within the 2006 Compendium of Pharmaceuticals and Specialties, and relates to Sandoz's allegations of the apparent lack of improvement in taste profile in Abbott's ER tablet as compared to the IR equivalent. The evidence of Dr. Thiessen is directed at undermining the conclusions of the Applicants' evidence. In this regard, I am satisfied that Dr. Thiessen's evidence is admissible as reply evidence.

[86] The exhibits attached to Dr. Thiessen's affidavit in relation to the challenged paragraphs consist of product monographs and labels, and are also admissible as they serve as the basis for his evidence in reply. Further, the documents were produced by Abbott in the course of its business and were known to the Applicants. While the Applicants argue that the documents should not be admitted into evidence because it has been shown, during the cross examination of Dr. Thiessen, that the Respondent failed to disclose certain materials to Dr. Thiessen before he gave his opinion, that is a matter that goes to the weight to be given to the evidence in question and not to its admissibility.

[87] In any event, in the course of oral argument, the Respondent did not actively pursue any submissions on the issue of the product labels.

Issue 2: Claims Construction

[88] The first step in determining whether Sandoz's allegations of invalidity are justified is to construe the disputed claims of the '266 and '395 Patents. As held by the Supreme Court of Canada

in *Whirlpool Corp. v. Camco Inc.*, [2000] 2 S.C.R. 1067 ("*Whirlpool*") and *Free World Trust v. Électro Santé Inc.* (2000), 9 C.P.R. (4th) 168 ("*Free World Trust*") the patent claim is to be construed in a "purposive" way and the Court must look at the entire specification of the patent in order to understand the words as stated in a disputed claim, provided this does not enlarge or contract the scope of the actual patent claims.

[89] Claims construction is a question of law for the Court to decide: *Whirlpool* at 1111. The key to purposive construction involves a realistic construction of the language of the claims through the eyes, and with the learning, of a person skilled in the art: *Whirlpool* at 1090-91. The Court must identify the particular words or phrases in the patent claims that describe what the inventor considered to be the "essential elements of his invention": *Whirlpool* at 1091.

[90] In *Free World Trust* at para. 31, Justice Binnie listed the principles that guide the purposive approach to the construction of a claim:

> (a) The Act promotes adherence to the language of the claims.
> (b) Adherence to the language of the claims in turn promotes both fairness and predictability.
> (c) The claim language must, however, be read in an informed and purposive way.
> (d) The language of the claims thus construed defines the monopoly. There is no recourse to such vague notions as the "spirit of the invention" to expand it further.
> (e) The claims language will, on a purposive construction, show that some elements of the claimed invention are essential while others are non-essential. The identification of elements as essential or non-essential 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 invention.

(f) There is no infringement if an essential element is different or omitted. There may still be infringement, however, if non-essential elements are substituted or omitted.

[91] The decisions in *Free World Trust* and *Whirlpool* emphasize the interpretation of claims in light of the specification of a patent. When applying a purposive approach to the interpretation of the words or phrases in a claim, the Court should keep within the four corners of the specification, limiting itself to the words of the claim, interpreted in the context of the specification as a whole. It should avoid the use of extrinsic evidence of intent: *Whirlpool* at 1095. While expert evidence is admissible, its use should be limited to assisting the Court in interpreting the claims in a knowledgeable way: *Whirlpool* at 1102.

[92] The claims of the '266 Patent that are relevant to this application are Claims 11 and 12. These state as follows:

> 11. The extended release pharmaceutical composition according to any one of claims 1 to 10, wherein the erythromycin derivative is clarithromycin.
>
> 12. The extended release pharmaceutical composition according to claim 11, wherein the composition comprises 50 percent, by weight, of clarithromycin.

[93] The claim of the ‘395 Patent that is relevant to this application is Claim 22. It states as follows:

> 22. The extended release pharmaceutical composition according to any of claims 12 to 21, wherein the composition has an improved taste profile compared to the immediate release composition of clarithromycin.

[94] The Applicants submit that a skilled person would understand Claims 11 and 12 to cover ER compositions of clarithromycin that have between 45-60 percent clarithromycin (Claim 11) or 50 percent clarithromycin (Claim 12), contain HPMC (Claim 10) in the range of 10-30 percent (Claim 10) and of a viscosity of 50 to 200 cps (Claim 5), and exhibit specific favourable p-kinetics (Claims 1, 2 and 3).

[95] Further, Abbott argues that the skilled person would understand Claim 22 in the ‘395 Patent to have the same meaning given above for Claim 12 of the ‘266 Patent, with the added limitation that the composition has an improved taste profile as compared to the IR composition.

[96] The Respondent submits that both claims should be construed as covering an ER clarithromycin tablet with p-kinetic factors described in three different ways (Claims 1 – 3), containing HPMC (Claim 4) with a low viscosity grade of 50 to 200 cps (Claim 5), where the amount of HPMC and/or clarithromycin is defined in one of four ways: (i) the HPMC is 5 to 45 percent of the weight of the tablet (Claim 7) or (ii) 10 – 30 percent of the weight of the tablet (Claim 10) or (iii) the clarithromycin is 45 – 60 percent of the weight of the tablet (Claim 8) or 50 percent weight of the tablet (Claim 9 or Claim 12). It argues that Claim 22 of the ‘395 Patent should be

construed so as to include the same ER tablet claimed in the ‘266 Patent, with the added limitation that such a formulation must exhibit an improved taste profile as compared to the IR equivalent.

[97] In the course of oral submissions, the Respondent argued that Claims 11 and 12 should be construed as multiple dependant claims referring back to Claim 1. The Applicants resisted this submission on two grounds.

[98] First, the Applicants submitted that this argument was not raised in the NOA and should not be entertained at this late stage. Second, the Applicants argued that pursuant to subsection 27.5 of the *Patent Act*, it is their choice as to which of Claims 1 through 10 they assert with respect to the construction of Claims 11 and 12. In support of this argument, they rely upon the decision of Justice Hughes in *G.D. Searle & Co. v. Novopharm Ltd.* (2007), 56 C.P.R. (4th) 1. On this point, they state that they have chosen to assert Claim 10, in that the formulation should contain between 10 and 30 percent by weight of HPMC.

[99] As previously noted, the ‘266 Patent is entitled “Extended Release Formulations of Erythromycin Derivatives”. Its filing date is March 6, 1998, with a publication date of October 22, 1998. It claims priority from US Patent 08/838,900, with a priority date of April 11, 1997. The ‘266 Patent contains twelve claims. Of these, Claims 11 and 12 are here at issue in this proceeding.

[100] In my opinion, the claims of the ‘266 Patent here at issue would be read by a skilled person as referring to an ER clarithromycin and polymer matrix composition that demonstrates improvements over its IR equivalent. The Abstract of the ‘266 Patent says the following:

> The composition comprises an erythromycin derivative and a pharmaceutically acceptable polymer so that, when ingested orally, the composition induces statistically significantly lower Cmax in the plasma than an immediate release composition…while maintaining bioavailability and minimum concentration substantially equivalent to that of the immediate release composition…

[101] Claims 11 and 12 must be construed upon the basis of the common knowledge of the person skilled in the art as of the date the patent was published, that is October 22, 1998.

[102] Claims 11 and 12 build upon the preceding claims of the ‘266 Patent, providing the skilled person with the ability to choose from amongst a range of possibilities in creating the claimed composition. As I have observed above, Claim 11 provides one limitation, however, that being that the erythromycin derivative that is selected must be clarithromycin. Claim 12 adds the further limitation, requiring that whatever formulation is created under Claim 11 must contain 50 percent by weight of clarithromycin.

[103] In my opinion, Claim 11 should be construed as follows:

(a) An ER clarithromycin formulation (Claims 1, 2, 3 and 11);

(b) which exhibits a significantly lower DFL than the IR equivalent (Claim 1);

(c) which exhibits a C-max lower than that produced by the IR equivalent (Claim 2);

(d) which maintains bioavailability substantially similar to the IR equivalent (Claim 1);

(e) which maintains a C-min substantially similar to the IR equivalent (Claim 2);

(f) which maintains an AUC substantially similar to the IR equivalent (Claims 2 and 3);

(g) which contains between 5 and 50 percent of clarithromycin by weight (Claims 1, 2 and 3);

(h) which is also comprised of the pharmaceutically acceptable polymer HPMC (Claim 4);

(i) the percentage of HPMC by weight being in a range between 10 and 30 percent by weight (Claim 10);

(j) and the HPMC also being of a low viscosity rating, ranging from 50 to 200 cps (Claim 5).

[104] Claim 12 should be construed in the same manner, with the added limitation that the percentage by weight of clarithromycin in the composition should be 50 percent.

[105] As stated above, the ‘395 Patent is also entitled “Extended Release Formulations of Erythromycin Derivatives”. Its filing date is March 6, 1998, with a publication date of October 22, 1998. It claims priority from US Patent 08/838,900, with a priority date of April 11, 1997. The ‘395 Patent contains 139 claims. Of these, only Claim 22 is at issue.

[106] The construction of Claim 22 must likewise be performed upon the basis of the common knowledge of the skilled person as of October 22, 1998. In my view, the person skilled in the art would read the ‘395 Patent as revealing what is essentially the same invention as that claimed in the

‘266 patent, with the added limitation listed in Claim 22 that the composition must exhibit an improved taste profile as compared against its IR equivalent.

Issue 3: Invalidity

A. Obviousness

[107] Obviousness is the only allegation of invalidity that the Respondent raised against the ‘266 Patent. It was also raised in respect of the ‘395 Patent. Given the similarities between what is claimed in the ‘266 and ‘395 Patents, I will assess the allegations of obviousness in respect of both patents together. Section 28.3 of the *Patent Act* requires that an invention disclosed in a patent not be obvious. Section 28.3 provides as follows:

The subject-matter defined by a claim in an application for a patent in Canada must be subject-matter that would not have been obvious on the claim date to a person skilled in the art or science to which it pertains, having regard to	L’objet que définit la revendication d’une demande de brevet ne doit pas, à la date de la revendication, être évident pour une personne versée dans l’art ou la science dont relève l’objet, eu égard à toute communication :
(a) information disclosed 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 information became available to the public in Canada or elsewhere; and	a) qui a été faite, plus d’un an avant la date de dépôt de la demande, par le demandeur ou un tiers ayant obtenu de lui l’information à cet égard de façon directe ou autrement, de manière telle qu’elle est devenue accessible au public au Canada ou ailleurs;
(b) information disclosed before the claim date by a person not mentioned in paragraph (a) in such a manner	b) qui a été faite par toute autre personne avant la date de la revendication de manière telle qu’elle est devenue accessible au public au Canada ou

that the information became available to the public in Canada or elsewhere.	ailleurs.

[108] In *Apotex v. Sanofi*, [2008] 3 S.C.R. 265 ("*Sanofi*"), the Supreme Court of Canada set out the prevailing test for obviousness in Canada. This requires the Court to look at the following elements:

(a) identify the skilled person to whom the patent is addressed and the state of the art known to that person;

(b) identify the inventive concept in the claims, having regard to the disclosure if the claims do not expand on that concept;

(c) determine the differences between what was previously known and the inventive concept in the claims; and

(d) determine if those differences would be obvious without the benefit of hindsight.

[109] If the "obvious to try" test is appropriate, Justice Rothstein in *Sanofi* identified four additional but non-exhaustive factors to consider under the fourth step:

(a) Is it more or less self-evident that what is being tried ought to work? Are there a finite number of identified predictable solutions known to persons skilled in the art?

(b) What is the extent, nature and amount of effort required to achieve the invention? Are routine trials carried out or is the experimentation prolonged and arduous, such that the trials would not be considered routine?

(c) Is there a motive provided in the prior art to find the solution the patent addresses?

(d) What is the course of conduct followed in arriving at the invention?

i.) The Person Skilled in the Art and the Common General Knowledge

[110] The Applicants' witness, Dr. Banker, suggests that the person skilled in the art would hold a Bachelor of Science degree in chemistry, physics or something similar, with at least two years experience in the pharmaceutical industry, including experience in the design and evaluation of formulations.

[111] On behalf of the Respondent, its witness, Dr. Chambliss says that the skilled person would hold a Ph.D. in a pharmaceutical science or related field, and have at least two years experience in either formulations or a related field. Alternatively, he would accept that the skilled person hold a Bachelor's or Master's degree in the same field, but have significantly more experience in formulating pharmaceutical products.

[112] I am not persuaded that the skilled person requires the higher academic qualification mentioned by Dr. Chambliss and find that, for present purposes, the person skilled in the art would satisfy the requirements identified by Dr. Banker. This would mean that the skilled person would possess a Bachelor's degree in chemistry or physics with at least two years experience in the pharmaceutical industry, including work in the design and evaluation of pharmaceutical formulations.

[113] Erythromycin and its derivatives fall within a class of drugs known as macrolides. This was amongst the known facts of which the skilled person would have been aware. In addition, it was well known that an IR composition of clarithromycin existed. HPMC was a well-known suspension agent, and I am satisfied that the skilled person would have been aware that this polymer was amongst those available that could be used in formulating an ER composition. The level of viscosity and water solubility of a drug were also known to impact on the release rate of a drug contained within a matrix formulation. Further, it was known that clarithromycin was a poorly soluble drug.

[114] There is no dispute between the parties that the p-kinetics disclosed within the ‘266 and ‘395 Patents are beneficial. I am satisfied that the skilled person would have recognized the importance of these p-kinetics. That being said, I do not find that the p-kinetics disclosed in the ‘266 Patent and ‘395 Patents were inherent in ER formulations or that it was otherwise self-evident that formulating the claimed compositions would have resulted in these p-kinetics. This will be addressed in greater detail below.

[115] In respect of the common general knowledge relating specifically to the ‘395 Patent, it was known that clarithromycin exhibited a bitter metallic taste, which was commonly referred to as taste perversion. This is taught in the article by Harold Neu and Thomas Chick labeled Sandoz Document 64 and is disclosed within the ‘395 Patent specification. The person skilled in the art would also understand that taste perversion was experienced by patients who took the IR formulation.

[116] There was some disagreement between the parties as to the correct definition of "taste perversion". While Dr. Banker, on behalf of the Applicants, suggested that taste perversion occurs following ingestion of the formulation, the Respondent argues that it includes both the taste of the product on the tongue, *and* the effect occurring following ingestion. I accept the Respondent's interpretation. There is nothing in the patent or the prior art that supports the narrow definition of taste perversion suggested by Dr. Banker. Rather, the '395 patent itself states that one method of countering taste perversion in the prior art has been to develop a palatable liquid oral dosage form of the drug. In my view, "palatable" suggests a substance with an acceptable taste in the mouth, and appears to support the broader interpretation of taste perversion. I conclude that it would be understood as part of the common general knowledge that taste perversion refers to both taste in the mouth and taste following ingestion.

ii) The Inventive Concept

[117] The Applicants argue that the inventive concept of Claims 11 and 12 of the '266 Patent is a specific ER composition with a clarithromycin–HPMC matrix that provides favourable p-kinetics such that it is suitable for once-daily dosing. The specific compositions are 45 to 60 percent, or 50 percent of clarithromycin and contain 10 to 30 percent HPMC of a low viscosity of 50 to 200 cps. In this regard, Abbott relies on the evidence of Dr. Banker.

[118] Sandoz submits that the inventive concept of the relevant claim is only the adaptation of known technology to produce an ER formulation of a known drug, that is clarithromycin, and that the favourable p-kinetics are not themselves claimed.

[119] I am not persuaded by the Respondent's submissions in this regard. The language of Claims 11 and 12 is clear. The subject of Claim 11 is "the extended release pharmaceutical composition according to any one of Claims 1 to 10…" The subject of Claim 12 is "the extended release pharmaceutical composition according to Claim 12, wherein the composition comprises 50% by weight, of clarithromycin." Claims 11 and 12 therefore relate to ER compositions that possess the favourable p-kinetics introduced in Claims 1, 2 and 3, those being a lower DFL, a lower C-max and a substantially comparable C-min, AUC and bioavailability as compared against an equivalent IR clarithromycin formulation.

[120] In my opinion, the inventive concept of the '395 Patent is essentially the same as that claimed in the '266 Patent, with the added limitation in Claim 22 that the composition must exhibit an improved taste profile as compared against its IR equivalent.

iii) Differences between the "state of the art" and the inventive concept of the claim

[121] This inquiry relates to the differences between the matter cited as forming part of the prior art and the inventive concept of the claims. In relation to the '266 Patent, the particular differences can be listed as follows:

(a) the selection of HPMC for an ER clarithromycin formulation;

(b) the selection of HPMC with a viscosity in the range between 50 and 200 cps for an ER clarithromycin formulation;

(c) the selection of HPMC in the range between 10 and 30 percent by weight within an ER clarithromycin formulation;

(d) the selection of clarithromycin in the range between 45 and 60 percent (Claim 11) or 50 percent (Claim 12) by weight within an ER clarithromycin formulation; and

(e) the creation of a precise ER clarithromycin formulation that demonstrates the particular p-kinetics claimed within the ‘266 Patent.

[122] With respect to the ‘395 Patent, the particular difference is the creation of a precise ER clarithromycin formulation that demonstrates an improved taste profile when compared against an IR equivalent formulation.

iv) Are these steps obvious to the skilled person or do they require a degree of invention?

(a) Is it self-evident that what is being tried ought to work?

The HPMC

[123] Although there is evidence contained within Sandoz Document 27, the various Dow Chemical brochures labeled as Sandoz Documents 23, 39 and 81 and the ’143 patent that reveal that HPMC was a commonly used polymer for creating extended release compositions, Dr. Celik on his cross-examination could not identify one poorly soluble drug, like clarithromycin, that utilizes HPMC.

[124] In addition, US Patent 4,871,548 (the "'548 patent"), Sandoz Document 40 teaches that for nearly insoluble drugs (of which clarithromycin is an example), hydrophilic matrices are not the most appropriate system for sustained delivery due to difficulties associated with the erosion process. In my view, this indicates that the skilled person would not favour the selection of HPMC in an attempt to formulate the claimed composition. As well, Dr. Banker explains the difficulties of using HPMC alone, and not in combination with another polymer, as disclosed in European Publication ER 0 280 571 (the "'571 patent"), Sandoz Document 32.

[125] While US Patent 4,369,172 Patent (the "'172 patent"), Sandoz Document 11 teaches the use of HPMC on its own, there is nothing in the prior art that would suggest that this formulation would be suitable for ER formulations containing clarithromycin.

[126] Further, Dr. Banker states in his affidavit that when HPMC was used as described within the prior art to control drug release, it was often done when all or the majority of the drug in question was being released in under eight hours. In my opinion, this would not lead the skilled person to create a drug composition for release over 24 hours as is required of the '266 Patent.

[127] Finally, the Applicants created '714 alginate composition without using HPMC. Following the decisions in *Sanofi* and *Windsurfing Int'l Inc. v. Bic Sports Inc.* (1985), 8 C.P.R. (3d) 241 (F.C.A.) ("*Windsurfing*"), the fact that a prior user failed to achieve the invention in question may serve as evidence of invention.

[128] In sum, I find that the prior art fails to disclose that it would have been self-evident to use HPMC in arriving at the claimed composition.

The Viscosity of the HPMC

[129] Next, there is the selection of the viscosity of the HPMC. In spite of the Respondent's argument, US Patent 5,393,765 (the "'765 patent), Sandoz Document 88 does not teach the use of a low viscosity polymer for poorly soluble drugs but rather the use of a low viscosity polymer for *highly* soluble drugs. In my opinion, this teaches away from the use of a low viscosity HPMC within a formulation containing a poorly soluble drug like clarithromycin. Consequently, it would not be self-evident to the skilled person to apply these teachings in order to arrive at the formulation contained within the '266 Patent.

[130] The '172 patent teaches the use of low viscosity polymers for ER formulations of both water soluble and poorly soluble drugs and is thus too broad to be of assistance. This patent does not make the choice of low viscosity HPMC self-evident.

[131] The '548 patent teaches a high viscosity HPMC as functioning together with a low viscosity HPMC. It is not clear from this patent that a skilled person could remove the high viscosity HPMC in order to arrive at the composition claimed in the '266 Patent.

[132] I conclude that the prior art would not lead the skilled person to use a low viscosity HPMC with a poorly water soluble drug like clarithromycin.

The Percentage by Weight of HPMC

[133] The Respondent relies on the affidavit evidence of Dr. Celik in support of its argument that the skilled person could have applied the "Higuchi equation", a complex mathematical calculation, in order to determine the appropriate amount of HPMC to use in arriving at the claimed composition.

[134] However, on cross-examination Dr. Celik admitted that this equation cannot be used to determine in advance the amount of polymer required in a matrix formulation. It stands to reason then that the requisite percentage of HPMC would not be made self-evident through the application of this equation.

[135] The '172 patent teaches the use of HPMC with a virtually infinite number of drugs in the unhelpful range of between 0.5 percent to 99.9 percent by weight of the polymer. Again, this would not assist the skilled person.

[136] US Patent 4,571,333 (the "'333 patent"), Sandoz Document 20 provides examples of HPMC by weight between 4 and 6 percent and 4 and 9 percent respectively. However, these are also of a viscosity between 80,000 to 130,000 cps. The viscosity of HPMC used in the '266 Patent is between 50 and 200 cps. This difference militates against obviousness in the choice of this amount of HPMC in formulating the composition.

[137] The ‘143 patent teaches the use of at least 1/3 by weight of the polymer. This exceeds the amount permitted within the composition claimed in the ‘266 Patent as construed.

[138] Finally, the Respondent relies upon the teachings of International Publication WO 95/30422 (the “’422 patent), Sandoz Document 92, which reveals the use of between 10 and 30 percent by weight of HPMC in a composition. For reasons discussed below, given the significant and important differences between clarithromycin and the azithromycin, the latter being the drug used in the ‘422 patent, I am not persuaded that the skilled person would have been led to apply the teachings of this patent to arrive at the claimed composition.

[139] In the result, I conclude that the skilled person would not have been directed by the prior art to utilize between 10 and 30 percent by weight of HPMC in formulating the matrix composition. Even if this proportion is obvious, however, the fact that the remaining components of the matrix formulation are not obvious supports the ultimate conclusion that the ‘266 Patent is not invalid for obviousness.

The Percentage by Weight of Clarithromycin

[140] The examples cited by the Respondent from the ‘172 patent do not show that it was obvious to use the specified percentage of clarithromycin in the composition. In this regard, the Respondent directs the Court to examples one to six and nine of the ‘172 patent.

[141] These examples show only the use of 50 percent of *a* drug. There is no indication that these drugs are similar to clarithromycin or that these teachings would apply to the claimed composition. None of the examples in the ‘172 patent are sufficiently specific to be helpful in leading the skilled person to formulate the claimed composition.

[142] The Respondent again relies upon the ‘422 patent, which demonstrates the use of 54 percent by weight of azithromycin within a composition. As stated, for reasons discussed below, I am not satisfied that the skilled person would be led to apply the teachings of this patent to arrive at the ‘266 Patent formulation.

[143] I find that the prior art fails to disclose that it would have been self-evident to select the specific percentage of clarithromycin called for in the ‘266 Patent.

The Favourable P-kinetics

[144] Initially, the Respondent argues that favourable p-kinetics are not a part of what is being claimed by the ‘266 Patent. However, I have construed the patent so as to include these p-kinetics.

[145] The Respondent then argues that favourable p-kinetics are inherent in any ER composition. This view, however, is not supported by Dr. Banker, whose evidence I prefer over that of the Respondent’s witnesses. Dr. Banker deposed that the favourable p-kinetics disclosed in the ‘266 Patent are not inherently found in ER formulations.

[146] Dr. Banker also said that there can be differences in the ADME of various compositions and accordingly *in vivo* testing is required to determine the comparator p-kinetics. He said that there was no *in-vivo / in-vitro* correlation ("IVIVC") established for any ER clarithromycin product as of 2006 such that the skilled person could accurately predict, absent *in-vivo* testing, the p-kinetics of an ER dosage.

[147] Furthermore, the alginate ER composition claimed by the '714 Patent, which contains clarithromycin as the active ingredient, did not demonstrate the favourable p-kinetics of the '266 Patent, indicating that these parameters are not "inherent" to every ER composition.

[148] Dr. Celik stated that the applicable Health Canada guidelines dealing with drug approvals actually require that the drug exhibit these p-kinetics. However, on cross examination he admitted that he had been mistaken as to the applicable guideline, and that the guideline to which the drug was actually subject does not require these p-kinetics.

[149] I conclude, then, that there is a lack of evidence demonstrating that the p-kinetics claimed in the '266 Patent are inherent in any ER formulation. Furthermore, it is not self-evident from the prior art that formulating the '266 matrix composition would have led to the favourable p-kinetics claimed.

Substituting Clarithromycin for Azithromycin

[150] The “substitution” argument advanced by the Respondent was based upon the evidence of Dr. Chambliss and Dr. Celik. These expert witnesses canvassed the similarities between azithromycin and clarithromycin, namely that both are macrolides, possess similar chemical structures and can exhibit similar p-kinetic parameters. They stated that in light of these similarities, the skilled person would understand that one drug could be substituted for the other.

[151] Each witness then pointed to the ‘422 patent, noting that it claimed an ER azithromycin composition containing HPMC. Given that the skilled person would understand that clarithromycin could be substituted for azithromycin, and in light of the significant similarities between the make-up of the formulations claimed within the ‘422 and ‘266 Patents, the two expert witnesses stated that the skilled person would have been led to apply the teachings of the ‘422 patent to arrive directly and without difficulty at the composition contained within the ‘266 Patent.

[152] While the Respondent submits that Abbott’s ‘714 Patent shows that substitution can work, this theory is not supported by the evidence. Azithromycin has very particular properties among macrolides, suggesting that it would not be obviously interchangeable with clarithromycin. The ‘333 patent teaches that wide variations in the physiochemical and p-kinetic properties of different drugs mean that formulations which are suitable for one drug cannot generally be predictably applied to others. This view is supported by at the textbook, *Pharmaceutical Dosage Forms and Drug Delivery Systems*, labeled as Sandoz Document 126.

[153] The dissimilarities between the two drugs include their distribution in body tissues, half-life, and first pass effect metabolism. I accept the evidence put forth by the Applicants that these differences mean that the performance of these two drugs in the body would be fundamentally different, such that one could not be readily substituted for another.

[154] In my opinion, on the basis of the foregoing, I conclude that the skilled person would not have been led to the composition claimed within the '266 Patent upon the basis of the teachings contained within the '422 patent.

The Improved Taste Profile

[155] There is also some dispute between the parties as to whether taste perversion was known to be dose-dependent and whether it was self-evident that extending the release of the formulation would address this adverse effect. The parties provided evidence supporting two diametrically opposing conclusions.

[156] The Respondent provided the Court with a number of references to the prior art in support of its argument. These included US Patent 3,065,143 (the "'143 patent"), being Sandoz Document 1, and the Robert E. Notari article labeled Sandoz Document 24, which each support the conclusion that higher C-max levels can lead to an increase in adverse effects, and that side effects are dose-dependent. Further, the article by Dr. J.K. Aronson and Dr. C.J. Van Boxtel posits that taste perversion as described by patients taking clarithromycin, seems to be dose-related.

[157] The Applicants pointed to the evidence of Dr. Banker, who disputes the Respondent's conclusion, stating that to this day, it is not known what exactly causes the bitter metallic taste associated with clarithromycin following ingestion.

[158] In addition, the Applicants point to the statements made on cross examination by Dr. Thiessen and Dr. Einarson. Dr. Thiessen stated that he believed it would take "a leap of faith" to conclude that an inventor could reasonably have expected the ER formulations to have resulted in a lowering of any adverse effect. Furthermore, Dr. Einarson stated that it is not true to state that there is a correlation between increased exposure to a drug and increases in the adverse effects associated with the drug, and that he does not believe that taste perversion is necessarily dose-related.

[159] Even if I accept that adverse effects may be dose-dependent, that higher C-max levels could lead to an increase in adverse effects and that it was self-evident that reducing a drug's C-max could serve as a method by which to reduce adverse effects, I do not believe that it was self-evident that the C-max could have been reduced simply by extending a drug's release rate.

[160] A reduction in the drug's C-max when compared against the IR formulation was amongst those favourable p-kinetics disclosed within the claimed compositions. I concluded above that the favourable p-kinetics disclosed within the compositions were not inherent in any ER formulation. Upon this basis, it could not inherently be the case that extending a drug's release would result in the lowering of the drug's C-max.

[161] If it was not self-evident that one could reduce a drug's C-max simply by extending the drug's release, then it follows that it also could not have been self-evident that any benefit flowing from the reduction in the drug's C-max would result simply by extending a drug's release.

[162] In sum, I find that it would not have been self-evident to the skilled person that extending the drug's release could lead to a reduction in the incidence of taste perversion and an improvement in the drug's taste profile.

(b) Effort required to achieve the invention

[163] As noted above, Dr. Banker said that there was no IVIVC correlation established for any ER clarithromycin product as of 2006 such that the skilled person could accurately predict, absent *in-vivo* testing, the p-kinetics of an ER dosage. In light of the dearth of prior art that would otherwise direct the skilled person to the composition claimed under the '266 Patent and its favourable p-kinetics, I am satisfied that *in-vivo* testing would be required. The question therefore becomes, how much effort would be required to conduct these tests in order to arrive at the claimed composition?

[164] Doctor Chambliss in his cross examinations was taken through the various steps required to complete the *in vivo* tests. In sum, the process would require the skilled person to create a number of different formulations and apply a trial-and-error approach, utilizing numerous subjects and testing thousands of blood samples until such time as the precise formulation revealing the specific p-kinetics of the Patent was discovered. I am satisfied that the steps required of the skilled person in

this regard are extremely arduous and in my opinion, far exceeds what would be called “routine testing”.

[165] With regards to the ‘395 Patent, the parties have not provided any evidence that would assist the Court in determining the level of effort required to achieve the invention.

(c) Motive in the prior art to find the solution addressed by the patent

[166] The prior art reveals that ER formulations reduce the frequency of dosing, thereby increasing compliance amongst patients. Prior to the creation of the claimed compositions, there was also a need to develop a drug that would exhibit an improved taste profile, which also addresses the issue of compliance. I am satisfied that there was a motive to create an ER clarithromycin formulation with the attributes disclosed in the ‘266 and ‘395 Patents.

(d) Course of conduct followed in arriving at the invention

[167] The Applicants did not file any evidence that would reveal the course of conduct followed in arriving at the ‘266 and ‘395 Patents. That being said, it is known that the Applicants first created the ‘714 Patent, which utilized an alginate composition but did not address the phenomenon of taste perversion. I accept that Abbott was led to create the ‘266 and ‘395 Patents, which sought to build upon the success of the ‘714 Patent, in as much that it would allow for once-daily dosing of the clarithromycin composition, but additionally address the issue of taste perversion. As stated above, the fact that a prior user failed to achieve the invention in question may serve as evidence of invention.

v) Conclusion on Obviousness

[168] In conclusion, I find that it would not have been obvious to the skilled person to arrive at the compositions claimed by the ‘266 and ‘395 Patents based upon the teachings contained within the prior art. As a result, I am satisfied that the Applicants have successfully shown that the Respondent’s allegations of obviousness are not justified.

B. Lack of Actual Utility

[169] The concept of utility was discussed by the Supreme Court of Canada in its decision in *Consolboard Inc. v. MacMillan Blodel (Saskatchewan) Ltd.*, [1981] 1 S.C.R. 504 at 521-527. At p. 525, the Supreme Court succinctly explained the concept of utility as follows:

> There is a helpful discussion in Halsbury’s Laws of England, (3rd ed.), vol. 29, at p. 59, on the meaning of “not useful” in patent law. It means “that the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do”. There is no suggestion here that the invention will not give the result promised. The discussion in Halsbury’s Laws of England, ibid., continues:
>
> > ... the practical usefulness of the invention does not matter, nor does its commercial utility, unless the specification promises commercial utility, nor does it matter whether the invention is of any real benefit to the public, or particularly suitable for the purposes suggested...
>
> and concludes:
>
> > ... it is sufficient utility to support a patent that the invention gives either a new article, or a better article, or a cheaper article, or affords the public a useful choice.

[170] The Applicants argue that Table VI of the ‘395 Patent and Abbott’s M97-667 and M97-756 studies show the utility of the ‘395 Patent insofar as the ER composition exhibits an improved taste profile as compared with the IR composition. For its part, Sandoz alleges that the ‘395 Patent simply repeats the state of the art, that is that an ER formulation should reduce taste perversion, and argues that the sum of the available data shows that the ER composition does not in fact exhibit an improved taste profile over its ER equivalent. It submits that the evidence of Dr. Weiner is flawed and that the Court should prefer the evidence of its expert, Dr. Einarson.

[171] Dr. Thiessen reviewed the 2006 *Compendium of Pharmaceuticals and Specialties* product monographs and labeling for BIAXIN, BIAXIN BID and BIAXIN XL. He concluded that these labels showed a lower incidence of taste perversion in the IR formulation as compared with the ER equivalent. However, upon his cross-examination, Dr. Thiessen disclosed that the dosages of the IR and ER formulation were different and the studies could not be considered head-to-head.

[172] In my opinion, the fact that the IR composition was given in a lower dosage than the ER composition calls into question the reliability of the comparative results concerning taste perversion. Since Dr. Thiessen did not have relevant information about the dosages, the probative value of his opinion is reduced accordingly.

[173] Dr. Thiessen rejected the results of Abbott’s M96-454 study upon the grounds that the ER tablets were allegedly coated in lactose which may have affected the taste, while the IR tablets were not. Dr. Thiessen suggested in cross examination that the lactose used in the ER tablets could be

recognized by taste buds in the gastrointestinal tract thereby altering the brain's perception as to mask the effect of taste perversion.

[174] This novel theory is not supported by any empirical evidence that Sandoz could identify. Neither could Sandoz identify empirical evidence that lactose could affect the taste perversion associated with clarithromycin.

[175] Dr. Einarson's evidence is also less preferable than the evidence presented by Abbott. Dr. Einarson testified that before a search is done for the appropriate studies to be included in the meta-analysis, the selection criteria must be established. The choice of selection criteria will determine which studies are selected. Abbott's expert witness, Dr. Weiner, followed this method, first setting the selection criteria as requiring head-to-head studies comparing the ER and IR clarithromycin formulations.

[176] Dr. Einarson accepted that this head-to-head selection criterion was the preferred standard and confirmed that the studies located by Dr. Weiner were the only head-to-head studies of this kind. However, when Dr. Einarson revisited Dr. Weiner's meta-analysis, he did not follow this approach, an approach with which he agreed.

[177] Rather, after accepting Dr. Weiner's selection criteria, Dr. Weiner concluded that there were only five studies that compared the ER and IR formulations and that these failed to reveal a sufficient number of subjects. Dr. Einarson then included an addition thirty-five studies that did not

match the original selection criteria, despite his insistence as to the importance of choosing the selection criteria.

[178] It was always open to Sandoz to conduct further head-to-head studies that matched the selection evidence and provided a larger number of subjects in order for it to assess whether the ER composition failed to show a statistically significant improvement over the IR composition, but it chose not to do so. It appears that Sandoz may have been in possession of certain additional head-to-head studies arising from litigation in the United States. It is now trying to rely on the selective results obtained by Dr. Einarson which are based upon thirty-five studies that did not match what he himself described as the preferable selection criteria. Dr. Weiner included his statistical tests in his affidavit; Dr. Einarson did not.

[179] While individually, Abbott's studies M96-454, M97-667 and M97-756 are too weak to individually confirm a statistically significant improvement in taste profile, as was admitted by Dr. Weiner, the results obtained by him when he pooled those studies conclusively demonstrated a statistically significant improvement in taste profile in the ER over the IR formulation. Dr. Weiner found that the results of his meta-analysis of the five head-to-head studies were statistically significant at the .05 confidence level, meaning that there was a five percent or less than a one in twenty chance that a difference in the incidence between the formulations was due to chance. In contrast to this conclusion, Dr. Einarson's results showed that there was less than a 5.1 percent chance that the improved taste profile was due to chance.

[180] This difference is not sufficiently distinct from the findings of Dr. Weiner to allow me to conclude that there was not an improved taste profile demonstrated in the ER composition.

[181] Furthermore, I observe that regardless of whether the ER formulation showed a statistically significant reduction in the incidence of taste perversion, Claim 22 only requires an improvement in taste profile, not a statistically significant reduction in taste perversion. In my opinion, even if the evidence falls short of supporting the conclusion that the ER composition demonstrates a statistically significant reduction in the incidence of taste perversion as compared to the IR composition, I am satisfied that the evidence shows an improvement in taste profile as claimed in Claim 22, thereby meeting the standards of utility.

[182] In concluding the discussion relative to the allegation that the ‘395 Patent lacks utility, I am satisfied that a review of this patent clearly shows that there was a motive to develop an ER clarithromycin formulation that exhibits an improved taste profile. In view of the need for such a formulation and in light of Sandoz’s efforts to market a generic version of the Applicants’ formulation, it seems to be disingenuous for the Respondent to now suggest that Abbott’s product does not in fact exhibit an improved taste profile. If the ‘395 Patent truly lacks utility as Sandoz alleges, why does Sandoz itself want to market a generic version? The submissions of the Respondent appear to undermine one of the central benefits it would realize by marketing its generic version.

C. Lack of Sound Prediction Utility

[183] The doctrine of sound prediction was reviewed by the Supreme Court of Canada in *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 S.C.R. 153. At paragraph 46 Justice Binnie explains that where the invention is a new use for an old product, the utility required for patentability must either be demonstrated or be a sound prediction based on the information and expertise then available.

[184] One doctrine of sound prediction has three components: first, there must be a factual basis for the prediction; second, the inventor must have a "sound" line of reasoning from which the desired result can be inferred from the factual basis, as of the date of the patent application; and third, there must be proper disclosure. These three elements are discussed by the Supreme Court of Canada in *Wellcome* at para. 70. The key date for consideration of the doctrine of sound prediction is the filing date of the patent application; see *Aventis Pharma Inc. v. Apotex Inc.* (2005), 43 C.P.R. (4^{th}) 161, aff'd (2006) 46 C.P.R. (4^{th}) 401 (C.A.).

[185] It is unnecessary for me to deal further with the Respondent's submissions under this heading. I am satisfied that the Applicants have shown that the allegation of lack of utility is not justified and it is not necessary for me to consider whether Claim 22 of the '395 Patent was not soundly predicted.

D. Double Patenting

[186] The Respondent also alleged that the '395 Patent was invalid on the basis of double patenting. The allegations of double patenting at issue in this proceeding concern "obviousness"

type double patenting. At pages 1105–1106 of its decision in *Whirlpool*, the Supreme Court of Canada defined this concept as follows:

> There is, however, second branch of the prohibition which is sometimes called "obviousness" double patenting. This is a more flexible and less literal test that prohibits the issuance of a second patent with claims that are not "patentably distinct" from those of the earlier patent. In Commissioner of Patents v. Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning, [1964] S.C.R. 49, the issue was whether Farbwerke Hoechst could obtain a patent for a medicine that was a diluted version of a medicine for which it had already obtained a patent. The claims were neither identical nor conterminous. Judson J. nevertheless held the subsequent patent to be invalid, explaining at p. 53:
>
> A person is entitled to a patent for a new, useful and inventive medicinal substance but to dilute that new substance once its medical uses are established does not result in further invention. The diluted and undiluted substances are but two aspects of exactly the same invention. In this case, the addition of an inert carrier, which is a common expedient to increase bulk, and so facilitate measurement and administration, is nothing more than dilution and does not result in a further invention over and above that of the medicinal itself…

[187] In *Consolboard*, Justice Dickson (as he then was) referred to the decision in *Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning*, [1964] S.C.R. 49 at p. 536 as "the main authority on double patenting", standing for the proposition that a second patent could not be justified unless the claims exhibited "ingenuity or novelty" over the first patent".

[188] The question, then, in the within proceeding, is whether the claims of the '395 Patent are distinct from the claims of the '266 and '541 Patents, as of the date of the patent's publication, that being October 22, 1998.

[189] Abbott makes two submissions in response to the allegations of Sandoz. First, it argues that because the Commissioner of Patents required it to divide its claims respecting the improved taste profile from the ‘266 Patent into a separate divisional application, that is the ‘541 Patent from which the ‘395 Patent ultimately issued, the ‘395 Patent should not be found to constitute double patenting over the ‘266 Patent. Abbott had to follow the instructions from the Commissioner of Patents.

[190] Second, Abbott submits that since all the claims of the ‘541 Patent have been dedicated to the public, which act of dedication gives rise to the legal effect that the claims were never issued, the ‘395 Patent should not be found to constitute double patenting over the ‘541 Patent.

[191] Sandoz argues that the claims of the ‘395 Patent claim the same improved taste profile as those of the ‘541 Patent and that, consequently, the ‘395 Patent is invalid for double patenting. It submits that the recent dedication of the ‘541 Patent to the public by Abbott is irrelevant to determining the issue of double patenting.

[192] Section 36 of the *Patent Act* addresses double patenting. Section 36(1), (2.1) and (4) are relevant and provide as follows:

> Patent for one invention only
>
> 36. (1) A patent shall be granted for one invention only but in an action or other proceeding a patent shall not be deemed to be invalid by reason only that it has been granted for more than one invention.
>
> Limitation of claims on direction of Commissioner
>
> (2.1) Where an application (the "original application") describes and claims more than one invention, the applicant shall, on the direction

> of the Commissioner, limit the claims to one invention only, and any other invention disclosed may be made the subject of a divisional application, if the divisional application is filed before the issue of a patent on the original application.
>
> Separate applications
>
> (4) A divisional application shall be deemed to be a separate and distinct application under this Act, to which its provisions apply as fully as may be, and separate fees shall be paid on the divisional application and it shall have the same filing date as the original application.

[193] I am satisfied that the ‘395 Patent should not be found invalid for double patenting over the ‘266 Patent. The Applicants provided evidence to show that claims respecting the improved taste profile were divided out of the ‘266 Patent at the request of the Commissioner of Patents. That was an administrative action lying within the mandate of the Commissioner of Patents. In my opinion, it would be unfair and inequitable to find that the ‘395 Patent should be invalidated, only because the Applicants had followed the directions of the Commissioner.

[194] The remaining question is whether the ‘395 Patent is invalid on the basis of double patenting over the ‘541 Patent. This question puts in issue the effect of the Notice of Dedication that was submitted to the Canadian Patent Office on January 20, 2009. The terms of that Notice of Dedication read as follows:

> Subject to the terms of this document, the patentee hereby dedicates to the public all rights that the patentee may hold in and to the invention defined in the claims of Canadian Patent No. 2,325,541.
>
> The present dedication is made without any prejudice to the rights of the patent owner in or to its rights under or in any other patent or pending patent application other than the present patent and in particular, but without limitation, does not dedicate any rights under

> Canadian Patent Nos. 2,285,266, or 2,358,395 or the inventions claimed therein.
>
> The present dedication shall apply to all subsequent owners of the patent and to all persons who now or in the future may hold any rights under this patent.

[195] In *Bristol-Myers Squibb Canada Co. et al. v. Apotex Inc. et al.*, 2009 FC 137 at paras. 51, 54-55, Justice Hughes said that a claim that is overbroad but which has yet to be declared invalid can be saved from such a finding if a disclaimer was filed. However, he cautioned that such a filing must be done in a timely manner. In that case, the applicants had filed a disclaimer after the respondent had filed its NOA and one day after the applicants had commenced their application for an order prohibiting the Minister from issuing a NOC.

[196] Justice Hughes found that the claims that had been disclaimed had to be construed as they appeared on the date of issuance of the NOA; otherwise the respondent would be disadvantaged in attacking the validity of the claims as they stood after the disclaimer since no revision of the NOA was permitted after the commencement of the prohibition proceedings.

[197] In the present case, Abbott executed a Notice of Dedication and relying on the decision in *G.D. Searle & Co. v. Merck & Co.* (2002), 20 C.P.R. (4th) 103 (F.C.T.D.) argues that since the effect of a dedication is as if the patent had never been issued, there is no object for the Respondent's allegation of invalidity.

[198] The Respondent submits that it would be prejudiced by recognition of the Notice of Dedication, at this time. It relies on the decision in *Bristol-Myers* in support of its argument in this regard.

[199] In the first place, I acknowledge that the Respondent's arguments as to prejudice are based upon a misunderstanding of the decision in *Bristol-Myers*. The Respondent used that decision to say that it would be prejudiced by the Dedication. This is a misunderstanding of the object of the Dedication which is the relinquishment by Abbott, the patentee, of its rights to the monopoly of the patent and the availability of invention of the patent of the public at large.

[200] Had the Dedication been executed prior to the service of the NOA, Sandoz would not have had a ground for alleging double patenting in respect of the '395 Patent. There would have been no foundation for any argument of prejudice.

[201] Be that as it may, 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.

[202] In *Bristol-Myers*, Justice Hughes focused on the NOA, particularly the date of service, for the purpose of determining the date at which the patent claim should be construed. He referred to and relied upon the decision in *Canadian Celanese Ltd. v. B.V.D. Co. Ltd.*, [1939] 2 D.L.R. 289 (P.C.).

[203] I see no reason to depart from the approach and the reasoning of Justice Hughes in the present case. While there may well be a difference between the effects of a disclaimer and a Notice of Dedication in an action involving the validity of a patent, the present proceeding is not an action but a summary proceeding for a limited purpose, that is about the issuance of a NOC. 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.]

[205] The Applicants' argument as to the effect of the Notice of Dedication, is novel but in my opinion, it is not sound. I am not satisfied that the Applicants have shown that the allegation of double patenting of the '395 Patent over the '541 Patent is not justified.

[206] The '395 Patent claims the same "improved taste profile" as that which was already claimed by the '541 Patent. It is not distinct from that which is claimed in the '541 Patent. The '395 Patent is therefore invalid for double patenting on this ground.

Conclusion

[207] In conclusion, I am satisfied that the Applicants have demonstrated on a balance of probabilities that the allegations of invalidity set out by the Respondent in its NOA dated May 7, 2007 respecting the '266 Patent are not justified. Accordingly, the Applicants are entitled to an Order of Prohibition in relation to the '266 Patent and an Order will issue in that regard.

[208] While I am satisfied that the Applicants have rebutted the Respondent's allegations of invalidity respecting obviousness and the lack of utility of the '395 Patent, I conclude that they have failed to rebut the Respondent's allegations of invalidity respecting the issue of double patenting over the '541 Patent. Accordingly, the Applicants' request for an Order of Prohibition in relation to the '395 patent is dismissed.

[209] This application proceeded upon the basis of a confidential record. The parties were asked if they wished to proceed on an in camera basis and advised that such hearing was not

necessary. However, in the interests of avoiding any inadvertent disclosure of confidential material, these reasons will be issued on a confidential basis. The parties will advise the Court within ten (10) days of the release of these reasons if any redaction is required.

[210] The parties requested the opportunity to make submissions on costs. In that regard, the parties shall file their submissions, not to exceed five (5) pages, on or before July 8, 2009.

"E. Heneghan"
Judge

SOLICITORS OF RECORD

DOCKET:	T-1129-07
STYLE OF CAUSE:	ABBOTT LABORATORIES and ABBOTT LABORATORIES LIMITED v. THE MINISTER OF HEALTH and SANDOZ CANADA INC.
PLACE OF HEARING:	Toronto, ON
DATE OF HEARING:	March 30 to April 2, 2009
REASONS FOR JUDGMENT:	HENEGHAN J.
DATED:	Confidential Reasons for Judgment filed June 19, 2009 and Public Reasons for Judgment filed July 7, 2009

APPEARANCES:

Andrew Reddon Steven Mason David Tait	FOR THE APPLICANTS
Edward Hore Kevin Zive	FOR THE RESPONDENT SANDOZ CANADA INC.

SOLICITORS OF RECORD:

McCarthy Tétrault LLP Barristers and Solicitors Toronto, ON	FOR THE APPLICANTS
Hazzard & Hore Barristers and Solicitors Toronto, ON	FOR THE RESPONDENT SANDOZ CANADA INC.
John H. Sims, Q.C. Deputy Attorney General of Canada Toronto, ON	FOR THE RESPONDENT THE MINISTER OF HEALTH