Federal Court Cour fédérale

Date: 20140507

Docket: T-1579-12

Citation: 2014 FC 436

CONFIDENTIAL REASONS AND JUDGMENT RELEASED: May 7, 2014
PUBLIC REASONS FOR JUDGMENT RELEASED: June 4, 2014

BETWEEN:

BAYER INC. AND
BAYER PHARMA AKTIENGESELLSCHAFT

Applicants

and

APOTEX INC. AND
THE MINISTER OF HEALTH

Respondents

PUBLIC REASONS FOR JUDGMENT

HUGHES J.

[1] This is an application brought by the Applicants Bayer Inc. and Bayer Pharma Aktiengesellschaft, collectively Bayer, under the provisions of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (*NOC Regulations*), to prohibit the Minister of Health from issuing a Notice of Compliance to the Respondent Apotex Inc. in respect of its proposed

drospirenone and ethinylestradiol combination until the expiry of Canadian Letters Patent No. 2,382,426 (the '426 Patent).

[2] For the reasons that follow I find that Apotex's allegations as to non-infringement are justified thus the application is dismissed.

I. INDEX

[3] The following is a table setting out the various topics dealt with in these Reasons by page number:

II. THE COBALT PROCEEDINGS

[4] I have previously heard and disposed of an application brought by Bayer in respect of the '426 Patent under the *NOC Regulations*, as against a different Respondent, Cobalt

Pharmaceuticals Company in proceeding Court Docket No. T-215-12. My decision dated October 22, 2013 is cited as 2013 FC 1061. This will be referred as the Cobalt Proceedings.

[5] In the Cobalt Proceeding I concluded that none of the allegations as to non-infringement or invalidity of the '426 Patent as raised by Cobalt in its Notice of Allegation and as restricted by Counsel in argument, were justified. Accordingly I gave Judgment prohibiting the Minister from issuing a Notice of Compliance to Cobalt until the expiry of the '426 Patent. That patent will expire on August 31, 2020.

[6] Cobalt has appealed to the Federal Court of Appeal from my decision (file no. A-376-13). The list of entries for that appeal indicates that a Record has been filed as have memoranda of argument by each party. No date for the hearing of that appeal has been set as of this time.

[7] At a pre-hearing conference which I held with Counsel for the parties I indicated that I had read the Record in the present proceedings and the memoranda of argument filed in these proceedings by each party. I indicated that I would be inclined to follow my decision in the Cobalt Proceedings unless a different issue has been raised in these proceedings or substantially different evidence was in the Record in these proceedings. On April 22, 2014 Counsel for Apotex, writing on behalf of both Apotex and the Applicants, filed a letter with the Court stating, *inter alia:*

> The parties will not be making any submissions in Court File No. T-1579-12 in respect of Apotex's allegation that Canadian Patent No. 2,382,426 is obvious, it being understood that, if the Court considers it necessary to dispose of this obviousness allegation, it will be found to be not justified for the reasons expressed in the Reasons for Judgment in the Cobalt Proceeding.

[8] With this in mind I have heard submissions from Counsel for each of the Applicants Bayer and the Respondent Apotex in the present proceedings. Some of the Reasons that follow are taken more or less directly from my Reasons in the Cobalt Proceedings 2013 FC 1061 in instances where the issues or evidence are not substantially different or the matters are not controversial.

III. THE PARTIES AND PRODUCT AT ISSUE

[9] The Applicant Bayer Inc. is a "first person" as described in the *NOC Regulations*. It has listed the patent at issue with the Minister of Health in apparent accordance with those *Regulations*.

[10] The other Applicant Bayer Pharma Aktiengesellschaft is the owner of the patent at issue.

[11] Bayer distributes in Canada birth control tablets under the brand name YAZ. The tablets include as active ingredients 3 mg drospirenone + 20 mg ethinylestradiol in tablet form for oral administration.

[12] The Respondent Apotex Inc. is a "second person" as described in the *NOC Regulations*. On or about July 10, 2012, Apotex served on Bayer a Notice of Allegation stating that it has applied to the Minister of Health for a Notice of Compliance in order to distribute in Canada a generic version of Bayer's YAZ tablets.

[13] The Respondent Minister of Health performs various duties as provided in the *NOC Regulations*; including, in appropriate circumstances, the issuance of a Notice of Compliance (NOC) to a second person, which would permit the sale of a generic version of a specified drug in Canada. The Minister took no active part in these proceedings.

IV. THE '426 PATENT GENERALLY

[14] The '426 patent is entitled "Pharmaceutical Combination of Ethinylestradiol and Drospirenone for Use as a Contraceptive". It names Wolfgang Heil, Jurgen Hilman, Ralph Lipp and Renate Heithecker as inventors.

[15] The application for this patent was filed under the provisions of the Patent Co-Operation Treaty with an effective filing date in Canada of August 31, 2000. The application was made available for public inspection March 8, 2001. The application claimed priority from both a United States and a European patent application, each filed August 31, 1999.

[16] The '426 patent was issued and granted in Canada on February 28, 2006. The term of the patent will expire August 31, 2020.

V. THE EVIDENCE

[17] As is usual in proceedings of this kind, the evidence consisted of affidavits tendered by each of the parties, and transcripts of the cross-examinations conducted upon those affiants selected for cross-examination. The Court had no opportunity to observe any witness in person.

Some witnesses were tendered as experts; no party objected to the fact that they were tendered as experts. I am satisfied that all experts have given evidence that assists the Court in resolving the matters at issue and I am not prepared, on the Record that I have, to find any of them lacking in credibility or lacking in sufficient expertise in the matters addressed in their evidence.

[18] Bayer filed the evidence of the following expert witness:

1. Dr. Martyn Davies of Nottingham, United Kingdom, a Professor in Biomedical Surface Chemistry, Laboratory of Biophysics and Surface Analysis at the School of Pharmacy at the University of Nottingham in the UK. He provided expert evidence as to the analysis of tablets of the kind Apotex wishes to sell in Canada and evidence as to several aspects of pharmaceutical chemistry matters at issue. At times his Affidavit strayed beyond the opinions of an expert into the areas of legal argument. I give those portions of his evidence little weight. Dr. Davies was cross-examined.

[19] Bayer also filed the evidence of the following fact witnesses

2. Dr. Wolfgang Heil of Seevetal, Germany. He presently works as a pharmacist. He was a member of the Pharmaceutical Development Group at Schering and is one of the named inventors of the ‘426 patent. He gave evidence as to the development of the product at issue. Schering was the predecessor of Bayer. He was cross-examined.

3. Dr. Michael Hümpel of Lübeck, Germany. He is now retired having worked at Schering (Bayer) from 1974 to 2006. He

gave evidence as to the development of the product at issue. He was cross-examined.

4. Dr. Joachim Marr of Berlin, Germany. He is a Vice-President of Global Clinical Development in Women's Health at Bayer. He gave evidence respecting the clinical studies of the product at issue. He was cross-examined.

5. Ms. Mira Rinnie of Aurora, Ontario. She is a law clerk in the offices of the solicitors for Bayer. Her affidavit served to make certain documents of record. She was not cross-examined.

6. Dr. Johannes W. Tack of Berlin, Germany. He presently works as COO of a pharmaceutical company unrelated to the parties to this proceeding, he did work for Schering between 1978 and 2001. He testified to the development of the product at issue. He was cross-examined.

[20] Apotex filed the evidence of the following fact witnesses:

1. Ms. Lisa Ebdon of Vaughan, Ontario. She is a law clerk in the offices of Apotex's solicitors. Her affidavit served to make certain documents of record. She was not cross-examined.

2. Ms. Raquel Fernandez, of (….)She is an employee of (….)who supplies the tablets at issue to Apotex. She identified samples of certain (…) products and their dispatch to Apotex's solicitors. She was cross-examined.

[21] Apotex filed the evidence of the following expert witnesses:

3. Dr. Michael Cima of Cambridge, Massachusetts. He is the David H. Koch Professor of Engineering and MIT Professor of Materials Science and Engineering at Massachusetts Institute of Technology (MIT). He gave evidence as to the testing of certain materials and as to pharmaceutical chemistry. He was cross-examined.

4. Dr. Paul J. Jarosz of Westminster, Colorado. He is a consultant in the pharmaceutical industry and has worked with a number of pharmaceutical companies in their research areas and has served as an adjunct professor. He gave evidence as to a number of pharmaceutical chemical matters. He was cross-examined.

5. Dr. Donald T. Jung of Cupertino, California. He is Director of Nonclinical and Clinical Pharmacology at Threshold Pharmaceuticals. He gave evidence directed to whether the claimed invention of the patent at issue was obvious. He was cross-examined. The issue of obviousness, hence his evidence, was not argued before me.

6. Mr. David Rosen of Cabin John, Maryland. He is a practicing United States attorney, a partner of Foley & Lardner LLP, FDA practice group leader and co-chair of its Life Sciences

Interest Team. He gave evidence as to the legal effect of circumstances related to the United States clinical tests of the Bayer product. He was cross-examined.

7. Dr. James A. Simon of McLean, Virginia. He is a physician and currently Clinical Professor in the Division of Reproductive Endocrinology and Infertility at George Washington University School of Medicine. He gave evidence respecting clinical testing. He was cross-examined.

VI. ISSUES

[22] Notwithstanding the disposition by this Court of issues of validity and infringement respecting the ‘426 patent in the Cobalt Proceedings, those issues are under appeal and thus are not yet finally determined in those proceedings.

[23] The parties have raised issues of validity and infringement in the present proceedings. As to infringement, the process used by Apotex to make the product at issue is arguably different from that used by Cobalt in the Cobalt Proceedings, and therefore requires fresh examination.

[24] In these proceedings Apotex has raised an issue as to whether the ‘426 patent was properly listed under the provisions of the *NOC Regulations*. That issue was not dealt with in the Cobalt Proceedings.

[25] As to validity of the ‘426 patent Apotex has raised several issues, some of which were dealt with in the Cobalt Proceedings. The issue of obviousness was dealt with in the Cobalt Proceedings and, as set out earlier in these Reasons, Apotex has, by the letter from its solicitors of April 22, 2014, agreed that, for the purposes of my decision, I may find that Apotex’s allegations as to obviousness are not justified. I so find.

[26] Further, by a letter from its solicitors dated April 28, 2014 Apotex advised that it did not intend to advance oral argument as to certain issues pertaining to construction, overbreadth and lack of utility and sound prediction but would rely on its written memorandum. In particular that letter advised the Court:

> *Apotex has decided to further streamline its oral argument and does not intend to advance oral arguments in respect of the following additional issues:*
>
> - *Construction re: dissolution profile of claim 31 (Memorandum para. 30)*
> - *Overbreadth re: claims to dissolution profile claim desired result (Memorandum paras. 92-93); and*
> - *Lack of demonstrated utility and sound prediction (Memorandum paras. 97-103)*
>
> *Apotex will instead rely only on the written arguments in its Memorandum of Fact and Law relating to these issues.*

[27] At the hearing Bayer’s Counsel advised the Court that Bayer would be relying on the following claims of the ‘426 patent: claim 1 and dependent claims 2 to 8 and 12; claim 30; and claim 31 and dependent claims 36, 37, 39 to 42 and 47 to 50.

[28] I will first deal with some preliminary issues.

VII. BURDEN

[29] The jurisprudence as to burden has not changed since I wrote my decision in the Cobalt Proceedings, therefore I will repeat that portion of my Reasons cited as 2013 FC 1060.

[30] I summarized the questions of burden in these matters where validity is at issue recently in *Novartis Pharmaceuticals Canada Inc v Cobalt Pharmaceuticals Company*, 2013 FC 985 at paragraph 23, which I adopt here:

> [23] Who bears the burden when validity of a patent is at issue in NOC proceedings has been discussed many times in this Court. In brief: a patent is presumed to be valid in the absence of evidence to the contrary (Patent Act, s. 43(2)). The party alleging invalidity (here Cobalt) has the burden of putting forth evidence supporting its allegations. Once evidence is led the matter is determined by the Court on the civil burden of proof; namely, balance of probabilities. If the Court finds the matter to be evenly balanced, then it should find in favour of the person alleging invalidity since, under the NOC Regulations, subsection 6(2), the first person (here Novartis) bears the burden of demonstrating that the allegations of invalidity are not justified.

[31] Similarly, with respect to the second person's [generic's] allegations of non-infringement, the first person [innovator] bears the burden of proving that such allegations are not justified. This matter was recently reviewed by the Federal Court of Appeal in *Pfizer Canada Inc v Minister of Health and Ratiopharm Inc*, 2011 FCA 215, where Létourneau JA, writing for the Court, referred to earlier decisions of that Court in *Fournier* and *Apotex* to emphasize that these proceedings are administrative in nature, the purpose being to determine if the Minister is free to issue a Notice of Compliance; the proceedings are not to be confused with infringement or impeachment actions. He wrote at paragraphs 15 and 18:

15 The nature, purpose and scope of the NOC proceedings and their relationship with impeachment proceedings have been conveniently summarized by Layden-Stevenson J. (as she then was) in Fournier Pharma Inc. v. Canada (Minister of Health) (2004), 38 C.P.R. (4th) 297, 2004 FC 1718. At paragraphs 6, 8 and 9, she writes:

> [6] As noted, this proceeding is brought under the Regulations. The history and scheme of the Regulations have been delineated in various decisions of the Federal Court of Appeal and need not be repeated here. See: Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare) (1994), 55 C.P.R. (3d) 302 (F.C.A.);...). Basically, issues of non-infringement and validity between the patent holder (first person) and the person seeking a NOC from the Minister (second person) originate with a NOA, served on the first person by the second person, setting out the second person's allegations, including the legal and factual basis in support. The first person may disagree and apply to the court for an order prohibiting the Minister from issuing a NOC to the second person until after expiration of the patent.
>
> ...
>
> [8] Section 6 proceedings are not to be likened to actions for determining validity or infringement. They are proceedings in judicial review, to be held expeditiously, whose aim is to determine whether the Minister is free to issue the requested NOC. Their scope is confined to administrative purposes: Apotex Inc. v. Canada (Minister of National Health and Welfare) (1997), 76 C.P.R. (3d) 1 (F.C.A.). The determination must turn on whether there are allegations by the second person sufficiently substantiated to support a conclusion for administrative purposes (the issuance of a NOC) that an applicant's patent would not be infringed if the second person's product is put on the market: Pharmacia Inc. v. Canada (Minister of National Health and Welfare) (1994), 58 C.P.R. (3d) 209 (F.C.A.).
>
> [9] By merely commencing the proceeding, the applicant obtains what is tantamount to an

> interlocutory injunction without having satisfied any of the criteria a court would require before enjoining issuance of a NOC: Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare) (1998), 80 C.P.R. (3d) 368 (S.C.C.);...). The Regulations allow a court to determine summarily, on the basis of the evidence adduced, whether the allegations are justified. Section 6 proceedings are not adjudicative and cannot be treated as res judicata. The patentee is in no way deprived of all the recourses normally available to enable it to enforce its rights. If a full trial of validity or infringement issues is required, this can be obtained in the usual way by commencing an action:
>
> Pfizer Canada Inc. v. Apotex Inc. (2001), 11 C.P.R. (4th) 245 (F.C.A.);...).

...

18 The scope of application of section 8 and its interplay with impeachment proceedings were reviewed by our Court in Apotex Inc. v. Syntex Pharmaceuticals International Ltd., 2010 FCA 155. Writing for a unanimous court, Dawson J.A. held at paragraph 36:

> [36] Under the 1993 version of the Regulations, when an innovator commenced a proceeding seeking a prohibition order it obtained the equivalent of an interlocutory injunction prohibiting the issuance of a notice of compliance for up to 30 months. The innovator need not have satisfied the criteria for obtaining injunctive relief and no undertaking for damages was required. In that circumstance, section 8 of the Regulations was intended to provide redress to the generic where the innovator failed to establish that the generic's allegations of invalidity or non-infringement were not justified. In my view, section 8 was not intended to provide redress where the innovator prevailed in the prohibition proceeding, even if the generic was later successful in patent litigation. It follows that I agree with the Judge that Apotex can not "reach back and apply the finding of invalidity in the action so as to argue that the '671 patent had

> 'expired' within the meaning of section 8" of the 1993 version of the Regulations.

[32] Here Bayer complains that in the course of these proceedings, Apotex has adduced only limited evidence as to its product, such as that it will contain 3 mg of drospirenone, and that the drospirenone will be formulated in accordance with a particular technique which it describes as molecular dispersion. The Court must then deal with Apotex's allegations as to non-infringement and such evidence as there is in the record, so as to determine if those allegations are justified or not.

VIII. GOING BEYOND THE NOTICE OF ALLEGATION

[33] It has been established by the Court of Appeal that the second person, a generic such as Apotex, has an obligation in its Notice of Allegation to raise all the facts and legal arguments upon which it relies in support of its allegations. It cannot craft new arguments, or raise new allegations or new facts or new prior art documents not set out in the Notice of Allegation. (*AB Hassle v Canada (Minister of National Health and Welfare*) (2000), 7 CPR (4^{th}) 272, at paras 21-24; *Proctor & Gamble Pharmaceuticals Canada, Inc v Canada (Minister of Health*), 2002 FCA 290, at paras 21-26.

[34] While this may seem draconian since, undoubtedly, new matters may be raised as experts are consulted and evidence emerges, it is equally draconian for the first person who decides to institute proceedings to face shifting allegations and facts. The process is in need of change, but no interested person seems to be pressing for that change.

[35] As matters stand now, the Court must reject arguments based on facts or documents not set out in the Notice of Allegation nor can the Court address new allegations.

[36] I repeat the words of Stone JA in *AB Hassle*, supra where he wrote at paragraph 21 that the Notice of Allegation must set forth the legal and factual bases for the allegations in a sufficiently complete manner so as to enable the first person (here Bayer) to assess its course of action in response to the allegations.

IX. PERSON OF ORDINARY SKILL IN THE ART

[37] The Field of Invention is set out at page 1 of the patent:

> FIELD OF THE INVENTION
>
> The present invention relates to a pharmaceutical composition comprising drospirenone and ethinylestradiol, a method of providing dissolution of drospirenone, methods of inhibiting ovulation by administration of drospirenone and the use of drospirenone and ethinylestradiol for inhibiting ovulation.

[38] The next section, Background of the Invention, acknowledges that oral contraceptive products made of a combination of a gestagen and an estrogen are prior art. It is acknowledged that one such gestagen, drospirenone, has been disclosed as useful in treating several disorders, and that a combination of drospirenone (drsp) and ethinylestradiol (ee) have been suggested as a possible, but not a preferred, combination for an oral contraceptive.

[39] The next section is Summary of the Invention, in which it is stated that a minimum dosage level, and a maximum dosage level, of drospirenone has been determined.

SUMMARY OF THE INVENTION

In the course of research leading to the present invention, it has surprisingly been found that a hitherto undisclosed minimum dosage level of drospirenone is required for reliable contraceptive activity. Similarly, a preferred maximum dosage has been identified at which unpleasant side effects, in particular excessive diuresis, may substantially be avoided.

[40] A "Detailed Disclosure of the Invention" begins at page 4. It is stated that, to ensure good bioavailability of drospirenone, it should be provided in a form that promotes rapid dissolution. The next paragraph addresses micronization, provides parameters of particle size and distribution, provides dissolution parameters, and indicates that it is possible to provide the product, invalid or micronized, by spraying onto an inert carrier. Without being limited to a particular theory, the patent says that the dissolution rate *in vivo* may result in higher bioavailability. The ethinylestradiol component may also be micronized or sprayed.

It has surprisingly been found that when drospirenone is provided in micronized form (so that particles of the active substance have a surface area of more than 10,000 cm^2/g, and the following particle size distribution as determined under the microscope: not more than 2 particles in a given batch with a diameter of more than 30 µm, and preferably ≤ 20 particles with a diameter of ≥ 10 µm and ≤ 30 µm) in a pharmaceutical composition, rapid dissolution of the active compound from the composition occurs in vitro ("rapid dissolution" is defined as the dissolution of at least 70% over about 30 minutes, in particular at least 80% over about 20 minutes, of drospirenone from a tablet preparation containing 3 mg of drospirenone in 900 ml of water at 37°C determined by the USP XXIII Paddle Method using a USP dissolution test apparatus 2 at 50 rpm). Instead of providing the drospirenone in micronized form, it is possible to dissolve it in a suitable solvent, e.g. methanol or ethyl acetate, and spray it onto the surface of inert carrier particles followed by incorporation of the particles containing drospirenone on their surface in the composition.

Without wishing to be limited to any particular theory, it appears that the in vitro dissolution rate of drospirenone is connected to the dissolution rate in vivo resulting in rapid absorption of drospirenone in vivo on oral administration of the compound. This is an advantage because isomerization of the compound in the gastric environment and/or hydrolysis in the intestine is substantially reduced, leading to a high bioavailability of the compound.

With respect to ethinylestradiol which is also a sparingly soluble substance, though less sensitive to degradation than drospirenone under conditions prevailing in the gastrointestinal tract, it is also an advantage to provide it in micronized form or sprayed from a solution, e.g. in ethanol, onto the surface of inert carrier particles. This has the added advantage of facilitating a more homogenous distribution of the ethinylestradiol throughout the composition which might otherwise be difficult to obtain because ethinylestradiol is incorporated in extremely small amounts. When ethinylestradiol is provided in micronized form, it preferably has the following particle size distribution as determined under the microscope: 100% of the particles have a diameter of ≤ 15.0 μm, 99% of the particles have a diameter of ≤ 12.5μm, 95% of the particles have a diameter of ≤ 10.0 μm, and 50% of the particles have a diameter of ≤ 3.0 μm. Furthermore, no particle is larger than 20 μm, and ≤ 10 particles have a diameter of ≥ 15 μm and ≤ 20 μm.

To obtain a more rapid rate of dissolution, it is preferred to include carriers or excipients which act to promote dissolution of both active substances. Examples of such carriers and excipients include substances that are readily soluble in water such as cellulose derivatives, carboxymethylcellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, gelled starch, gelatin or polyvinylpyrrolidone. In particular, it appears as though polyvinylpyrrolidone might be particularly helpful to promote dissolution.

The composition of the invention preferably comprises drospirenone in an amount corresponding to a daily dosage of from about 2.5 mg to about 3.5 mg, in particular about 3 mg. The amount of ethinylestradiol preferably corresponds to a daily dosage of from about 0.015 mg to about 0.04 mg, in particular from about 0.015 mg to about 0.03 mg. More particularly, the present composition comprises an amount of drospirenone corresponding to a daily dosage of from about 3.0 to about 3.5 mg and ethinylestradiol in an amount corresponding to from about 0.015 to about 0.03 mg.

Apart from its ability to inhibit ovulation, the composition of the invention has been found to possess pronounced anti-androgenic properties and may therefore be used in the prevention or treatment of androgen-induced disorders, in particular acne. Such use may be independent from or concomitant with the use as a contraceptive disclosed above. Furthermore, since drospirenone is an aldosterone antagonist, it has diuretic properties and is therefore suitable for counteracting the water-retentive properties of ethinylestradiol.

In a particular embodiment, the invention relates to a pharmaceutical preparation consisting of a number of separately packaged and individually removable daily dosage

from a solution, e.g. in ethanol, onto the surface of inert carrier particles. This has the added advantage of facilitating a more homogenous distribution of the ethinylestradiol throughout the composition which might otherwise be difficult to obtain because ethinylestradiol is incorporated in extremely small amounts. When ethinylestradiol is provided in micronized form, it preferably has the following particle size distribution as determined under the microscope: 100% of the particles have a diameter of ≤ 15.0 µm, 99% of the particles have a diameter of ≤ 12.5µm, 95% of the particles have a diameter of ≤ 10.0 µm, and 50% of the particles have a diameter of ≤ 3.0 µm. Furthermore, no particle is larger than 20 µm, and ≤ 10 particles have a diameter of ≥ 15 µm and ≤ 20 µm.

DETAILED DISCLOSURE OF THE INVENTION

Drospirenone, which may be prepared substantially as described in, e.g., US 4,129,564 or WO 98/06738, is a sparingly soluble substance in water and aqueous buffers at various pH values. Furthermore, drospirenone is rearranged to an inactive isomer under acid conditions and hydrolysed under alkaline conditions. To ensure good bioavailability of the compound, it is therefore advantageously provided in a form that promotes rapid dissolution thereof.

[41] The detailed disclosure goes on to describe carriers and excipients, particular dosages, other uses, dosage packaging, daily dosage and rest period.

[42] At page 9, the patent addresses formulation in any manner known in the pharmaceutical art:

> The composition of the invention may be formulated in any manner known in the pharmaceutical art. In particular, as indicated above, the composition may be formulated by a method comprising providing drospirenone and, if desired, ethinylestradiol in micronized form in said unit dosage form, or sprayed from a solution onto particles of an inert carrier in admixture with one or more pharmaceutically acceptable excipients that promote dissolution of the drospirenone and ethinylestradiol so as to promote rapid dissolution of drospirenone and preferably ethinylestradiol on oral administration. Examples of suitable excipients include fillers, e.g. sugars such as lactose, glucose or sucrose, sugar alcohols such as mannitol, sorbitol or xylitol, starch such as wheat, corn or potato starch, modified starch or sodium starch glycolate, lubricants such as talc, magnesium stearate, calcium stearate, colloidal silica or stearic acid, and binders such as polyvinylpyrrolidone, cellulose derivatives, carboxymethyl cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose or gelatin, for making oral dosage forms such as tablets, pills or capsules.

[43] There follows a discussion that the tablets may be film-coated (not to be confused with enteric coated) and that the composition may be formulated in liquid form. Packaging, parenteral formulation, and transdermal formulation are discussed.

[44] Five examples follow. Example 1 deals with the preparation of tablets containing drospirenone and ethinylestradiol; both micronized. Example 2 deals with the dissolution rate of the drospirenone in such tablets. Example 3 with the dissolution rate of ethinylestradiol. Example 4 deals with the bioavailability of those components in the tablets. Example 5 deals with the contraceptive efficacy.

[45] The claims – 53 in all – follow.

X. CLAIM CONSTRUCTION

[46] It is well established law in Canada that construction of the claims at issue must precede the inquiry as to infringement and validity. Construction is for the Court aided by expert evidence, if needed, as to the background state of the art and the meaning of specific terms. Construction is done in the context of the description contained in the patent, care being taken not simply to take this or that gloss from the description in interpreting the claim.

[47] Claim construction is not done in a vacuum, the Court must be cognizant as to the contentious issues raised by the parties. Sometimes this is referred to as "where the shoe pinches". In the Cobalt proceedings the shoe pinched only in one place, whether all claims including claims 30 and 31 required that the drospirenone compound comprised only "micronized" particles of drospirenone or whether they including other forms such as particles onto which drosprirenone has been sprayed.

[48] In the present case the pinching of the shoe is broader, namely, do the claims include drospirenone found as a molecular dispersion(….). A further pinching here is whether the claims include ethinylestradiol in the form of a clathrate.

[49] In the present proceeding Bayer is asserting more claims than it did in the Cobalt Proceedings. In the Cobalt Proceedings, Bayer asserted, at the end of the day, only claims 30 and 31. In the present case Bayer asserts claim 1 and dependent claims 2 to 8 and 12; claim 30; and claim 31 and dependent claims 36,37, 39 to 42 and 47 to 50.

[50] I will start by repeating some of what I wrote at paragraphs 50 to 59 of my decision in the Cobalt Proceedings 2013 FC 1061.

> [50] Claim 1 specifies micronized drospirenone, without stating the form in which ethinylestradiol is present:
>
> 1. A pharmaceutical composition comprising from about 2 mg to about 4 mg of micronized drospirenone particles, about 0.01 mg to about 0.05 mg of 17α-ethinylestradiol, and one or more pharmaceutically acceptable carriers;
> the composition being in an oral dose form, and the composition being effective for oral contraception in a human female.
>
> [51] Claim 3 specifies that the ethinylestradiol may be micronized or sprayed:
>
> 3. A composition according to claim 1 or 2, wherein the ethinylestradiol is in micronized form or sprayed from a solution onto particles of an inert carrier.
>
> [52] It is to be noted that no claim of the '426 patent specifically claims that the drospirenone component may be sprayed. This is unlike the circumstances in the United Kingdom Court of Appeal in Gedeon Richter, supra, where it can be seen from paragraph 30 of the Reasons of that Court that claim 2, and all claims dependent of claim 2, stipulate that the drospirenone may be "in micronized form or sprayed". The patent laws of the United Kingdom permit claims to be amended by the Courts.
>
> [53] Claim 30 defines the drospirenone component only by particle size (but not particle distribution, as also recited in the Description of the patent):
>
> 30. A pharmaceutical composition comprising:
> from about 2 mg to about 4 mg of drospirenone particles, wherein the drospirenone has a surface area of more than 10,000 cm^2/g;
> about 0.01 to about 0.05 mg of 17α-ethinylestradiol; and
> one or more pharmaceutically acceptable carriers;
> the composition being in an oral dose form, and the composition being effective for oral contraception in a human female.
>
> [54] Claim 31 defines the drospirenone component only by its dissolution rate:

31. A pharmaceutical composition comprising:

from about 2 mg to about 4 mg of drospirenone particles, wherein the drospirenone is in a form, which when provided in a tablet containing 3 mg of drospirenone, has a dissolution such that at least 70% of said drospirenone is dissolved in 900 ml of water at 37° C. (±0.5° C.) within 30 minutes, as determined by USP XXIII Paddle Method using a USP dissolution test apparatus 2 at a stirring rate of 50 rpm, including 6 covered glass vessels and 6 paddles;

about 0.01 mg to about 0.05 mg of 17α-ethinylestradiol; and

one or more pharmaceutically acceptable carriers;

the composition being in an oral dose form, and the composition being effective for oral contraception in a human female.

[55] In considering claims 30 and 31, the parties are in contention. Cobalt argues that the particle size and dissolution rate parameters relate only to the micronized form of drospirenone. Bayer argues that at least the dissolution rate relates to drospirenone in any form, whether micronized or sprayed.

[56] Cobalt supports its argument by referring to page 4 of the Description of the patent where the particle size (and distribution) parameters, and the dissolution parameters, follow the discussion of the micronized drospirenone, and by referring to the claims in which explicit reference to spraying is made only in respect of the ethinylestradiol component.

[57] Bayer supports its position by saying that spraying the drospirenone component is mentioned at page 4 of the Description, and that at page 9 of the Description, it says that the composition may be formulated "in any manner known in the art: whether micronized or sprayed". Bayer argues that the essential point of the patent is not micronized drospirenone; rather, it is rapid dissolution, as stated in the last sentence of the first paragraph at page 4, in the Detailed Disclosure:

> To ensure good bioavailability of the compound, it is therefore advantageously provided in a form that promotes rapid dissolution thereof.

[58] This is followed up by the statement at the beginning of the last full paragraph at page 4:

> Without wishing to be limited to any particular theory, it appears that the in vitro dissolution rate of drospirenone is connected to the dissolution rate in

> vivo resulting in rapid absorption of drospirenone in vivo on oral administration of the compound.
>
> [59] While the matter is by no means free of doubt, I am of the opinion that Bayer's interpretation is the correct one, and that claim 31, and its dependent claims, is not limited to drospirenone in its micronized form, but to any form in which the rapid dissolution rate stipulated by that claim can be achieved.

[51] Here, I must go further. In particular I must consider whether claim 31, including its dependent claims, include a circumstance where drospirenone appears in the form of a molecular dispersion (….). Also, I must consider whether the ethinylestradiol called for in any of the claims at issue include a clathrate of that compound.

[52] First I address claims 1 and its dependent claims, claims 2 to 8 and 12. I am satisfied that those claims are directed just to what they say they are directed, namely "micronized drospirenone particles" and not to any other form, for instance not to particles onto which drospirenone is sprayed and not to a composition wherein drospirenone appears as a molecular dispersion (….).

[53] In the Cobalt decision I did not particularly construe claim 30 as to the "drospirenone particles" but here I will so construe that term, as I did with claim 31, so as to include not only micronized drospirenone particles but also particles onto which drospirenone has been sprayed, so long as those particles meet the size parameters of claim 30.

[54] I did construe claim 31 and its dependent claims in the Cobalt decision so as not to be limited to drospirenone in its micronized form, but to any form in which the rapid dissolution by the claim can be achieved.

[55] The present issue for construction is whether claim 31 and its dependent claims, which requires "drospirenone particles" which "when provided the tablet form" has a particular dissolution profile can extend to forms other than particles of drospirinone or inert particles onto which drospirinone has been sprayed .

[56] The question can be put as whether "drospirenone particles" are particles <u>of</u> drospirenone, or can extend to particles onto which drospirenone <u>has</u> been sprayed as I have found in my Cobalt decision, or whether it can also extend to "particles of a solid matrix in which drospirenone has been dissolved."

[57] I return to the description of the patent in particular at pages 4 and 9 which I set out earlier in these reasons but will repeat. At page 4:

> DETAILED DISCLOSURE OF THE INVENTION
>
> Drospirenone, which may be prepared substantially as described in, e.g., US 4,129,564 or WO 98/06738, is a sparingly soluble substance in water and aqueous buffers at various pH values. Furthermore, drospirenone is rearranged to an inactive isomer under acid conditions and hydrolysed under alkaline conditions. To ensure good bioavailability of the compound, it is therefore advantageously provided in a form that promotes rapid dissolution thereof.
>
> It has surprisingly been found that when drospirenone is provided in micronized form (so that particles of the active substance have a surface area of more than 10,000 cm2/g, and the following particle size distribution as determined under the microscope: not more

> than 2 particles in a given batch with a diameter of more than 30um, and preferably <20 particles with a diameter of >10 um and <30 um) in a pharmaceutical composition, rapid dissolution of the active compound from the composition occurs in vitro ("rapid dissolution" is defined as the dissolution of at least 70% over about 30 minutes, in particular at least 80% over about 20 minutes, of drospirenone from a tablet preparation containing 3mg of drospirenone in micronized form, it is possible to dissolve it in a suitable solvent, e.g. methanol or ethyl acetate, and spray it onto the surface of inert carrier particles followed by incorporation of the particles containing drospirenone on their surface in the composition.

At page 9:

> The composition of the invention may be formulated in any manner known in the pharmaceutical art. In particular, as indicated above, the composition may be formulated by a method comprising providing drospirenone and, if desired, ethinylestradiol in micrnoized form in said unit dosage form, or sprayed from a solution onto particles of an inert carrier in admixture with one or more pharmaceutically acceptable excipients that promote dissolution of the drospirenone and ethinylestradiol so as to promote rapid dissolution of drospirenone and preferably ethinylestradiol and oral administration.

[58] The patent describes, therefore, drospirenone that is provided in one of two forms, in micronized form, or drospirenone that has been dissolved in a solvent, sprayed in to an inert carrier particles, then dried. Reference is also made to formulation by "any manner known in the pharmaceutical art" The formulation of those particles (micronized or sprayed on) with other excipients can then proceed in any manner known in the pharmaceutical art.

[59] No mention is made of a process whereby drospirenone is dissolved into a matrix(….), then mixed in with the other ingredients. In such a process drospirenone is no longer a "particle" or even sprayed onto a "particle", it is in solution.

[60] I therefore construe the term "drospirenone particles" as appearing in all of the claims at issue not to include a drospirenone solution nor particles of a matrix into which drospirenone has previously been dissolved.

[61] As to the other area in which the shoe pinches with respect to the ethinylestradiol I have discussed the evidence fully later in these reasons as to whether the '426 patent was eligible for listing. I conclude as I did in respect of that reasoning that the claims at issue include a clathrate of ethinylestradiol within the term ethinylestradiol.

XI. INFRINGEMENT

[62] Having construed all of the claims at issue not to include a formulation in which the drospirenone is provided in form wherein it has been dissolved in a matrix I find that the Apotex product is prepared by a method in which the drospirenone has been provided in a form where it is first dissolved in a matrix. The process then proceeds (….) the material is compressed into tablets, and the tablets coated with a non-enteric material; all as more particularly explained at paragraphs 124 to 127 of Dr. Cima's affidavit.

[63] The dissolution profile of the resulting tablet is almost identical to that of Bayer's YAZ tablets and, to that extent, meets the parameters of claim 31 of the '426 patent.

[64] Each of Bayer's and Apotex's witnesses have provided evidence as to testing of certain samples by a technique known as Raman or, in the case of Dr. Cima, Raman and a scanning electron microscope. Dr. Davies' evidence, presented on behalf of Bayer comments on tests

conducted on samples of product produced by (….) for the South African market. Dr. Cima's tests, presented on behalf of Apotex were performed on bulk drospirenone particles and representative Apotex tablets. As recited in my Order dated October 22, 2013 in these proceedings Apotex does not challenge that both Dr. Davies and Dr. Cima tested the same thing.

[65] The conclusions reached by Dr. Davies and Dr. Cima as to the results exhibited by their respective tests, are different. Dr. Davies argues, and I emphasize the word argue, at paragraphs 175 to 183 of his affidavit that Apotex has not proved that its product is a molecular dispersion of drospirenone. His opinion is largely based on an analysis of documents rather than scientific evidence; in so doing he stepped into the role of an advocate rather than providing expert scientific opinion. Dr. Cima, on the other hand, sticks to the role of a scientist. At paragraphs 129 and following of his affidavit he reviews the testing conducted under his direction and concludes, at paragraphs 153 to 159 that there are no particles of drospirenone or micronized drospirenone particles in the samples tested. I accept what Dr. Cima wrote at paragraphs 154 and 155 of his affidavit:

> 154. (….)
>
> 155. The results of the Raman spectroscopic analysis conducted in my laboratory on the tablet samples support the conclusion that the drospirenone is present in the granules as a solid solution (molecular dispersion). (….)

[66] I prefer Dr. Cima's evidence, but, even if the evidence were equally balanced, Bayer has not overcome the burden that it bears of proving, on a balance of probabilities, that Apotex's allegations of non-infringement are not justified.

[67] Given that the drospirenone is provided in a form which I have found is not within any claim at issue, and given that this is the basis upon which Apotex has alleged non-infringement, I find that Bayer has not established that Apotex's allegation in this regard is not justified.

XII. INELIGIBILITY OF THE '426 PATENT FOR LISTING

[68] Apotex has alleged that the '426 patent is ineligible for listing by Bayer under the provisions of the *NOC Regulations* as amended October 5, 2006. These allegations were raised in Apotex's Notice of Allegation but no motion was brought, in this respect, under subsection 6 (5)(a) of those *Regulations*.

[69] The gist of Apotex's allegation is that Bayer listed the '426 patent under the NOC Regulations in December 2008 as against its YAZ tablets. Those tablets contain, as the active ingredients, drospirenone and a molecular inclusion complex formed between ethinylestradiol (EE) and B-cyclodextrin (ie. EE-B-cyclodextrin complex). This is defined to by Apotex's expert Jarosz as a clathrate. Apotex argues that this clathrate is not the ethinylestradiol as claimed in the '426 patent thus the patent is improperly listed in respect of the YAZ product.

[70] Bayer argues that Apotex cannot raise this issue at the hearing, it must do so by a motion brought before the hearing, which it did not do. In any event, Bayer argues that the '426 patent has been properly listed.

[71] First, as to whether this issue can be raised at the hearing or must be raised at an earlier motion, there have been several decisions of this Court which address the issue.

[72] In *Pfizer* Canada *Inc. v Apotex Inc.*, 2005 FC 1421 Justice Mosley held that the issue could be raised at a hearing without a previous motion hearing been brought. He wrote at paragraphs 177 and 178:

> [177] At any time prior to the hearing of this application, Apotex could have brought a motion under 6(5)(a). Apotex argues, however, that it would have been imprudent to do so and would have likely wasted time and resources because of the high standard required to strike out an application; that the listing was so plainly improper to be bereft of any chance of success : David Bull Laboratories (Canada) Inc. v. Pharmacia Inc. et al., [1995] 1 F.C. 588, 58 C.P.R. (3d) 209 (C.A.). If they can bring it at this stage, they also enjoy the tactical advantage that the burden to disprove the allegations rests with the applicants whereas Apotex would have carried the burden on a preliminary motion to dismiss.
>
> [178] I accept that Apotex can make its allegation as part of these proceedings and is not required to bring a motion under subsection 6(5) in advance of the hearing of the 6(1) application. I am also satisfied that Pfizer has failed to establish on a balance of probabilities that the '071 patent was properly listed on the patent register as it was out of time when the NOC for the accelerated dosing regime for the 500 mg tablets was issued.

[73] In Abbott *Laboratories v Canada (Minister of Health)*, 2007 FCA 187, the Court of Appeal determined that while the issue of eligibility is usually raised by way of a prior motion, the Trial Judge was not wrong in dealing with the matter at the hearing. Noel JA, for the Court on this panel, wrote at paragraphs 44 and 45:

> [44] Finally, I note that Heneghan J. spoke on occasion of the '361 Patent (or parts thereof) not meeting "the eligibility requirements for inclusion in the Patent List" (see for instance, Reasons at para. 134). The eligibility of a Patent for inclusion on the Register is usually raised by way of a separate motion made pursuant to paragraph 6(5)(a) of the NOC Regulations (see Apotex Inc. v. Canada (Minister of Health and Welfare), (2000), 3 C.P.R. (4^{th}) 1 (F.C.A.), as applied in Apotex Inc. v. Canada (Minister of Health), 2004 FC 650 at paras. 59 to 64). It does not appear as though such a motion was made in this instance.

> [45] However, nothing turns on this as Heneghan J.'s conclusion is properly stated at paragraph 133 of her reasons where she holds that claim 31 "is ineligible under the NOC Regulations".

[74] I commented on this decision in *Novartis Pharmaceuticals Inc. v Cobalt Pharmaceuticals Company*, 2013 FC 985 and determined that I would deal with the question of eligibility at the hearing particularly where claim construction was a live issue. I wrote at paragraph 109:

> In the present case, Cobalt argues that it could not have brought its motion earlier since it did not know what construction Novartis would place on the claims, and that Cobalt believed only the Swiss-type claims were at issue. I find no basis for Cobalt to believe that only the Swiss claims were at issue; however, if that were the case, I would allow the matter of listing to be raised at the hearing. In any event, the "use" claims 10 to 16 are at issue and do meet the criteria for listing.

[75] Justice Gauthier (as she then was) in *Solvay Pharma Inc. v Apotex Inc.*, 2008 FC 308 also reviewed the Federal Court of Appeal decision, above, as well as earlier jurisprudence and determined that certain issues, such a eligibility related to eligibility could not be raised at the hearing but that only "relevant" claims need to be addressed. At paragraphs 56 and 66 of her reasons she wrote:

> The Court was initially attracted to the view that the filing of a motion under subsection 6(5) of the Regulations was more in the nature of a procedural vehicle for the quick dismissal of applications rather than a matter of substance and jurisdiction, if the application for prohibition was filed in response to a NOA that expressly included the second person's arguments on eligibility, such that the first person would have a full opportunity to know the case to meet and to file evidence in response. (In that respect, the Court notes that except for the letter of the Minister dated July 30, 2007, there is no indication that Altana sought and was refused the opportunity to file reply evidence pertaining to the patents' eligibility for listing, as nothing of the sort was discussed in Prothonotary Tabib's decision of June 15, 2007, or in Justice Pierre Blais' Order of August 28, 2007, 2007 FC 857). Moreover, costs

> could normally be used to discourage second persons from raising listing in the application itself, given that the filing of a subsection 6(5) motion early in the process is the only way to avoid useless prohibition proceedings, as was noted by the Federal Court of Appeal in Wyeth at paragraph 3.
>
> ...
>
> Thus, in light of the above, the Court concludes that it has no jurisdiction to consider eligibility issues (section 4) or the early working issues. However, as mentioned above, pursuant to subparagraph 5(1)(b)(iv), the Court must consider whether the claims that are still at issue in respect of infringement are claims for the medicine itself or for the use of the medicine because as mentioned, these are the only relevant claims that need to be addressed in the NOA and which can justify a prohibition order if Apotex' allegations of non-infringement are not justified.

[76] It is time to put the matter to rest. Proceedings under the *NOC Regulations* are arcane enough. In many respects they have become a minefield where one party or the other set traps for the unwary or unaccustomed party or lawyer. Going back to Justice Gauthier's reasoning in *Solvay* at paragraph 56 I believe there is sufficient basis to be satisfied that her "initial attraction" that section 6(5) provided a convenient vehicle for early disposition and not a precursory prohibition against raising the issue of eligibility at a hearing, was the right approach.

[77] In looking at the *NOC Regulations* subsections 5 (1) or (2) provides that a second person "shall" make certain allegations, namely:

> (a) state that the second person accepts that the notice of compliance will not issue until the patent expires; or
>
> (b) allege that
>
> (i) the statement made by the first person under paragraph 4(4)(d) is false,
>
> (ii) the patent has expired,

> (iii) the patent is not valid, or
>
> (iv) no claim for the medicinal ingredient, no claim for the formulation, no claim for the dosage form and no claim for the use of the medicinal ingredient would be infringed by the second person making, constructing, using or selling the drug for which the submission is filed.

[78] While *these* allegations, or such as are applicable, are mandatory there is nothing to preclude other relevant allegations, such as eligibility for listing, to be raised also.

[79] Subsection 5(3) of the *NOC Regulations* provides that the second person shall serve the Notice of Allegation together with a *"a detailed statement of the legal and factual basis for the allegation"*. Thus every allegation shall be supported, where necessary, with a detailed statement of the legal and factual basis for the allegation made. This would include the mandatory allegations as well as any other allegations made.

[80] Subsection 6(5)(a) of the *NOC Regulations* provides that a second person "may" bring a motion to dismiss the application in whole or in part in respect of patents ineligible for testing. That subsection does not say "must" it says "may". There is no language in that subsection or anywhere else in the *NOC Regulations* that requires such a motion to be brought or precludes the issue from being raised at the hearing on the merits.

[81] I find therefore, that Apotex having raised the allegations as to eligibility for listing in its Notice of Allegation, can argue the matter at the hearing notwithstanding that no motion was brought under subsection 6(5) of the *NOC Regulations*.

[82] Turning then to the merits of the issue. Apotex's argument is based on its interpretation of certain provisions of the *NOC Regulations* as amended October 5, 2006. In particular it relies on the new definition of "claim for a medicinal ingredient" or "revendication de l'ingrédient medicinal" in section 2 of those Regulations, which reads:

"claim for the medicinal ingredient" "claim for the medicinal ingredient" includes a claim in the patent for the medicinal ingredient, whether chemical or biological in nature, when prepared or produced by the methods or processes of manufacture particularly described and claimed in the patent, or by their obvious chemical equivalents, and also includes a claim for different polymorphs of the medicinal ingredient, but does not include different chemical forms of the medicinal ingredient; (revendication de l'ingrédient médicinal)	*« revendication de l'ingrédient médicinal » S'entend, d'une part, d'une revendication, dans le brevet, de l'ingrédient médicinal — chimique ou biologique — préparé ou produit selon les modes ou procédés de fabrication décrits en détail et revendiqués dans le brevet ou selon leurs équivalents chimiques manifestes, et, d'autre part, d'une revendication pour différents polymorphes de celui-ci, à l'exclusion de ses différentes formes chimiques. (claim for the medicinal ingredient)*

[83] Apotex them turns to subsections 4(2)(a) and (b) of the NOC Regulations that require that, in order for a patent to be eligible for listing, it must in relation to a new drug submission, such as that of Bayer for its YAZ product a claim for a "medicine ingredient":

(1) A first person who files or who has filed a new drug submission or a supplement to a new drug submission may submit to the Minister a patent list in relation to the submission or supplement for addition to the register.	*(2) Est admissible à l'adjonction au registre tout brevet, inscrit sur une liste de brevets, qui se rattache à la présentation de drogue nouvelle, s'il contient, selon le cas :*

(2) A patent on a patent list in relation to a new drug submission is eligible to be added to the register if the patent contains	
(a) a claim for the medicinal ingredient and the medicinal ingredient has been approved through the issuance of a notice of compliance in respect of the submission;	• *a) une revendication de l'ingrédient médicinal, l'ingrédient ayant été approuvé par la délivrance d'un avis de conformité à l'égard de la présentation;*
(b) a claim for the formulation that contains the medicinal ingredient and the formulation has been approved through the issuance of a notice of compliance in respect of the submission;	• *b) une revendication de la formulation contenant l'ingrédient médicinal, la formulation ayant été approuvée par la délivrance d'un avis de conformité à l'égard de la présentation;*

[84] Apotex points out that the change in the definition of "medicinal ingredient" is such that "polymorphs" of such ingredients are included but "different chemical forms" are not. It points to the Regulatory Impact Analysis Statement (RIAS) accompanying the amendments in the Canada Gazette, Vol. 140, No. 21 at pages 1517-1518 which address this change:

A definition for the first of these phrases is necessary to ensure that product-by-process patents continue to qualify for protection under the regulations, and to confirm that the same is true of patents for biologic drugs. It also serves to clarify, in so far as small molecule drugs are concerned, that patents claiming different crystalline, amorphous, hydrated and	*Il est nécessaire d'établir une définition de « revendication de l'ingrédient médicinal » pour que les brevets protégeant un produit par procédé continuent de pouvoir bénéficier de la protection du règlement et pour confirmer qu'il en est de même pour les brevets relatifs à des médicaments biologiques. Une telle définition sert également à préciser, concernant les*

solvated forms of the approved medicinal ingredient (i.e. "polymorphs") are eligible for listing when submitted in relation to the NDS, but that different chemical forms, such as salts and esters, are not. This accords with Health Canada policy on what constitutes an "identical medicinal ingredient" for the purposes of establishing pharmaceutical equivalence under section C08.001.1 of the Food and Drug Regulations. None of these changes is intended to disturb prior jurisprudence to the effect that patents claiming intermediates or metabolites of the medicinal ingredient are ineligible for listing.	*médicaments à petites molécules, que les brevets revendiquant différentes formes cristallines, amorphes, hydratées et solvatées de l'ingrédient édicinal approuvé (c.-à-d., des « formes polymorphiques ») peuvent être inscrits au registre lorsqu'ils sont soumis en relation avec la PDN, mais que les diverses formes chimiques comme les sels et les esters ne le sont pas. Ceci est conforme à la politique de Santé Canada, laquelle définit ce qui constitue un « ingrédient médicinal identique » aux fins de l'établissement d'une équivalence pharmaceutique aux termes de l'alinéa C08.001.1 du Règlement sur les aliments et drogues. Ces changements n'ont pas pour objet de modifier la jurisprudence antérieure selon laquelle les brevets dont les revendications portent seulement sur des intermédiaires ou des métabolites de l'ingrédient médicinal ne peuvent pas être inscrits au registre*

[85] Section C08.001.1 of the *Food and Drug Regulations* referred to in the RIAS is not particularly enlightening, it says as to pharmaceutical equivalent or equivalent pharmaceutical:

"pharmaceutical equivalent" *means a new drug that, in comparison with another drug, contains identical amounts of the identical medicinal*	« équivalent pharmaceutique » *S'entend d'une drogue nouvelle qui, par comparaison à une autre drogue, contient les mêmes quantités*

ingredients, in comparable dosage forms, but that does not necessarily contain the same non-medicinal ingredients; (équivalent pharmaceutique)	*d'ingrédients médicinaux identiques, sous des formes posologiques comparables, mais pas nécessairement les mêmes ingrédients non médicinaux. (pharmaceutical equivalent)*

[86] In a "Policy" statement entitled "Interpretation of 'Identical Medical Ingredient" adopted effective 2003/07/08, that is before the change in the NOC Regulations, Health Canada purported to provide, among other things, certain "Guiding Principles" and a "Glossary".

[87] The "Guiding Principles" stated:

> The term identical medicinal ingredient could literally be interpreted to imply medicinal ingredients that are both physically and chemically identical. However, in the context of the Regulations, only the "chemical identicality" of the medicinal ingredients is taken into account while determining pharmaceutical equivalence. Pharmaceutically equivalent drug products should contain chemically identical, but not necessarily physically identical, medicinal ingredients. It is recognized that differences in physical properties (e.g., particle size, polymorphism) of the medicinal ingredients could potentially cause differences in the safety and efficacy profiles of the drug products. To address concerns arising from differences in physical properties, appropriate in vivo and / or in vitro studies should be conducted and results provided with the drug submission. The term identical is to be understood in this context.
>
> Based on the above considerations, medicinal ingredients containing the same active moiety are classified into identical or non-identical medicinal ingredients according to the following guiding principles:
>
> 4.1 Anhydrous, anhydrate and the various hydrated forms of the same active moiety would generally be considered identical.
>
> 4.2 Unsolvated and the various solvated forms of the same active moiety would generally be considered identical, provided the

> solvate content is within acceptable levels. Levels within the limits recommended in the ICH Q3C "Impurities: Guideline for Residual Solvents", would be considered acceptable without further justification. Solvate levels exceeding the ICH Q3C limits should be justified, on a case by case basis, and supporting data provided. Supporting data could be based upon concepts of qualification outlined in ICH impurity guidelines Q3A, Q3B and Q3C.
>
> 4.3 Different complexes, esters, or salts of the same active moiety are considered non-identical.
>
> 4.4 Different isomers or mixtures with different proportions of isomers are considered non-identical.

[88] The "Glossary" contained the following definitions, among others:

> Active moiety (or Therapeutic moiety)
> The molecule or ion, excluding those appended portions of the molecule that cause the drug substance to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.
>
> Clathrate
> A solid mixture in which small molecules of one compound or element are trapped in the holes of the crystal lattice of another substance. Molecules are not held by chemical bonding interactions, but rather by physical entrapment.
>
> Complex
> A compound which is formed by the equilibrium association of two or more interacting molecules or ions. Complexes may be formed in solution or in the solid state.

[89] On the issue of listing, Apotex who is the party asserting that the '462 patent should not have been listed, bears the burden of proving this assertion. Unlike the allegations mandated by subsections 5(1) or (2) of the *NOC Regulations*, listing is not an allegation that "shall" be made. Thus it is not an allegation which Bayer must demonstrate was not "justified". This allegation as

to the propriety of listing a particular patent, is one which Apotex has raised outside subsections 5(1) and (2) and, as is usual in a civil case, it must prove what it alleges.

[90] Apotex turns to the evidence of one of its experts, Jarosz, who states in his affidavit that the ethinylestradiol component in Bayer's YAZ product is in the form of a clathrate or molecular inclusion complex: He says at paragraph 48 of his affidavit:

> 48. Is the YAZ formulation within the claims of the '426 Patent?: Based on the description of Bayer's YAZ tablets in the Compendium of Pharmaceuticals and Specialties, 2011 edition, pages 2863-67 (Schedule C Document 13), this formulation does not fall within the scope of the claims of the '426 Patent since the ethinylestradiol included in the YAZ formulation is in the form of a clathrate, or molecular inclusion complex, with betadex, and the latter is not within the patent.

[91] Jarosz defines what he means by a clathrate or molecular inclusion complex at paragraph 308 of his affidavit:

> 308. The ethinylestradiol included in the YAZ formulation is in the form of a clathrate, or molecular inclusion complex, with betadex. A clathrate refers to a chemical substance that consists of a lattice that contains other molecules trapped inside, i.e., where a guest molecule is in a cage surrounded by a host molecule. Betadex, or beta cyclodextrin, is a cyclic compound composed of seven alpha-(1-4) linked D-glucopyranosyl units, with the following structure (DIAGRAM OMITTED)

[92] Jarosz was cross-examined on this point. I repeat what is set out at pages 201-202 of the transcript in this regard:

> Q. You don't have any specific recollection of seeing the CPS before?
>
> A. Correct.

Q. And this entry talks about YAZ?

A. Yes.

Q. And it says—underneath the heading YAZ, it says, drospirenone ethinylestradiol; right?

A. Yes.

Q. And then under summary product information, dosage from strength, it says, a tablet containing 3.0 milligrams of drospirenone and .020 milligrams of ethinylestradiol?

A. Yes.

Q. So those are two active ingredients in YAZ; right?

A. Yes.

Q. Before formation of a clath rate, does not involve the rearrangement of molecular structure of a compound; correct?

A. Well, it involves potentially some rearrangement in the clath, what's doing the surrounding of the molecule. But if you're referring to the active species, ethinylestradiol is not changing the molecular entity, but it is perhaps bonding with what is the substance surrounding it.

Q. It's not—it's—the composition still contains ethinylestradiol; right?

A. Ethinylestradiol is contained within a clath rate.

Q. Right. So it's accurate to describe the YAZ tablets as containing ethinylestradiol?

A. Yes, it is accurate to say YAZ contains ethinylestradiol.

[93] Apotex also relies upon a Canadian Patent Application, CA2432151 filed by Schering (now Bayer) under the provisions of the Patent Co-operation Treaty (PCT) effective 2001/12/20. That application names as one of the inventors Wolfgang Heil, who is also one of the persons named as an inventor in the '426 patent and who filed an affidavit and was cross-examined in the

present proceedings. That application is directed to an ethinylestradiol clathrate that is said to be a "significant improvement" over conventional compositions. Surprisingly Heil was not cross-examined on this application. I find the application of limited assistance here since the issue before me is whether the clathrate is a "medicinal ingredient" within the meaning of the NOC Regulations and not whether it is a "significant improvement" or different from ethinylestradiol.

[94] There is no relevant jurisprudence that is of assistance in this regard. The '426 patent does not mention, whether in the description or in the claim any clathrate or molecular complex of ethinylestradiol.

[95] In the portion of the Abbreviated New Drug Submission (ANDS) filed with the Minister by Apotex it describes the comparison products Jasminelle and YAZ, as containing ethinylestradiol and refers to them throughout by that name even though in a footnote below a table at section 3.2.P.2 it refers to the ethinylestradiol component of both products as "stabilized by betadex as a clathrate (molecular inclusion complex)."

[96] Therefore, I find, on the evidence of Jarosz including his cross-examination and including Apotex's (ANDS) that a clathrate of ethinylestradiol is not distinguished as such from the simpler term ethinylestradiol and that ethinylestradiol includes the clathrate. I note that Apotex, in making its allegations as to non-infringement, made no issue of the fact that its ethinylestradiol component was, in fact, a clathrate of that component.

[97] Given, therefore, the evidence which I find demonstrates that ethinylestradiol in the particulars of this case includes a clathrate of that compound, listing of the ‘426 patent was not improper.

XIII. VALIDITY- ANTICIPATION

[98] Apotex alleges that the claims at issue of the ‘426 patent are invalid because, more than one year before the filing date of the application for that patent, Bayer conducted certain clinical studies in Europe and the United States whereby what was claimed was both disclosed and enabled.

[99] I repeat part of Apotex’s allegations in this respect:

> Apotex alleges that, during Phase II trials conducted from about January 1990 to September 1990 in Europe and Phase III trials conducted from about December 1992 to April 1996 in Europe and from about December 1996 to July 1998 in the United States, the patentee’s oral contraceptive tablet was being publicly used by the participants enrolled in these trials.
>
> …
>
> There was no restriction imposed on participants that prevented them from disseminating information about the Bayer Tablets to the public. Additionally, the investigators, doctors and participants were free to disclose to the general public that the participants were using the Bayer Tablets as an oral contraceptive, and that these tablets contained 3 mg of drospirenone and 0.03 mg of EE. The investigators, doctors and participants were also free to show the Bayer Tablets to members of the general public.
>
> Furthermore, the investigators, doctors and participants did not sign confidentiality agreements or, alternatively, did not maintain confidentiality of the kits and their contents.
>
> Moreover, some of the participants withdrew from the trials, while others were not fully compliant with the regimen and either

> intentionally or unintentionally did not administer one or more Bayer Tablets during the course of the trials. In both instances, participants were not required to, nor did they, return any unused Bayer Tablets.
>
> At all material times, the participants were not precludes from having the Bayer Tablets analyzed and were free to perform such an analysis.

[100] What has not been alleged, and what has not been proved in evidence, is that any of those participating in the tests were told what the precise ingredients of the tablets were. Nor is there any evidence that any of the tablets were actually tested by the participants, or passed on to any others for testing, as to their ingredients.

[101] Bayer has provided the affidavit evidence of Dr. Marr who has held a position with Bayer since 2008 wherein he oversees the clinical development of certain women's health care products. He provides, as business records, documents relating to the clinical studies which he describes as experimental research. He notes that participants were provided documents marked as confidential and that no information as to the micronized form of the medication was disclosed. The participants were required to return all unused tablets.

[102] Apotex provided the expert evidence of Rosen, a United States lawyer practicing in the healthcare and US regulatory area and Dr. Simon, a United States medical doctor with experience in clinical studies. Both provided opinion evidence, as to the Bayer clinical studies.

[103] Rosen's evidence can be summarized with reference to paragraphs 42 and 57 of his affidavit:

> 42. In conclusion, it is my opinion that the clinical investigators, enrolled participants and potential participants would all have been aware of the following details of YASMIN:
>
> (a) that it was an oral contraceptive containing 3 mg of drospirenone and 0.03 mg of EE;
>
> (b) that it was in the form of a tablet;
>
> (c) that the tablets were contained within blister packs comprising 21 active pills and 7 placebo pills; and
>
> (d) that the intended use was for contraception.
>
> …
>
> 57. Accordingly, in my opinion, there was no prohibition precluding the clinical investigators from disclosing information relating to YASMIN to the three groups mentioned above, and, no prohibition precluding the enrolled and potential participants from publicly sharing information about the details of YASMIN. Such information relating to YASMIN was known to the clinical investigators, participants and potential participants and was not intended to be confidential.

[104] Dr. Simon's opinion can be summarized with reference to paragraph 35 of his affidavit:

> 35. Whatever extraordinary efforts are made on the part of the clinical investigator, in my experience, it will not ensure that all OC packets and tablets are returned and a great number of distributed tablets are never accounted for. Thus, a clinical investigator has no knowledge of what has come of such tablets. In my experience, in an OC clinical trial having a duration of thirteen cycles and including hundreds of participants, it is inevitable that OC packets and tablets would not be returned to the clinical investigators.

[105] The circumstances of these studies have been considered by the United States District Court for the District of New Jersey in *Bayer Schering Pharma AG et al v Barr Laboratories, Inc.*, Civil Action No. 05-CV-2308 (PGS) wherein Judge Sheridan of that Court gave a lengthy

decision dated March 3, 2008. That decision was affirmed by the United States Court of Appeal for the Federal Court (US CAFC) on August 5, 2009, No 2008-1282 without discussion as to this issue.

[106] The circumstances of these studies have also been considered by the Technical Board of Appeal of the European Patent Office, Case Number T 0007/07-3.3.2 in a decision dated 7 July 2011.

[107] I am concerned that Rosen seems to have been unaware of the decisions of the United States Courts or the European Board. On cross-examination at page 14 of the transcript he said that he had not reviewed any court decisions regarding drospirenone in America or otherwise. Given that there has been a decision of the United States Courts or European Board as to the very circumstances at issue here I am puzzled and disappointed that Rosen did not look for or have his attention drawn to the relevant decisions.

[108] The reasons for the decision of Judge Sheridan respecting the alleged public use begins at page 71 of his reasons, part VII and continues to page 82. I repeat a portion of his conclusion at page 78 and pages 81-82:

> Barr has failed to meet their burden of clear and convincing evidence that the U.S. Clinical trial was public, and therefore is unable to establish a bar under ss.102(b).
>
> Assuming Barr had established that the U.S. clinical trial was a public use, their ss. 102(b) would still fail, as Bayer has successfully asserted that the U.S. clinical trial was experimental in nature.
>
> …

> Barr did not present any testimony to counter the statements of Dr. Shulan and Dr. Heithecker, or otherwise make this Court doubt their understanding that the U.S. clinical trial was necessary to determine effectiveness in the more diverse U.S. population. The extensive clinical testing demonstrates that there was a lack of confidence that the efficacy of the claimed invention could be based solely on the European trials.
>
> The testing here indicates that the determination of whether the '531 Patent formula would be effective was still being determined, and Barr has not presented any evidence to counter the statements of Dr. Heithecker, Shluman and Ellman. As a consequence Barr has failed to meet its burden of establishing a reduction to practice by clear and convincing evidence.

[109] In brief Judge Sheridan found that Bayer's studies were experimental and that Barr had failed in its burden to establish that the clinical trial was public within the meaning of the relevant statutory provision.

[110] On the other hand the European Board found that, under its relevant law, if even a single member of the public, not under any obligation of secrecy, had the theoretical possibility of access to the particular information the information would have been made public. I repeat part of its decision at pages 16 to 18:

> The respondent did not contest that clinical trials were carried out prior to the priority date and that the principal investigators but not the participants entered into confidentiality agreements. The participants were informed about the active agents of the contraceptive, but were not told that the drospirenone was present in micronized form. Nor did the respondent contest that the oral contraceptive used for the study comprised all the features of the subject-matter according to claim 1.
>
> It is established board of appeal case law that if a single member of the public, who is not under an obligation to maintain secrecy, has the theoretical possibility to access particular information, this information is considered as being available to the public within the meaning of Article 54(2) EPC.

> The respondent argued that the drug had not become publicly available before the priority date as according to the established board of appeal case law any persons involved in clinical trials are (implicitly) bound to confidentiality.
>
> The board does not agree with the respondent's interpretation of the case law. Both decisions cited by the respondent (T0152/03 of 22 April 2004 and T0906/01 of 28 September 2004) concern prototype devices that were to be implanted in a small number of patients. Therefore, even if the patients did not sign a confidentiality agreement, they would not have been in a position to pass the prototypes on or even inspect them themselves.
>
> Such trials are to be distinguished from trials where a large number of patients are given tablets to take home with them and use over a longer period of time. It has been acknowledged by the US court that not all of the unused study drugs were returned. Therefore, it appears that after having handed out the drugs the respondent effectively lost control over them as the participants in the clinical trials were in no way barred from disposing of the drugs as they wanted.
>
> In view of these circumstances, the board comes to the conclusion that the handing out of the drugs to the participants made them became publicly available.

[111] In the present Bayer argues that there is no evidence that any person connected with the clinical studies ever, in fact, received sufficient information so as to know exactly what the ingredients were in the tablets and there is no evidence that any person in fact analyzed any tablet or was likely to have done so. I agree.

[112] Bayer also argues that it took reasonable precautions so as to keep relevant information confidential and to require participants to return any unused tablets. Again, I agree.

[113] The opinion evidence of Dr. Simon is that it is "inevitable" that not all unused tablets would be returned. His opinion is not confined to the particular study at issue here but to, as he

says in paragraph 21 of his affidavit, "a clinical trial (that) had been conducted in the mid 1990s in the United States" that was an "open-labelled study that included 300 participants". His evidence, if taken to its logical conclusion, would be that a great many such studies would result in the "inevitable" failure to return tablets.

[114] Rosen's evidence is questionable since he does not address and was apparently unaware of the decisions of the United States Courts or the European Board.

[115] No evidence demonstrates or even suggests that a participant in the study knew the pharmaceutical make-up of the tablets or had the knowledge to discern that from the tablets provided. At best we have counsel's speculation that, as the European Board found, there is a "theoretical possibility" that such an analysis could have been conducted.

[116] There are two considerations that must be taken into account here with respect to the law. The first is whether there was a disclosure of the invention such as would constitute an anticipation under subsection 28.2(1)(a) of the *Patent Act*. The second is whether, nonetheless, the disclosure is exempted from those provisions because it was experimental.

[117] As to the first of these considerations Justice Rothstein (as he then was) in the Federal Court of Appeal in *Canwell Enviro-Industries Ltd. v Baker Petrolite Corp.* (2002), 17 CPR (4^{th}) 478 provided a very thorough analysis of the legal requirements respecting disclosure under the provisions of subsection 28.2(1)(a) of the *Patent Act*. I provided an edited version of what he

wrote at pages 497 to 500 of the decision as reported where he set out eight (non-exhaustive) principles:

> 1. Sale to the public or use by the public alone is insufficient to prove anticipation. Disclosure of the invention is required to constitute anticipation under para. 28.2(1)(a).
>
> 2. For a prior sale or use to anticipate an invention, it must amount to "enabling disclosure".
>
> 3. The prior sale or use of a chemical product will constitute enabling disclosure to the public if its composition can be discovered through analysis of the product.
>
> 4. The analysis must be able to be performed by a person skilled in the art in accordance with known analytical techniques available at the relevant time.
>
> 5. In the context of patent anticipation under para. 28.2(1)(a), when reverse engineering is necessary and capable of discovering the invention, an invention becomes available to the public if a product containing the invention is sold to any member of the public who is free to use it as she or he pleases.
>
> 6. It is not necessary to demonstrate that a member of the public actually analyzed the product that was sold.
>
> 7. The amount of time and work involved in conducting the analysis is not determinative of whether a skilled person could discover the invention. The relevant consideration, in this respect, is only whether inventive skill was required. There must be some evidence from which the use of inventive skill may be inferred. Complexity or time and work involved alone are insufficient.
>
> 8. It is not necessary that the product that is the subject of the analysis be capable of exact reproduction. It is the subject matter of the patent claims (the invention) that must be disclosed through the analysis. Novelty of the claimed invention is destroyed if there is disclosure of an embodiment which falls within the claim.

[118] In applying these principles to the present case I find that there has been established a "theoretical" possibility that a tablet could have been kept and analyzed, therefore the requirements of subsection 28.2(1) (a) of the *Patent Act* have been met.

[119] However that does not end the matter. The law in Canada has long been established that experimental use in order to bring the invention to perfection, does not constitute public use e.g. *Conway v Ottawa Electric Railway Co.*, (1904), 8 ExCR 432 at 442; *Gibney v Ford Motor Co. of Canada*, [1967] 2 ExCR 279 at para 49 in citing *Elias v Grovesend Tinplate Co.* (1890), 7 RPC 455 at 466. This applies in particular where, of necessity, the experimental use must be conducted in public.

[120] A practical application of the principle of experimental use can be seen with reference to the decision of this Court (Tremblay-Lamer J) in *Hi-Qual Mfg Ltd v Rea's Welding & Steel Supplies Ltd* (1994), 55 CPR (3rd) 224, aff'd 61 CPR(4th) 270 (FCA) where a farmer placed a feeder that he was experimenting with in the back of his farm where it could possibly have been seen by a delivery man. Tremblay-Lamer J wrote as reported at pages 238-239 of this decision:

> Counsel for the defendant argues that the plaintiffs built and used the feeder on his farm as of February, 1983. The plaintiffs allege that it was built outside in the pads but that it was in a protected area that could not be seen by the public.
>
> Photographs taken of the property show that the feeder was indeed located in a protected area and that there was no practical vantage point on any raod from which the feeder could be seen clearly. The evidence showed that the only possible witness was the oil delivery man given the height of his delivery truck. This, however, was not confirmed as the driver did not testify.
>
> Furthermore, I am satisfied, based on the testimony of Mr. Delichte whom I find to be a credible witness, that during that period until the publication of the article in 1985, he was experimenting.
>
> …
>
> As pointed out at p. 160 in Gibney v. Ford Motor Co. of Canada Ltd. by Noel J:

> I would indeed think that a common sense view should be taken in dealing with the means taken by an inventor to complete his invention and thereby ensure that a half-baked device is not patented and provided he is experimenting, the means employed should not be too important.
>
> Indeed, the small man, in my view, is entitled to an invention as well as the large corporation and whether he is or not a dedicated or professional inventor, he should still be entitled to what he invents.

Counsel for the defendant also argues that the plaintiff made a commercial use of the feeder because he was selling the cattle used for the experiment. I do not accept this proposition. To test the device, Mr. Delichte had no alternative other than to use the cattle on his farm since they were part of his operation and had to be sold at one point. In cannot be said, in my view, that this amounts to a commercial use of his invention.

[121] In the present case clinical studies were necessary to prove that the drug was safe and effective and, thereby, gain government approval for sale. Until this had been demonstrated, no commercial sale of the drug could have been made. Bayer took reasonable steps to ensure the confidentiality of the relevant documents and to ensure that unused tablets were returned. The theoretical possibility that some tablets were retained and analyzed is just that, theoretical. This theoretical possibility does not preclude the fact that the studies were experimental, and of necessity, conducted by the provision of tablets to members of the public. Thus these clinical studies are exempted from public use.

[122] I find that Apotex's allegations that the clinical studies conducted an anticipation of the claims at issue are not justified.

XIV. VALIDITY- AMBIGUITY/ INSUFFICIENCY

[123] Apotex alleges, in brief, that claim 31 of the '426 patent is ambiguous/insufficient because a skilled person could not ascertain whether a composition other than a tablet comprising 3 mg of drospirenone possessed by the dissolution profile required by that claim. In particular, it alleges that claim 31 embraces compositions comprising from about 2 mg to about 4 mg of drospirenone yet the dissolution test described in the patent relates only to 3 mg tablets. Further it alleges that claim 31 embraces compositions including tablet, capsule and liquid dosage forms, yet the dissolution test described in the patent relates only to a tablet.

[124] In the Cobalt Proceedings allegations as to ambiguity and insufficiency as raised by Cobalt were discussed in my Reasons at paragraphs 101 to 106 (2013 FC 1061). Those allegations were in respect of different "ambiguities" or "insufficiencies" raised by Apotex in the present proceeding. It must be noted that in raising those allegations that are different from each other Apotex and Cobalt seem more intent in casting about to pick at whether they can than to argue genuine ambiguities or insufficiencies. Cobalt never thought that testing 3 mg could never support a claim to 2 to 4 mg and never thought that claim 31 extended beyond tablets.

[125] Apotex does not argue on the basis on any evidence that it presented rather, it picks at the evidence presented by Bayer through Dr. Davies.

[126] I am entirely satisfied on the basis of Dr. Davies' evidence, particularly at paragraphs 385 to 387 of his affidavit that Apotex's allegations in this respect are not justified.

XV. VALIDITY- OTHER ALLEGATIONS

[127] At the hearing Apotex's Counsel dropped all argument as to overbreadth. No arguments remain.

XVI. CONCLUSION AND COSTS

[128] In conclusion I have found that Apotex's allegation as to non-infringement is justified and, on that basis, this application must be dismissed. I have found that Apotex's allegations as to invalidity are not justified but this is irrelevant as to the dismissal of these proceedings.

[129] While Apotex has been successful in the result that the application is dismissed, it was successful only in the respect of the non-infringement issue. Therefore, subject to the following terms, Apotex is permitted to recover only one-half of its taxable costs and disbursements to be assessed at the middle of Column IV. In assessing these costs and disbursements the following principles shall be applied:

- Fees and disbursements shall be allowed only for Dr. Cima and no other expert witness, his allowable fees shall not exceed the fees chargeable by Apotex's senior counsel for like time;
- Fees for one senior and one junior counsel at trial are allowed;
- Fees for only one counsel in attendance at any cross-examinations are allowed at a senior counsel level.

"Roger T. Hughes"
Judge

Toronto, Ontario
May 7, 2014

FEDERAL COURT
SOLICITORS OF RECORD

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