F ederal Court  Cour fédérale

Date: 20100511

Docket: T-1476-08

Citation: 2010 FC 510

Toronto, Ontario, May 11, 2010

PRESENT: The Honourable Mr. Justice Hughes

BETWEEN:

MERCK & CO., INC. AND
MERCK FROSST CANADA LTD.

Applicants

and

PHARMASCIENCE INC. AND
THE MINISTER OF HEALTH

Respondents

REASONS FOR JUDGMENT AND JUDGMENT

[1] This is an application brought under the provisions of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 as amended (*NOC Regulations*). The Applicants are the owner (Merck & Co., Inc.) and Canadian licensee (Merck Frosst Canada Ltd.) of the patent at issue.

I will refer to them collectively as Merck. The Respondent Pharmascience Inc. is a generic drug company seeking to gain approval from the other Respondent, the Minister of Health, to market a drug in Canada known as finasteride for the treatment of male baldness.

[2] While the original allegations made by Pharmascience involved several patents and several claims, only one patent, Canadian Patent No. 2,173,457 (the '457 Patent) and only one claim of that patent, claim 5, remains for determination. The only issue before this Court is whether Pharmascience's allegation that claim 5 of the '457 Patent is invalid, on a variety of grounds, is "justified" within the provisions of section 6(2) of the *NOC Regulations*. For the Reasons that follow I find that the allegation is justified and that the application is dismissed with costs to Pharmascience.

The '457 Patent and Claim 5

[3] The patent at issue, the '457 Patent, is entitled **"Use of 5-Alpha Reductase Inhibitors and Compositions for Treating Androgenic Alopecia".** It is governed by the provisions of the post-October 1, 1989 version of the *Patent Act*, R.S.C. 1985, c.P-4, sometimes called the "new" *Patent Act*, since the application for that patent was filed in Canada after that date namely, on October 11, 1994. The patent application was made available to the public on April 20, 1995, the publication date. The patent was issued and granted to the Applicant Merck & Co. Inc. on March 23, 1999. The term of the patent expires twenty (20) years after the Canadian filing date, that is, on October 11, 2014.

[4] The only claim of the ’457 Patent at issue is claim 5. It is a “dependant” claim since it is drafted in such a way so as to incorporate the provisions of other claims. In this case one must read each of claims 1, 2, 3 and 4 so as to understand claim 5. I repeat each of those claims:

> *1. The use of a 5α-reductase 2 inhibitor for the preparation of a medicament adapted for oral administration useful for the treatment of androgenic alopecia in a person and wherein the dosage amount is about 0.05 to 3.0 mg.*
>
> *2. The use of claim 1, wherein the 5α-reductase 2 inhibitor is 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one.*
>
> *3. The use of claim 2, wherein the dosage is about 0.05 to 1.0 mg.*
>
> *4. The use of claim 3, wherein the dosage is about 1.0 mg.*
>
> *5. The use of claim 4, wherein the androgenic alopecia is male pattern baldness.*

[5] To incorporate all the references to the prior claims into claim 5 it would read:

> *5. The use of 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one for the preparation of a medicament adapted for oral administration useful for the treatment of male pattern baldness in a person and wherein the dosage amount is about 1.0 mg.*

[6] Fortunately, the descriptive part of the ’457 Patent at page 2, lines 9-10 uses the word “finasteride” in place of the long complex chemical description set out above , therefore claim 5 can be written as follows:

> *5. The use of finasteride for the preparation of a medicament adapted for oral administration useful for the treatment of male pattern baldness in a person and wherein the dosage is about 1.0 mg.*

[7] This claim is drafted in a peculiar style that originated in Europe called a "Swiss" claim. I will address the "Swiss" style of this claim later in these Reasons.

The '457 Patent

[8] The '457 Patent is to be read from the viewpoint of a person skilled in the art to which it pertains as of the publication date, April 20, 1995. It must be remembered that statements made by the patentee, such as what constitutes the prior art, are to be treated as binding admissions by the patentee (*Eli Lilly Canada Inc. v. Novopharm Limited,* 2007 FC 596, 58 C.P.R. (4th) 214 at para. 142 (FC); *Whirlpool Corp. v. Camco Inc.* (1997), 76 C.P.R. (3d) 150 at page 186 (F.C.T.D.), affirmed [2000] 2 S.C.R. 1067; *Shire Biochem Inc. v. Canada (Minister of Health),* 2008 FC 538, 67 C.P.R. (4th) 94 at para. 24; *Pfizer Canada Inc. v. Novopharm Limited,* 2005 FC 1299, 42 C.P.R. (4th) 502 at para. 78).

[9] The patent begins at page 1 with a general statement as to the field of the invention. It is the treatment of a condition called androgenic alopecia (called "aa" by the English Courts), including male pattern baldness (sometimes referred to in these proceedings by the acronym MPB) with compounds described as 5-alpha reductase isozyme 2 inhibitors (sometimes referred to as 5α-reductase:

> *The present invention is concerned with the treatment of androgenic alopecia, including male pattern baldness, with compounds that are 5-alpha reductase Isozyme 2 inhibitors.*

[10] At pages 1 and 2 the patent describes the background to the invention with particular discussion as to steroids and hormonal effects. The physical manifestation described as benign prostatic hyperplasia is often referred to by the acronym BPH in these proceedings:

> *BACKGROUND OF THE INVENTION*
>
> *Certain undesirable physiological manifestations, such as acne vulgaris, seborrhoea, female hirsutism, androgenic alopecia which includes female and male pattern baldness, and benign prostatic hyperplasia, are the result of hyperandrogenic stimulation caused by an excessive accumulation of testosterone (PT") or similar androgenic hormones in the metabolic system. Early attempts to provide a chemotherapeutic agent to counter the undesirable results of hyperandrogenicity resulted in the discovery of several steroidal antiandrogens having undesirable hormonal activities of their own. The estrogens, for example, not only counteract the effect of the androgens but have a feminizing effect as well. Non-steroidal antiandrogens have also been developed, for example, 4'-nitro-3'-trifluoromethylisobutyranilide. See Neri, et al., Endocrinol 1972, 91 (2). However, these products, though devoid of hormonal effects, compete with all natural androgens for receptor sites, and hence have a tendency to feminize a male host or the male fetus of a female host and/or initiate feed-back effects which would cause hyperstimulation of the testes.*

[11] The next paragraph in the background description portion of the '457 Patent identifies 5α-dihydrotestosterone (DHT) as being something formed in target organs such as the prostate by a 5α-reductase. Inhibition of 5α-reductase in those organs will have a beneficial effect. It is noted that these are at least two types of 5α-reductase, called type 1 and type 2. In these proceedings, there is much discussion as to interaction with type 1 and type 2 5α-reductase and where in the body such types may occur:

> *The principal mediator or androgenic activity in some target organs, e.g. the prostate, is a 5α-dihydrotestosterone ("DHT"), formed*

> *locally in the target organ by the action of testosterone-5α-reductase. Inhibitors of testosterone-5α-reductase will serve to prevent or lessen symptoms of hyperandrogenic stimulation in these organs. See especially United States Patent No. 4,377,584 assigned to Merck & co., Inc., issued March 22, 1983. It is now known that a second 5α-reductase isozyme exists, which interacts with skin tissues, especially in scalp tissues. See, e.g., G. Harris, et al., Proc. Natl. Acad. Sci. USA, Vol. 89, pp. 10787-10791 (Nov. 1992). The isozyme that principally interacts in skin tissues is conventionally designated as 5α-reductase 1 (or 5α-reductase type 1), while the isozyme that principally interacts within the prostatic tissues in designated as 5α-reductase 2 (or 5α-reductase type 2).*

The above passage makes reference to a Harris paper which was extensively discussed by the experts and in argument. The patent says that Harris says that type 1 reductase occurs in skin tissues and type 2 in the prostate.

[12] The next paragraph in the background portion of the ’457 patent is an important acknowledgement by the patentee as to what constitutes the prior art. The patentee acknowledges that the drug in question, finasteride, is a known drug and has been commercialized for use as a 5α-reductase inhibitor to treat prostatic conditions. Utility of that drug in treating androgenic alopecia (aa) is acknowledged. The paragraph states, however, that dosages exemplified in the prior art ranged from 5 to 2000 mg. per patient per day:

> *Finasteride (17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-one), which is marketed by Merck & co., Inc. under the tradename PROSCAR®, is an inhibitor of 5α-reductase 2 and is known to be useful for the treatment of hyperandrogenic conditions. See e.g., U.S. Patent No. 4,760,071. Finasteride is currently marketed in the United States and worldwide for the treatment of benign prostatic hyperplasia. Finasteride’s utility in the treatment of androgenic alopecia and prostatic carcinoma is also disclosed in the following documents: EP 0 285,382, published 5 October 1988; EP 0 285 383,*

> *published 5 October 1988; Canadian Patent no. 1,302,277; and Canadian patent no. 1,302,276. The specific dosages exemplified in the above-noted disclosures varied from 5 to 2000 mg. per patient per day.*

[13] The last paragraph in the background section of the ’457 Patent serves two functions. First, it acknowledges the desirability of administering the drug in the lowest dosage possible. Second, it describes the invention as the *“surprisingly unexpected”* discovery that a low daily dosage of a 5α-reductase inhibitor is particularly useful in treating androgenic alopecia:

> *In the treatment of androgenic alopecia, which includes both female and male pattern baldness, and other hyperandrogenic conditions, it would be desirable to administer the lowest dosage possible of a pharmaceutical compound to a patient and still maintain therapeutic efficacy. Applicants have surprisingly unexpectedly discovered that a low daily dosage of a 5α-reductase 2 inhibitor is particularly useful in the treatment of androgenic alopecia. Furthermore, a low daily dosage of a 5α-reductase 2 inhibitor may also be particularly useful in the treatment of the hyperandrogenic conditions of acne vulgaris, seborrhoea, female hirsutism, and polycystic ovary syndrome.*

[14] A detailed description of the invention begins at page 35 of the patent. The first three paragraphs at page 3 describe three different “aspects” of the invention – the use of a 5α-reductase inhibitor in dosages from about 0.05 to 3.0 mg., a solid composition of such inhibitor in such dosages, and a pharmaceutical composition of such inhibitor in such dosage. The fourth paragraph describes a “particular embodiment” that tracks the language of the “Swiss” claims. The fifth paragraph simply states that a “particular embodiment” is the use of such inhibitor in such dosages. The final paragraph on page 3 is a general statement as to the invention being the treatment of conditions such as androgenic alopecia in dosages under 5 mg per day:

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DETAILED DESCRIPTION OF THE INVENTION

In accordance with one aspect of the invention there is provided the use of a 5α-reductase 2 inhibitor for the preparation of a medicament adapted for oral administration useful for the treatment of androgenic alopecia in a person and wherein the dosage amount is about 0.05 to 3.0mg.

In accordance with another aspect of the invention there is provided a solid composition containing 17β-(N-tert-butylcaramoyl)-4-aza-5α-androst-ene-3-one useful for the treatment of androgenic alopecia wherein the dosage is about 0.05 to 3.0 mg.

In accordance with still another aspect of the invention there is provided an anti-androgenic alopecia pharmaceutical composition comprising a 5α-reductase 2 inhibitor in an amount effective to provide a dosage of about 0.05 to 3.0 mg, in association with a pharmaceutically acceptable carrier.

In a particular embodiment of the invention there is provided use of 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-l-ene-3-one in the manufacture of a medicament providing a dosage of said 5α-androst 1-ene-3-one of 0.05 to 3.0 mg, for the treatment of androgenic alopecia.

In another particular embodiment of the invention there is provided 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-l-ene-3-one for use at a dosage of about 0.05 to 3.0 mg in the treatment of androgenic alopecia.

The instant invention is concerned with treating and/or reversing androgenic alopecia and promoting hair growth, and treating acne vulgaris, seborrhea and female hirsutism. in particular the treatment comprises administering to a patient in need of such treatment a 5α-reductase 2 inhibitor in a dosage amount under 5 mgs/day.

[15] The first paragraph on page 3a states that the drug can be administered in dosage amounts ranging from 0.01 to 3.0 mg/day to narrower ranges such as 0.05 to 0.2 mg/day:

In one embodiment of this invention, the 5α-reductase 2 inhibitor is administered in a dosage amount of from 0.01 to 3.0 mgs/day. In one class of this embodiment, the 5α -reductase 2 inhibitor is administered in a dosage amount of from 0.05 to 1.0 mg/day, and in a sub-class of this embodiment, the 5α-reductase 2

> *inhibitor is administered in dosage amounts of about 0.05 to 0.2 mg/day. Illustrating this subclass are dosage amounts of about 0.05, 0.1, 0.15 and 0.2 mg/day. Exemplifying the subclass are dosages of 0.05 and 0.2 mg/day. Compounds which are inhibitors of 5α - reductase 2 can be determined by employing the assay described below in Example 3.*

[16] There follows from pages 3a to 5 a description as to the chemistry of the drugs and processes for making them. This description is not relevant to these proceedings.

[17] At page 5, the first full paragraph, there is a repetition of the dosage ranges, followed by a statement that the drug can be used in combination with other drugs such as minoxidil. This is important because some prior art, in particular a patent application by Diani, who was working for a competitor of Merck (Upjohn), deal with Upjohn's drug minoxidil and mixtures of that drug with finasteride. The paragraph ends with a statement that the two drugs can be administered topically or orally or one by one method and the other one by the other method:

. . .

> *Exemplifying the invention are dosages of 0.05 and 0.2 mg/day. The term "treating androgenic alopecia" is intended to include the arresting and/or reversing of androgenic alopecia, and the promotion of hair growth. Also, a 5α-reductase 2 inhibitor, e.g., finasteride, at a dosage under 5 mgs/day can be used in combination with a potassium channel opener, such as minoxidil or a pharmaceutically acceptable salt thereof, for the treatment of androgenic alopecia, including male baldness. The 5α-reductase 2 inhibitor and the potassium channel opener may both be applied topically, or each agent can be given via different administration routes; for example, the 5α-reductase 2 inhibitor may be administered orally while potassium channel opener may be administered topically.*

[18] The paragraph that begins at the bottom of page 5 and over to page 6 states that the drug can be administered in a variety of forms, all said to be known to those of ordinary skill. Tablets can be scored which, counsel before me agree, means they can be broken into pieces for administration in smaller doses. This point is picked up at the beginning of the last paragraph on page 6:

> *The present invention also has the objective of providing suitable systemic, oral, parenteral and topical pharmaceutical formulations for use in the treatment of the present invention. The compositions containing 5α-reductase 2 inhibitor compounds as the active ingredient for use in the treatment of the above-noted hyperandrogenic conditions can be administered in a wide variety of therapeutic dosage forms in conventional vehicles for systemic administration. For example, the compounds can be administered in such oral dosage forms as solid or liquid compositions, for example as tablets, capsules (each including timed release and sustained release formulations), pills, powders, granules, elixirs, tinctures, solutions, suspensions, syrups and emulsions. Likewise, they may also be administered in intravenous (both bolus and infusion), intraperitoneal, subcutaneous, topical with or without occlusion, or intramuscular form, all using forms well known to those of ordinary skill in the pharmaceutical arts. For oral administration, for example, the compositions can be provided in the form of scored or unscored tablets containing 0.01, 0.05, 0.1, 0.2, 1.0, 2.0 and 3.0 milligrams of the active ingredient for the symptomatic adjustment of the dosage to the patient to be treated.*
>
> . . .
>
> *Advantageously, compounds of the present invention may be administered in a single daily dose or the total daily, dosage may be administered in divided doses of two, three or four times daily.*

[19] At page 7, the patent acknowledges that dosage regimen can be selected by a physician of ordinary skill having regard to a variety of factors:

> *The dosage regimen utilizing the compounds of the present invention is selected in accordance with a variety of factors including type, species, age, weight, sex and medical condition of the patient; the*

> *severity of the condition to be treated; the route of administration; the renal and hepatic function of the patient; and the particular compound thereof employed. A physician or veterinarian of ordinary skill can readily determine and prescribe the effective amount of the drug required to prevent, counter, arrest or reverse the progress of the condition. Optimal precision in achieving concentration of drug within the range that yields efficacy without toxicity requires a regimen based on the kinetics of the drug's availability to target sites. This involves a consideration of the distribution, equilibrium, and elimination of a drug.*

[20] There follows from pages 7 to 9 a discussion as to formulation of the drug which is not relevant to these proceedings.

[21] Commencing at page 9 to the end of the descriptive portion of the patent, five examples are presented. Only example 5 is relevant to these proceedings. Example 1 deals with the preparation of finasteride, as does Example 2. Example 3 deals with the preparation of human 5α-reductase. Example 4 describes a procedure for measuring hair loss - essentially by taking photographs over a period of time. Example 5 is all that is said in respect of the effect of the administration of finasteride:

> *EXAMPLE 5*
> *In another test, finasteride was orally administered for 6 weeks to men with male pattern baldness at doses of 0.2 mg/day, 1.0 mg/day and 5.0 mgs/day. The results of this test showed a significant reduction in DHT content in scalp tissue of the test participants.*

[22] There is nothing else to tell the reader why it was concluded that a *"significant reduction"* of DHT (*5*α -dihydrotestosterone) occurred and at what dosage, whether 0.2 or 1.0 or 5.0mg/day.

[23] The claims follow. I repeat claim 5, as I have redrafted it by incorporating claims 1 to 4 and substituting finasteride for the chemical formula:

> *5. The use of finasteride for the preparation of a medicament adapted for oral administration useful for the treatment of male pattern baldness in a person and wherein the dosage is about 1.0 mg.*

THE ISSUES

[24] The main issue is whether Pharmascience's allegations as to invalidity of claim 5 of the '457 Patent are justified within the meaning of section 6(2) of the *NOC Regulations.* In determining that issue, I must determine the following matters, which I will do in the following order:

1. Burden
2. Evidence
3. Person of Ordinary Skill in the Art
4. Claim Construction
    a) History of a Claims Requirement in Canada
    b) History of a Claims Requirement in Great Britain
    c) Current State of the Law in Canada
    d) Tying it All Together
    e) The U.K. and European Decisions as to "Swiss" Claims
    f) "Swiss" Claims in Canada
    g) Claim Construction – Notice of Allegation
    h) Construing Claim 5
5. Method of Medical Treatment

6. Double Patenting

7. Novelty and Obviousness

    a) General

    b) The ’457 Patent

    c) The Prior Art

    d) Viewing the Prior Art Through the Eyes of a Person Skilled in the Art

    e) Conclusions as to the Evidence Respecting Novelty and Obviousness

    f) Novelty

    g) Obviousness

8. Sound Prediction/Overbreadth

[25] I am grateful to Counsel for each of the parties for their cooperation and civility throughout this hearing. I am particularly grateful for the concise and organized manner in which their arguments were presented, including the provision of skeleton outlines, compendia and USB electronic storage devices containing the various arguments and evidence, including hyperlinks in some cases. Their conduct and preparation was exemplary. No Counsel participated in these proceedings on behalf of the Minister.

1) Burden

[26] The only issue is that of validity of claim 5 of the '457 Patent. I considered the issue as to who bears the burden of proof as to validity in the context of proceedings brought under the *NOC Regulations* several times, including in *Eli Lilly Canada Inc. v. Apotex Inc.* (2008), 63 C.P.R. (4th) 406 at para. 58 (FC), and *Pfizer Canada Inc. v. Canada (Minister of Health),* 2008 FC 11, 69 C.P.R. (4th) 191 at paras. 28 to 33. I adopted the reasoning of Justice Mosley in *Pfizer Canada Inc. v. Apotex Inc.,* 2007 FC 971, 61 C.P.R. (4th) 305. To repeat what I said at paragraph 32 of *Pfizer*, 2008 FC 11, 69 C.P.R. (4th) 191:

> *[32] I do not view the reasoning of the two panels of the Federal Court of Appeal to be in substantial disagreement. Justice Mosley of this Court reconciled these decisions in his Reasons in Pfizer Canada Inc. v. Apotex Inc., 2007 FC 971 at paragraphs 44 to 51. What is required, when issues of validity of a patent are raised:*
> *1. The second person, in its Notice of Allegation may raise one or more grounds for alleging invalidity;*
> *2. The first person may in its Notice of Application filed with the Court join issue on any one or more of those grounds;*
> *3. The second person may lead evidence in the Court proceeding to support the grounds upon which issue has been joined;*
> *4. The first person may, at its peril, rely simply upon the presumption of validity afforded by the Patent Act or, more prudently, adduce its own evidence as to the grounds of invalidity put in issue.*
> *5. The Court will weigh the evidence; if the first person relies only on the presumption, the Court will nonetheless weigh the strength of the evidence led by the second person. If that evidence is weak or irrelevant the presumption will prevail. If both parties lead evidence, the Court will weigh all the evidence and determine the matter on the usual civil balance.*
> *6. If the evidence weighed in step 5 is evenly balanced (a rare event), the Applicant (first person) will have failed to prove that the allegation of invalidity is not justified and will not be entitled to the Order of prohibition that it seeks.*

[27] In the present case, Pharmascience has made extensive allegations and both parties have led evidence as to the validity of claim 5 of the ’457 patent. Subject to the arguments raised by Merck as to whether Sound Prediction/Overbreadth was raised in the Notice of Allegation, I must decide the issue of validity before me on the weight of the evidence and arguments presented. If that weight is evenly balanced in respect of any allegation, I must find that particular allegation made by Pharmascience to be justified.

2) The Evidence

[28] Each of Merck and Pharmascience led evidence. Merck led the evidence of two persons offered as expert witnesses – Doctor Russell and Doctor Shapiro – with exhibits. Both were cross-examined. Pharmascience led the evidence of two persons also offered as expert witnesses – Doctor Steiner and Doctor Taylor – with exhibits. Again, both were cross-examined. Since these proceedings are conducted by way of an application, all this evidence was led by way of affidavits and only transcripts of the cross-examinations were filed. The Court had no opportunity to observe the witnesses in person; thus there is difficulty in coming to any proper conclusions as to credibility, or whose evidence is to be preferred. To comment more particularly as to these witnesses:

1. For Merck

a) Dr. David Russell is a distinguished professor of molecular genetics at the University of Texas Southwestern Medical Centre. He has been extensively involved in research respecting *5*α -reductase inhibitors, including being a consultant to Merck in the early 1990’s when the subject matter of the ’457 Patent was being

developed. Doctor Russell testified in the *Actavis* English action, which I will discuss more fully later. That proceeding had many close parallels to the present proceeding. In those proceedings, (*Actavis U.K. Limited v. Merck & co. Inc* [2007] EWHC 1311 (Ch)) The Trial Judge, Justice Warren, had this to say about Doctor Russell at paragraph 36:

> *Merck obtained expert evidence from only one expert, Professor Russell. He was, as Mr. Thorley accepts, clear, lucid and well informed. He is clearly a leading authority with perhaps an unrivalled depth of knowledge and experience as a molecular biologist in the field of 5α-reductase. He and his team at the University of Texas were, as Mr. Thorley points out, at the cutting edge of the ongoing investigations into the existence and nature of the 5α-reductase isozymes and privy to unpublished work of all the leading commercial workers in the field. I accordingly take on board the note of caution sounded by Mr. Thorley when he says that care must be taken in attributing the breadth and depth of Professor Russell's knowledge to the notional scientist with knowledge of a 5α -reductase who would form part of the skilled team which one is required to assume exists. Professor Russell made no claim to any particular expertise in hair biology or in the design of clinical trials, although it would be idle to suggest that he was not generally knowledgeable about both.*

Having read Doctor Russell's affidavit and cross-examination in these proceedings, I agree in general with Justice Warren's assessment, including the note of caution that Doctor Russell may be "over qualified" when considering his evidence as to a person of ordinary skill in the art. Doctor Russell acknowledges this at paragraph 19 of his affidavit in these proceedings where he states *"my own qualifications exceed that of a Skilled Person",* although he goes on to assert that he can, nevertheless, speak from the vantage point of the Skilled Person.

Counsel for Pharmascience drew attention to two places during the cross-examination of Doctor Russell where he gave evidence on relevant matters which were clearly contradictory to evidence that he gave in respect of the same matters at the English trial (cross-examination, pages 125-127 and 148-149). Doctor Russell's explanation for those inconsistencies namely: that he was tired during the U.K. trial – hardly so because the answers were given early in the U.K. trial – and that his characterization of a prior art scientific paper was coloured by what he perceived to be the differences between Canadian and U.K. law- are not very satisfactory.

Overall, I view Doctor Russell as being a highly qualified scientist dealing in the 5α -reductase inhibitor area at the relevant time, who has perhaps been overstretched in giving evidence on behalf of Merck in two related proceedings.

b) Dr. Jerry Shapiro is a clinical professor at the University of British Columbia in the Department of Dermatology and Skin Care. He has been active in the hair care research and treatment area since 1986. He has written several papers in that area and consulted for a number of organizations, including Merck. I accept his evidence as an expert in the area of dermatology, especially relating to hair.

2. For Pharmascience

a) Dr. Joseph E. Steiner is the Dean and Professor of the College of Health Services at the University of Wyoming. His background is in pharmacy, in which he received a

doctorate and practiced in a clinical setting from 1975 to 1997. It appears that the main focus of Doctor Steiner's work is, I addition to the administrative requirements in being a Dean, in the area of ambulatory care. Doctor Steiner has written a number of review articles in which the publications in a given scientific area are reviewed and presented to the reader as reflecting the state of the art at the time. One such review article in *Clinical Pharmacy* dealt with the pharmacology, pharmaceutics and clinical use of the drug finasteride as of 1992. While Doctor Steiner lacks the in-depth experience of Merck's witnesses, I accept his evidence, presented as an expert in reviewing the state of the art respecting drugs, as helpful in the Court's understanding as to what was known about finasteride in the scientific community as of 1992.

b) Dr. E. Kent Taylor is a medical doctor located in Burlington, Ontario, who has for over 23 years been practicing as a clinical dermatologist. It appears that about ten percent of his practice is directed to hair loss which percentage he says is normal for a practising dermatologist. He has acted as a consultant to Upjohn during the launch of their minoxidil product for the treatment of hair loss, a product that will be more fully discussed later. I accept that Doctor Taylor can provide useful expert evidence to the Court as to the views of a person practicing in the field of hair loss at the relevant time.

[29] Merck's Counsel strenuously attacks the evidence of Doctors Steiner and Taylor, citing *R v. Mohan,* [1994] 2 S.C.R. 9, at paragraph 27, saying that the expert must show *"special or peculiar"* knowledge before the evidence can be admitted. It was argued that Doctors Steiner and Taylor had no such knowledge.

[30] Pharmascience's Counsel argued, relying on *Regina v. Marguard* (1993), 108 D.L.R. (4th) 47 (S.C.C.) at page 78, that *"The only requirement for the admission of expert opinion is that the "expert" witness possesses special knowledge and experience going beyond that of the trier of fact."*

[31] I am prepared to admit the evidence of Doctors Steiner and Taylor as expert evidence. Their evidence is material to the issues and goes beyond the knowledge that this Court is expected to have. I do not view *Mohan*, *supra*, as requiring superlative or exceptional expertise before such evidence is admissible. The matter can be left to assessment as a matter of weight.

3) <u>Person of Ordinary Skill in the Art</u>

[32] The Person of Ordinary Skill is the Art (POSITA) or as such person is called in some countries, Person Having Ordinary Skill in the Art (PHOSITA) is a fictional person used as a measuring stick or guide in certain aspects of patent law just as the "reasonable person" or "man in the Clapham omnibus" has played a role in tort law.

[33] There have been many attempts by Canadian Courts and Courts elsewhere to define a POSITA. The Supreme Court of Canada considered such a person in *Whirlpool Corp. v. Camco Inc.,* [2000] 2 S.C.R. 1067 at paragraphs 70, 71 and 74 where Binnie J. for the Court wrote

> *[70] ...Someone with Mr. Pielemeier's connection to the respondents, burdened as he is with inside information, is not a very satisfactory proxy for the "ordinary worker". He is a skilled addressee but he is not operating on the basis of common knowledge in the trade. The patent claims were not addressed by Whirlpool's research engineers to their colleagues in Whirlpool's product development group. The patent claims were necessarily addressed to the wider world of individuals with ordinary skills in the technology of clothes washing machines As Aldous L.J. observed in Beloit Technologies Inc. v. Valmet Paper Machinery Inc., [1997] R.P.C. 489 (Eng. C.A.) at p. 494:*
>
> > *The notional skilled addressee is the ordinary man who may not have the advantages that some employees of large companies may have. The information in a patent specification is addressed to such a man and must contain sufficient details for him to understand and apply the invention. <u>It will only lack an inventive step if it is obvious to such a man</u>. [Emphasis added].*
>
> *Dickson J. placed the same emphasis on "ordinariness" in Consolboard, supra, at p. 523:*
>
> > *"The persons to whom the specification is addressed are "ordinary workmen", ordinarily skilled in the art to which the invention relates and possessing the ordinary amount of knowledge incidental to that particular trade. The true interpretation of the patent is to be arrived at by consideration of what a competent workman reading the specification at its date would have understood it to have disclosed and claimed."*
>
> *[71] "Ordinariness" will, of course, vary with the subject matter of the patent. Rocket science patents may only be comprehensible to rocket scientists. The problem with Mr Pielemeier is that he could not be a good guide to a common knowledge of "ordinary workers" in the industry because his opinions were predicated on Whirlpool's in-house knowledge, and he made no bones about that fact.*

. . .

> *[74] ...While the hypothetical "ordinary worker" is deemed to be uninventive as part of his fictional personality, he or she is thought to be reasonably diligent in keeping up with advances in the field to which the patent relates. The "common knowledge" of skilled workers undergoes continuous evolution and growth.*

[34] The AIPPI (Association Internationale pour la Protection de la Propriete Intellectuelle) is a politically neutral, non-profit organization, domiciled in Switzerland, which currently has almost 9000 members representing more than 100 countries, including a strong representation of leading practitioners from the Canadian intellectual property bar and agencies. It seeks to develop and improve laws relating to intellectual property. One of the methods which it uses is to pose certain questions to its members. The members in each country will formulate answers which are then submitted for debate and resolution at a general meeting of that organization.

[35] A question put for the meeting to be held in Paris in the fall of this year relates to the best way to define a POSITA. I have been provided with a copy of the submissions made by the Canadian Group of AIPPI for that purpose, in which a number of questions were answered reflecting Canadian law. A summary was given at the end as to what, under Canadian law, a POSITA is understood to be. It reads:

> *Q.213 Summary*
>
> *In Canada, the "person of ordinary skill in the art" is the hypothetical person to whom the patent is addressed. This may be a single individual or a group representing different disciplines, depending on the nature of the invention. The person of ordinary skill in the art is deemed to be unimaginative and uninventive, but at the same time is understood to have an ordinary level of competence and knowledge incidental the field to which the patent relates (i.e.*

> *the common general knowledge) and to be reasonably diligent in keeping up with advances. The common general knowledge is that knowledge generally known by persons skilled in the relevant art at the relevant time. Accordingly, it can include knowledge passed amongst people in the field, including information that is not in published form. Likewise, not everything that has been published is within the common general knowledge.*

[36] I put this summary to Counsel for the parties and they generally agreed with it, but each had a point to make. Merck's Counsel agreed that the POSITA must be, or the group must include, those who were actually in the field. Counsel relied on a statement by Warren J. in *Actavis UK Limited v. Merck & Co. Inc*. [2007] EWHC 1311, a case that I will discuss in detail later, at paragraph 46. This proposition has been expressly rejected by this Court in *Janssen-Ortho Inc. v. Novopharm Ltd*., 57 C.P.R. (4th) 6, 2006 FC 1234, at paragraph 90 (aff'd 2007 FCA 217), 59 C.P.R. (4TH) 116) where it was held that a witness giving evidence on the issue need not have been a person actually involved in the field at the time, so long as they are in a position to provide appropriate evidence as to what a skilled person at the time would have known.

[37] Counsel for Pharmascience raised what he described as a *quaere* as to whether, given the definition of obviousness in section 28.3 of the "new" *Patent Act,* which requires a person skilled in the art to have considered "information available to the public" as of the claim date, whether that definition is broader than "knowledge generally known by persons skilled in the relevant art at the relevant time" as stated in the AIPPI summary. I agree that "information available" may be broader than information "generally known", and to that extent, the AIPPI statement of Canadian law could be modified to remove the word "generally".

[38] In dealing with individual cases, the Court must guard against making too fine a distinction as to identifying the "ideal" POSITA. Counsel for each party will argue meanings and shades of meanings most favourable to their case and the witness(es) they present. Each Counsel will argue that their witness(es) best fit the description of the ideal POSITA while there are numerous shortcomings with each of the witness(es) for the opposing party.

[39] The Court must generally define the person or group to whom the patent is addressed. It may be that the patent can be read by different persons, each having a different interest. Consideration may have to be given to each such different person. Merck's Counsel went so far as to suggest that the Court must consider who has the "loudest voice" when considering a team of persons or group of different persons. In this case, it obviously suits Merck to put forward Doctor Russell as the "loudest voice".

[40] To require fine precision and ranking of voices is to place a series of "trip wires" upon which a Court may be expected to stumble or risk sanctions by a higher Court. There must be some generalized treatment of the question of defining a POSITA and a level of generalization applied.

[41] In the present case, the Court can look at the opening words of the '457 Patent and obtain reasonable guidance as to the person(s) to whom the patent is directed:

> *"The present invention is concerned with the treatment of androgenic alopecia, including male pattern baldness, with compounds that are 5α-reductase isozyme 2 inhibitors."*

[42] Thus a POSITA in considering the ’457 Patent is directed to persons concerned with the treatment of male pattern baldness and, in particular, a person or group who were interested in using compounds such as 5α-reductase inhibitors for that person. It could be a researcher or clinician, or both. That person is to be reasonably well read as to the state of the art. That person is to be unimaginative, but that does not mean that the person is slow-witted or graduated (if at all) at the bottom of the class. Nor is the person the gold medallist who graduated at the top of the class. That person is the average person in the group. Just as a “reasonable man” is expected to be reasonable, the POSITA is expected to possess the ordinary skill in the art.

4) Claim Construction

a) History of a Claims Requirement in Canada

[43] The Canadian *Patent Act, R.S.C.1985, c. P-4,* in the “new” version applicable to applications for a patent filed after October 1, 1989 and patents maturing from such applications, requires that a patent contain both a specification which describes the invention and claims which define the monopoly claimed by the patentee. Sections 27(3) and (4) of that *Act* provide:

> *27(3) The specification of an invention must*
> *(*a*) correctly and fully describe the invention and its operation or use as contemplated by the inventor;*
> *(*b*) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, compound or use it;*
> *(*c*) in the case of a machine, explain the principle of the machine and the best mode in which the inventor has contemplated the application of that principle; and*

> *(*d*) in the case of a process, explain the necessary sequence, if any, of the various steps, so as to distinguish the invention from other inventions.*
>
> *27(4) The specification must end with a claim or claims defining distinctly and in explicit terms the subject-matter of the invention for which an exclusive privilege or property is claimed.*

[44] The function of the specification is to describe the invention so that a person skilled in the art can understand what the invention is and, when the patent expires, put it into practice. The function of the claims is to define the monopoly that the patentee is asserting. Dr. Fox, in his textbook *The Canadian Law and Practice Relating to Letters Patent for Inventions* 4th ed., 1969, Carswell, Toronto, expressed the nature of the claims at pages 193–4 as follows:

> *II. THE CLAIMS*
>
> ***History:*** *Although not required at common law, claims gradually came to be recognized as an effective means of defining and delimiting the ambit of the grant, and are now an essential part of the statutory consideration for the grant. As Lord Russell of Killowen pointed out in Electric and Musical Industries Ltd. et al. v. Lissen Ltd. et al.: "…the patentee is under a statutory obligation to state in the claims clearly and distinctly what is the invention which he desires to protect." The function of the claims was succinctly stated by him in the same case: "A patentee who describes an invention in the body of a specification obtains no monopoly unless it is claimed in the claims."*
>
> *A claim is a portion of the specification that fulfils a separate and distinct function. The forbidden field must be found in the language of the claim and not elsewhere. It and it alone defines the monopoly; and the patentee is under a statutory obligation to state in the claims clearly and distinctly what is the invention that he desires to protect. The nature of the invention must be ascertained from the claims. They should be so distinct as to enable the public to ascertain what is protected by the patent without referring to the body of the specification, but they should not go beyond the invention.*

> ***Claim is a Limitation:*** *The claim is not, therefore, an added description of the invention, but a limitation of the description of the invention contained in the body of the specification.*

[45] The first Canadian *Patent Act,* enacted after Confederation in 1867 was the 1869 Act, 32 & 33 Vict., c.11. The 1869 Canadian *Patent Act,* as Dr. Fox tells us at pages 5 ff. of his text, *supra*., was modeled after earlier United States patent statutes, including that of April 10, 1790 (1. St. at L. 109), which provided that a claim for invention be made in the patent although not separately necessarily. Section 2 said:

> *SEC. 2. And be it further enacted, That the grantee or grantees of each patent shall, at the time of granting the same, deliver to the Secretary of State a specification in writing, containing a description, accompanied with drafts or models, and explanations and models (if the nature of the invention or discovery will admit a model) of the thing or things, by him or them invented or discovered, and described as aforesaid, in the said patents; which specification shall be so particular, and said models so exact, as not only to distinguish the invention or discovery from other things before known and used, but also to enable a workman or other person skilled in the art or manufacture, whereof it is a branch or wherewith it may be nearest connected, to make, construct, or use the same, to the end that the public may have full benefit thereof, after the expiration of the patent term;*

[46] The Supreme Court of the United States in the well known *Markman* case (*Markman v. Westview Instruments Inc.* 517 U.S. 370 (1996)) provided a useful history of claims in the law of that country in the opening paragraphs of the unanimous decision of that Court delivered by Justice Souter:

> *The question here is whether the interpretation of a so-called patent claim, the portion of the patent document that defines the scope of the patentee's rights, is a matter of law reserved entirely for he court, or subject to a Seventh Amendment guarantee that a jury will determine the meaning of any disputed term of art about which*

expert testimony if offered. We hold that the construction of a patent, including terms of art within its claim, is exclusively within the province of the court.

I

The Constitution empowers Congress "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Rights to their respective Writings and Discoveries." U.S. Const., Art I, 8, cl. 8. Congress first exercised this authority in 1790, when it provided for the issuance of "letters patent," Act of Apr. 10, 1790, ch. 7, l, l Stat. 109, which, like their modern counterparts, granted inventors "the right to exclude others from making, using, offering for sale, selling, or importing the patented invention," in exchange for full disclosure of an invention, H. Schwartz, Patent law and Practice 1, 33 (2d ed. 1995). It has long been understood [2] that a patent must describe the exact scope of an invention and its manufacture to "secure to [the patentee'] all to which he is entitled, [and] to apprise the public of what is still open to them." McClain v. Ortmayer, 141 U.S. 419, 424 (1891). Under the modern American system, these objectives are served by two distinct elements of a patent document. First, it contains a specification describing the invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art…to make and use the same" 35 U.S.C. 112, see also 3E. Lipscomb, Walker on Patents 10:1, pp. 183-184 (3d ed. 1985) (Lipscomb)(listing the requirements for a specification). Second, a patent includes one or more "claims" which "particularly poin[t] out and distinctly clai[m] the subject matter which the applicant regards as his invention." 35 U.S.C. 112. "A claim covers and secures a process, a machine, a manufacture, a composition of matter, or a design, but never the function or result of either, nor the scientific explanation of their operation. " 6 Lipscomb 21:17, at 315-316. The claim "define(s) the scope of a patent grant," 3 id, 11:1, at 280, and functions to forbid not only exact copies of an invention, but products that go "to the heart of the invention but avoid the literal language of the claim by making a noncritical change," Schwartz, supra, at 82, 1 In this opinion, the word "claim" is used only in the sense peculiar to patent law.

[47] Since the decision of the Supreme Court of the United States in *Markman,* it has been usual in patent actions in that country for the parties to apply for a determination by the judge before a trial is heard, to place a construction on the claims. The judge may hear evidence in that regard. There are many reasons given for such a procedure, some say that once a construction is made, the questions of infringement and validity may be quickly determined by a jury, or the parties may settle. Others say that patent trials may often be too complex to be determined by a usually unsophisticated jury, thus putting the hardest part, claim construction, in the hands of a judge alone takes considerable burden off a jury. In Canada, the Courts have resisted making "Markman" rulings before trial. A Canadian trial, in the Federal Court, and usually in other Courts, is before a judge alone, and hearing evidence, particularly expert evidence, twice is hardly as efficient as doing it all at once.

[48] The 1869 Canadian *Patent Act, supra*, did not explicitly require a claim or claims in the sense that we know it today. Section 13 of that *Act* required that the "*invention or discovery"* be described in *"full, clear and exact terms".* Section 14, which is much like our current section, requires a description that is given *"clearly and distinctly":*

> ***13.*** *The applicant shall, in his Petition for a Patent, insert the title or name of his invention or discovery, its object and a short description of the same, and shall distinctly allege all the facts which are necessary under this Act to entitle him to a Patent in duplicate, of his invention or discovery, describing the same in such full, clear and exact terms as to distinguish it from all contrivances or processes for similar purposes.*
>
> ***14.*** *The specification shall correctly and fully describe the mode or modes of operating contemplated by the applicant, and shall state clearly and distinctly the contrivances and things which he claims as new, and for the use of which he claims an exclusive property and*

> *privilege; - it shall bear the name of the place where it is made, the date, and be signed by the applicant and two witnesses; - in the case of a machine the specification shall fully explain the principle and the several modes in which it is intended to apply and work out the same; in the case of a machine or in any other case where the invention or discovery admits of illustration by means of drawings, the applicant shall also, with his application, send in drawings in duplicate showing clearly all parts of the invention or discovery; and each drawing shall bear the name of the inventor or discoverer and shall have written references corresponding with the specification, and a certificate of the applicant that it is the drawing referred to in the specification; but the Commissioner may require any greater number of drawings than those above mentioned, or dispense with any of them, as he may see fit; once duplicate of the specification and of the drawings, if any drawings, shall be annexed to the Patent, of which it forms an essential part, and the other duplicate shall remain deposited in the Patent Office.*

[49] Illustrative of the techniques used in these early days in compliance with these sections 13 and 14 is the first Canadian Patent, Patent No. 1, entitled *A Machine for Measuring Liquids* granted August 18, 1869, in which Claim 1 reads as follows:

> *"l. The combination and arrangement substantially as described of the balanced reciprocating piston 1 cc and balance valves cc constructed and operated substantially in the manner described for the purpose set forth."*

Thus a reader, and a Court, are driven to the specification in order to construe and understand what the invention claimed is. Construction was a necessity at that time.

[50] The requirements respecting claims evolved as the Canadian *Patent Act* was amended. Dickson J. (as he then was) in *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Limited,* [1981] 1 S.C.R. 504 provided a good summary of this evolution where he wrote at page 518:

> *All later patent legislation is based upon The Patent Act of 1869, 1869 (Can.), c. 11, which in turn followed generally the United States statute of 1836 (5 Stat. 117). The 1869 Act required (s. 14) the specifications to describe, correctly and fully, the mode or modes of operating contemplated by the applicant and to state clearly the contrivances and things which he claimed as new, and for the use of which he claimed an exclusive property and privilege. The opening words of the present s. 36(1) and the requirements of s. 36(2) are in much the same language. A new statute was enacted in 1872, amended from time to time, consolidated in 1886, and again in 1906, but with little change in what is now s. 36. In 1923 a new Act was brought into force which adopted the exact words now found at the commencement of s. 36(1). It required the inventor to set forth clearly the various steps in a process and to end the specification with a claim or claims stating distinctly the things or combination of things which the applicant regarded as new and in which he claimed an exclusive property and privilege. There was thus established a distinction between the "claims" and the body of the specification.*

[51] Section 14(1) of the 1923 Canadian *Patent Act*, 13–14 Geo v. c. 23 as referred to by Dickson J. provided:

> ***14.*** *(1) The specifications shall correctly and fully describe the invention and its operation or use as contemplated by the inventor. It shall set forth clearly the various steps in a process, or the method of constructing, making or compounding, a machine, manufacture, or composition of matter. It shall end with a claim or claims stating distinctly the things or combinations which the applicant regards as new and in which he claims an exclusive property and privilege.*

This provision caused a change in the manner in which the Court viewed claims. It was no longer necessary to turn to the specification in order to understand the claim. Rinfret J. in *Gillette Safety Razor Co. v. Pal Blade Corp.*, [1933] S.C.R. 142 wrote at page 147:

. . .

> *...we must be guided primarily by the provisions of the 14th section of the Patent Act.*

> *That section requires the specifications to be a correct and full statement of what the invention is. The inventor must describe its operation or use as contemplated by him. He must set forth clearly the method of constructing or making the manufacture he has invented. He must end the specification with claims stating distinctly the things or combinations which he regards as new and in which he claims an exclusive property and privilege. In any case in which the invention admits of illustration by means of drawings, the inventor shall, with his application, send in drawings showing clearly all parts of the invention and each drawing shall have written references corresponding with the specification. One duplicate of the specification and of the drawings, if there are drawings, shall be annexed to the patent, of which it shall form an essential part.*
>
> *It follows that the nature of the invention protected by a patent and the extent of the monopoly thereby granted must be ascertained from the claims. The claims should be construed with reference to the specification and to the drawings, but, as pointed out by Lindley, M.R., in The Pneumatic Tyre Company Limited v. The Tubeless Pneumatic Tyre and Capon Headon Limited (1); whether the patentee has discovered a new thing or whether he has not, his monopoly is confined to what he has claimed as his invention.*

[52] The Canadian *Patent Act* was further amended to provide for the requirement of claims which must particularly, distinctly and in explicit terms set out the monopoly. It did so in section 36(1)(e) and again in section 36(2). These provisions become sections 34(1)(e) and 34(2) in later versions as follows:

> ***34. Specification –(1)*** *An applicant shall in the specification of his invention*
>
> *(a) correctly and fully describe the invention and its operation or use as contemplated by the inventor;*
>
> *(b) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which is appertains, or with which it is most closely connected, to make, construct, compound or use it;*

> *(c) in the case of a machine, explain the principle thereof and the best mode in which he has contemplated the application of that principle;*
> *(d) in the case of a process, explain the necessary sequence, if any, of the various steps, so as to distinguish the invention from other inventions; and*
>
> *(e) particularly indicate and distinctly claim the part, improvement or combination that he claims as his invention.*
>
> *(2) Claims to be stated distinctly – The specifications referred to in subsection (1) shall end with a claim or claims stating distinctly and in explicit terms the things or combinations that the applicant regards as new and in which he claims an exclusive property or privilege.*

[53] In *Consolboard, supra*, Dickson J. described section 36 (now 34) as lying at the heart of the patent system. He described the wording of that section as not being "happily phrased" and stated that section 36(2) did not add much to section 36(1)(e) and was little more than a pleonasm. He wrote at pages 517–519:

> *Section 36 of the Patent Act lies at the heart of the whole patent system. The description of the invention therein provided for is the quid pro quo for which the inventor is given a monopoly for a limited term of years on the invention. As Fox points out in Canadian patent Law and Practice (4th ed.), p. 163, the grant of a patent is in the nature of a bargain between the inventor on the one hand and the Crown, representing the public, on the other hand. The consideration for the grant is twofold: "first, there must be a new and useful invention, and secondly, the inventor must, in return for the grant of a patent, give to the public an adequate description of the invention with sufficiently complete and accurate details as will enable a workman, skilled in the art to which the invention relates, to construct or use that invention when the period of the monopoly has expired". The "description" to which Fox refers is that required by s. 36 of the Patent Act.*
>
> *It cannot be said that s. 36 of the Act is happily phrased. It gives the impression of a mélange of ideas gathered at random rather than an attempt to enunciate, clearly and concisely, a governing principle or*

> *principles. This is perhaps understandable in that the section is the product of amendment over a period of many years. The language simply does not lend itself to a tight, literal interpretation. It is, and should be treated as, a parliamentary pronouncement, in general terms, of that which must be set forth by the applicant to the world before binge qualified to receive the grant of monopoly under a patent.*
>
> . . .
>
> *In 1935 another Patent Act was enacted, s. 35 of which is virtually the same as the present s. 36. Two changes were made, or particular relevance in the present inquiry: (i) it was required that the explanatory steps be addressed to a person skilled in the art – this merely gave statutory recognition to what had always been the common law – and (ii) the concluding words of subs. (1), central to this appeal, were added, namely "He shall particularly indicate and distinctly claim the part, improvement or combination which he claims as his invention".*
>
> *It is not entirely clear what was intended to be achieved by the addition of the quoted words. They may have been added ex abundante cautela, seeking greater particularity of description, but they appear to be little more than pleonasm, when read with s. 36(2) and the definition of "invention". It is not readily apparent that anything of substance was added in 1935 to that which had been required since 1869.*

[54] Thus, in dealing with the disclosure and claims of a patent, collectively called the specification, Dickson J., in *Consolboard,* instructed that the claims are to be read in light of the disclosure in a fair manner. At pages 520–521 he wrote:

> *In essence, what is called for in the specification (which includes both the "disclosure", i.e. the descriptive portion of the patent application, and the "claims") is a description of the invention and the method of producing or constructing it, coupled with a claim or claims which state those novel features in which the applicant wants an exclusive right. The specifications must define the precise and exact extent of the exclusive property and privilege claimed.*

> *Section 36(1) seeks an answer to the questions: "What is your invention? How does it work?" With respect to each question the description must be correct and full in order that, as Thorson P. said in Minerals Separation North American Corporation v. Noranda Mines, Limited:*
>
> > *...when the period of monopoly has expired the public will be able, having only the specification, to make the same successful use of the invention as the inventor could at the time of his application. [at p. 316]*
>
> *We must look to the whole of the disclosure and the claims to ascertain the nature of the invention and methods of its performance, (Noranda Mines Limited v. Minerals Separation North American Corporation), being neither benevolent nor harsh, but rather seeking a construction which is reasonable and fair to both patentee and public. There is no occasion for being too astute or technical in the matter of objections to either title or specification for, as Duff C.J.C. said, giving the judgment of the Court in Western Electric Company, Incorporated, and Northern Electric Company v. Baldwin International Radio of Canada, at p. 574, "where the language of the specification, upon a reasonable view of it, can be so read as to afford the inventor protection for that which he has actually in good faith invented, the court, as a rule, will endeavour to give effect to that construction". Sir George Jessel spoke to like effect at a much earlier date in Hinks & Son v. Safety Lighting Company. He said the patent should be approached "with a judicial anxiety to support a really useful invention".*

b) <u>History of a Claims Requirement in Great Britain</u>

[55] Much of the Canadian jurisprudence respecting patent law, particularly until the latter part of the last century, has relied upon the jurisprudence coming from Great Britain. In so doing, our Courts have, from time to time, been distracted when it comes to claims and claim construction because the laws of Great Britain, as interpreted by the Courts there, have come rather later to the concept of an independent claim or claims whose function it is to set out clearly what the monopoly is. These Courts were more willing to look at the description in order to "construe" the monopoly.

Great Britain did not, until the Acts of 1883 to 1888 (46 & 47 Vict. c.57, 48 & 49 Vict. c.63, 49 & 50 Vict. c.37, 51 & 52 Vict. c.50) expressly require that there be a separate claim set out in a patent. The patent consisted only of the specification which set out the details of the invention. The Court was required to look at the specification and determine what the invention was and whether it was valid or infringed. Illustrative is the decision of the Court of Appeal in *Lister v. Leather* (1858), 8 B.l. & El. 1004, 120 E.R. at 384-385 where Williams J. delivered judgment saying, in part:

> *A combination is here expressly stated to be part of the invention; the judgment of the Court below must therefore, on this point, be affirmed. So the third point, whether the patent of 1852 was for a combination, seems to us decided by the description of a combined nipping and combing action in the very beginning of the specification, as it would stand after the disclaimer. It may be that a combination is not distinctly and expressly claimed in either of these patents. But neither a claim nor a disclaimer is essential to a specification; that which appears to be the invention, or a part of it, will be protected, though there be no claim; and those matters which manifestly form no part of the invention need not be disclaimed.*

[56] This practice encouraged patentees to expand their arguments so as to say that not only what they described in the specification constituted their monopoly, but also, anything that constituted the "equity" of what was described. This argument was put to rest by the House of Lords in *Dudgeon v. Thomson* (1877), 3 App. Cas. 34 where the Lord Chancellor (Lord Cairns) said at pages 44 and 45:

> *Now, my Lords, what I understand by that, is this, if there is a patented invention, and if you, the Defendant, are found to have taken that invention, it will not save you from the punishment or from the restraint of the Court that you have at the same time that you have taken the invention dressed it up colourably, added something to it, taken, it may be, something away from it, so that the whole of it may be said, as is said in the injunction, Here is a machine which is either the Plaintiff's machine or differs from it only colourably. But underlying all that, there must be a taking of the invention of the*

> *Plaintiff. There used to be a theory in this country that a person might infringe upon the equity of a statute, if it could not be shewn that they had infringed the words of a statute; it was said that they had infringed the equity of the statute, and I know there is, by some confusion of ideas, a notion sometimes entertained that there may be something like an infringement of the equity of a patent. My Lords, I cannot think that there is any sound principle of that kind in our law; that which is protected is that which is specified, and that which is held to be an infringement must be an infringement of that which is specified. But I agree it will not be less an infringement because it has been coloured or disguised by additions or subtractions, which additions or subtractions may exist and yet the thing protected by the specification be taken notwithstanding.*

And Lord Blackburn at page 53:

> *Now, my Lords, as to that I agree with what was said by the noble and learned Lord on the woolsack, that the questions is whether it is an infringement of the patent, - a taking of a part of the property in the use of that invention which has been given by the letters patent. The phrase "colourably" is very apt to mislead in these cases. If part of the property in the invention be really taken there is an infringement, however much that may be disguised or sought to be hidden. If that is detected by the patentee, and if what is taken is really part of his property given to him by the letters patent, he has a right to proceed against the infringer, however ingeniously the colours may have been contrived to try to conceal the fact that there has been a taking of part of the property. But for all that it is not correct to say that doing anything that answers the same object is necessarily an infringement of the specification; we must look at what is shewn in the specification. The terms and condition of the patent are that the patentee shall "particularly describe and ascertain the nature of the invention and in what manner the same was to be performed." Accordingly we look at the specification to see what is the nature of the invention for which the patent has been taken out as described and ascertained by the specification.*

[57] Thus the British Courts would look critically at the specification (description) itself to find the claimed invention. A patentee would, in the specification, sometimes make a statement as to what is claimed to be the invention. This is illustrated by the decision of the English Court of Appeal in *Plimpton v. Spiller* (1876), 6 Ch. D. 412 where James L.J. said at pages 426-427:

> *It is important to bear in mind that there is nothing in the Act or in the patent law which says anything about claims. A patentee gets a patent for his invention, and he is obliged to specify that invention in such a way as to show to the public not only the mode of giving practical effect to that invention, but what the limits of the invention are for which his patent is taken out; and the real object of what is called a claim, which is not much more commonly put in than it used to be formerly, is not to claim anything which is not mentioned in the specification, but to disclaim something. A man who has invented something gives in detail the whole of the machine in his specification. In doing that he is of necessity very frequently obliged to give details of things which are perfectly known and in common use – he describes new combinations of old things to produce a new result, or something of that kind. Therefore, having described his invention, and the mode of carrying that invention into effect, by way of security, he says: "But take notice I do not claim the whole of that machine, I do not claim the whole of that modus operandi, but that which is new, and that which I claim is that which I am now about to state." That really is the legitimate object of a claim, and you must always construe a claim with reference to the whole context of a specification.*
>
> *Now, we have to consider what is the effect of this part of the claim. He says, "I claim first," and so on – and then he says, "Secondly, the mode of securing the runners and making them reversible as above described."*

[58] The British Courts continued, however, to find the invention within the specification (description) even though the statute required that the specification end with a claim or claims. The requirement for claims was seen as mere form, rather than substance, as illustrated by the decision

of the House of Lords in *Tubes Ltd. v. Perfecta Seamless Steel Tube Company Ltd.* (1902), 20 R.P.C. 77 where Lord Halsbury wrote at pages 99-100:

> *My Lords, of course no one could deny that the claim, like every other material part of the Specification (and it is part of the Specification) must be construed with reference to what the Specification means, and no one would question if they meant that if, looking at it, it raised the doubt to which they have given expression, there might be ground for saying that the Specification was bad, because the statement in the whole of the Specification taken together, including the claim, was not that which the Patentee was bound to give. But if they meant that, taking the claim as a distinct and separate statement, that was an independent ground, because there was no distinct claim in it, then, my Lords, that is absolutely inconsistent with the judgment of this House in Vickers v. Siddell. I do not think that it would be accurate to speak of that judgment as obiter, because it turned upon the question of what were the facts there, and it is not accurate to say that one ground of the judgment was rendered unnecessary by what the facts proved were. I will read what I said myself; "The objection that no distinct claim is made is one of form only, and I think the legislature did not intend to make the direction which undoubtedly the Act contains, a condition upon the non-compliance with which the Patent should be void. There is no trace of any such intention in the Statute, and there does not seem any good reason why it should be inferred from the general polity of the Statute. On the contrary, the questions of mere form, I think, were intended to be dealt with under the new machinery provided." Then Lord Herschell, agreeing with me, puts the question more at length: "The last objection taken to the Patent is that the Complete Specification does not 'end with a distinct statement of the invention claimed,' as required by section 5, subsection 5, of the Act. The Act does not provide that if the requirement is not complied with the Patent shall be void, and I think it is impossible to imply any such condition. There is no more warrant for doing so in this case than in the case of non-compliance with any other of the provisions of the section. The provision should 'commence with the title.' It could hardly be gravely contended that if the Comptroller accepted a Specification where the title did not occupy the first place, the Patent granted ought, on that account, to be held void. I need not detain your Lordships further upon this point as it was fully dealt with, and, to my mind, satisfactorily disposed of by the learned Judges in the Court of Appeal." Now that judgment in the Court of Appeal, affirmed by the House, ought, I think, not to be so summarily*

> *dismissed by the simple observation that the statutable requirement has not been complied with. I wish, therefore, to express my concurrence in the former judgment, which is binding upon your Lordships. I observe that none of the other noble and learned Lords, who took part in the discussion, dissented from what was said by Lord Herschell and myself. Under these circumstances, it appears to me that if that is put, as it looks to me as if the learned Judges intended that it should be put, as a distinct ground, it is clearly inconsistent with the judgment of your Lordships' House.*

[59] The British *Patents Act* of 1949 (12, 13 & 14 Geo 6, Ch 87) set out the requirements for claims separate in sections 4(1) to 4(4):

> *Contents of specification.*
> ***4.***
> *(1) Every specification, whether complete or provisional, shall describe the invention, and shall begin with a title indicating the subject to which the invention relates.*
> *(2) Subject to any rules made by the Board of Trade under this Act, drawings may, and shall if the comptroller so requires, be supplied for the purposes of any specification, whether complete or provisional; and any drawings so supplied shall, unless the comptroller otherwise directs, be deemed to form part of the specification, and references in this Act to a specification shall be construed accordingly.*
> *(3) Every complete specification –*
> *(a) shall particularly describe the invention and the method by which it is to be performed;*
> *(b) shall disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection; and*
> *(c) shall end with a claim or claims defining the scope of the invention claimed.*
> *(4) The claim or claims of a complete specification must relate to a single invention, must be clear and succinct, and must be fairly based on the matter disclosed in the specification.*

[60] The matter of claim construction under the 1949 *Act* came before the House of Lords in *Catnic Components Limited v. Hill & Smith Limited,* [1982] R.P.C. 183. In that case, Lord Diplock with whom all the other Law Lords concurred, wrote as to claim construction at pages 242-243:

> *"My Lords, a patent specification is a unilateral statement by the patentee, in words of his own choosing, addressed to those likely to have a practical interest in the subject matter of his invention (i.e. 'skilled in the art'), by which he informs them what he claims to be the essential features of the new product or process for which the letters patent grant him a monopoly. It is those novel features only that he claims to be essential that constitute the so-called 'pith and marrow' of the claim. A patent specification should be given a purposive construction rather than a purely literal one derived fro applying to it the kind of meticulous verbal analysis in which lawyers are too often tempted by their training to indulge. The question in each case is: whether persons with practical knowledge and experience of the kind of work in which the invention was intended to be used, would understand that strict compliance with a particular descriptive word or phrase appearing in a claim was intended by the patentee to be an essential requirement of the invention so that any variant would fall outside the monopoly claimed, even though it could have no material effect upon the way the invention worked."*

[61] Subsequently, Britain joined the European Union, and in 1977 amended its *Patents Act* (1977, c.37) to bring it into conformity with the *European Patent Convention*. Articles 69 and 84 of the *European Patent Convention* provide:

> *69. "The extent of the protection conferred by a European patent or a European patent application shall be determined by the terms of the claims. Nevertheless, the description and drawings shall be used to interpret the claims."*
>
> . . .
>
> *84. "The claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description".*

[62] Section 125 of the British *Patents Act,* as amended in 1977, is intended to be in conformity with these provisions of the *European Patent Convention* (see section 130(7) of the British *Act*) and provides:

> ***125.*** *–(1) For the purposes of this Act an invention for a patent for which an application has been made or for which a patent has been granted shall, unless the context otherwise requires, be taken to be that specified in a claim of the specification of the application or patent, as the case may be, as interpreted by the description and any drawings contained in that specification, and the extent of the protection conferred by a patent or application for a patent shall be determined accordingly.*
> *(2) […]*
> *(3) The Protocol on the Interpretation of Article 69 of the European Patent Convention (which Article contains a proviso corresponding to subsection (1) above) shall, as for the time being in force, apply for the purposes of subsection (1) above as it applies for the purposes of that Article."*

[63] These provisions came under consideration by the House of Lords in *Kirin Amgen v. Hoechst Marion Roussel,* [2005] R.P.C. 9 in which Lord Hoffman, with whom the other Law Lords concurred, confirmed that the *Catnic* approach referred to above was still correct. He wrote at paragraph 48:

> *"The Catnic principle of construction is therefore in my opinion precisely in accordance with the Protocol. It is intended to give the patentee the full extend, but not more than the full extent, of the monopoly which a reasonable person skilled in the art, reading the claims in context, would think he was intending to claim."*

[64] Lord Hoffman made it very clear that in considering the construction of a claim, the Court is not interested in determining what the author of the patent meant or intended. The Court is to determine what the addressee would understand the document to mean. He wrote at paragraph 32:

> *"Construction, whether of a patent or any other document, is of course not directly concerned with what the author meant to say. There is no window into the mind of the patentee or the author off any other document. Construction is objective in the sense that it is concerned with what a reasonable person to whom the utterance was addressed would have understood the author to be using the words to mean. Notice, however, that it is not, as is sometimes said, "the meaning of the words the author used", but rather what the notional addressee would have understood the author to mean by using those words. The meaning of words is a matter of convention, governed by rules, which can be found in dictionaries and grammars. What the author would have been understood to mean by using those words is not simply a matter of rules. It is highly sensitive to the context of and the background to the particular utterance. It depends not only upon the words the author has chosen but also upon the identity of the audience he is taken to have been addressing and the knowledge and assumptions which one attributes to that audience."*

[65] This remains essentially a statement of the law in Great Britain at the highest level of the Court system today.

c) <u>Current State of the Law in Canada</u>

[66] It has become virtually mandatory in a proceeding respecting patent infringement or validity, or both, that the Court in arriving at its determination first embark upon construction of the claim(s) at issue. The principles of the current approach to claim construction were thoroughly reviewed by the Supreme Court of Canada in *Whirlpool Corp. v. Camco Inc.,* [2000] 2 S.C.R. 1067. I repeat portions of what Binnie J., for the Court, wrote at paragraphs 42 to 52:

> *1. The Principles of Patent Claims Construction*
> *[42] The content of a patent specification is regulated by s. 34 of the Patent Act. The first part is a "disclosure" in which the patentee must describe the invention "with sufficiently complete and accurate details as will enable a workman, skilled in the art to which the invention relates, to construct or use that invention when the period of the monopoly has expired": Consolboard Inc.*

v. MacMillan Bloedel (Saskatchewan) Ltd., [1981] 1 S.C.R. 504, at p. 517, 56 C.P.R. (2d) 145, 122 D.L.R. (3d) 203. The disclosure is the quid provided by the inventor in exchange for the quo of a 17-year (now 20-year) monopoly on the exploitation of the invention. The monopoly is enforceable by an array of statutory and equitable remedies and it is therefore important for the public to know what is prohibited and where they may safely go while the patent is still in existence. The public notice function is performed by the claims that conclude the specification and must state "distinctly and in explicit terms the things or combinations that the applicant regards as new and in which he claims an exclusive property or privilege" (s. 34(2)). An inventor is not obliged to claim a monopoly on everything new, ingenious and useful disclosed in specification. The usual rule is that what is not claimed is considered disclaimed.
[43] The first step in a patent suit is therefore to construe the claims. Claims construction is antecedent to consideration of both validity and infringement issues.

. . .

[45] The key to purposive construction is therefore the identification by the court, with the assistance of the skilled reader, of the particular words or phrases in the claims that describe what the inventor considered to be the "essential" elements of his invention.

. . .

A patent must therefore be given such interpretation according to s. 12 of the Interpretation Act "as best ensures the attainment of its objects". Intention is manifested in words, whose meaning should be respected, but words themselves occur in a contest that generally provides clues to their interpretation and a safeguard against their misinterpretation. P.-A. Cote, in The Interpretation of Legislation in Canada (3rd ed. 2000), puts the matter succinctly when he writes, at p. 387, "Meaning flows at least partly from context, of which the statute's purpose is an integral element" (emphasis added". To the same effect see Rizzo & Rizzo Shoes Ltd. (Re), [1998] 1 S.C.R. 27, 154 D.L.R. (4th) 193, at para. 21. These principles apply to claims construction by virtue of the Interpretation Act.

. . .

Purposive construction is capable of expanding or limiting a literal text, as Hayhurst, supra, points out at p. 194 I words that anticipate the trial judgment in this case:

> *Purposive construction may show that something that might literally be within the scope of the claim was not intended to be covered, so that there can be no infringement…*

Similarly, two other experienced practitioners, Carol V.E. Hitchman and Donald H. MacOdrum have concluded that "[a] purposive construction is not necessarily a broader construction than a purely literal one, although it may be" (Hitchman and MacOdrum, "Don't Fence Me In: Infringement in Substance in Patent Actions" (1990), 7 C.I.P. Rev. 167, at p. 202).

. . .

[52] I have already given my reasons for concluding that to the extent the appellants are arguing for a simple "dictionary" approach to construction of the '803 claims, it must be rejected. In Western Electric Co. v. Baldwin International Radio of Canada, [1934] S.C.R. 570, [1934] 4 D.L.R. 129, the Court cited earlier authority dealing with the word "conduit" as used in a patent claim. Duff C.J. at p. 572 accepted the proposition that "[y]ou are not to look into the dictionary to see what "conduit" means, but you are to look at the specification in order to see the sense in which the patentees have used it". In Consolboard, supra, as mentioned, Dickinson J. considered that the whole of the specification (including the disclosure and the claims) should be looked at "to ascertain the nature of the invention". To the same effect is the statement of Taschereau J. in Metalliflex Ltd. v. Rodi & Wienenberger Aktiengesellschaft, [1961] S.C.R. 117, at p. 122, 35 C.P.R. 49:

> *The claims, of course, must be construed with reference to the entire specifications, and the latter may therefore be considered in order to assist in apprehending and construing a claim, but the patentee may not be allowed to expand his monopoly specifically expressed in the claims "by borrowing this or that gloss from other parts of the specifications".*

More recently, Hayhurst, supra, at p. 190, cautioned that "[t]erms must be read in context, and it is therefore unsafe in many instances

> *to conclude that a term is plain and unambiguous without a careful review of the specification". In my view, it was perfectly permissible for the trial judge to look at the rest of the specification, including the drawing, to understand what was meant by the word "vane" in the claims, but not to enlarge or contract the scope of the claim as written and thus understood.*

[67] This approach to construction of a claim was concisely put by the Federal Court of Appeal in *Janssen-Ortho Inc. v. Novopharm Ltd.,* 2007 FCA 217, 59 C.P.R. (4th) 116, , per Sharlow J. for the Court at paragraph 4:

> *Construction of Claim 4*
> *[4] In any case in which the validity or infringement of a patent claim is in issue, it is necessary to construe the claim: Whirlpool Corp. v. Camco Inc., [2000] 2 S.C.R. 1067 at paragraph 43. The relevant date for the construction of the 080 patent is the date of its issuance, June 23, 1992. The patent must be understood as being addressed to a person skilled in the art, taking into consideration the knowledge that such a person is expected to possess on that date. The construction of a patent claim is a task for the Court and must be based on the whole of the disclosure and the claim, assisted by expert evidence as to the meaning of certain terms and the knowledge that a person skilled in the art is expected to possess on the relevant date.*

d) Tying It All Together

[68] Having looked at the history of patent claims and claim construction in Canada as influenced by Great Britain, it can be seen that, originally, it was essential for a Court to construe the patent and its claims because the "invention" - hence, the monopoly - was to be found in the specification. As the statutes became clearer in respect of claims, the specification became divided into two parts. The description served the purpose of "purchasing" the monopoly by describing the

invention in sufficient detail so that a person skilled in that art could understand what the invention was and how to put it into practice. The other part of the specification was the claims, which served to define and set limits as to the monopoly that the patent was intended to secure.

[69] Construction of the claim no longer meant that the Court had to scour the description so as to arrive at what the monopoly was; rather, the Court now begins with the claim and determines what a person skilled in the art would understand it to mean. This is done using the description as a context and, if necessary, using expert evidence to assist in putting the Court in a position of understanding at the level of a person skilled in the art. The purpose of the exercise is to understand what the patentee is claiming as its monopoly.

[70] Thus, claims construction today in the Canadian Courts is an easier task than in earlier days, because the function of the claims has been made clearer by statute. That function is to define distinctly and in explicit terms what the claimed monopoly is. To the extent that the claim is now to be “construed”, that is the function of the Court alone. Experts may assist in two ways; first, they may inform the Court as to the knowledge that a person skilled in the art would have had at the relevant time, so as to bring that knowledge to bear reading both the description and the claims; second, an expert may assist in explaining any technical terms not within the experience expected of a Court. Thus, while construction is for a Court alone, the Court may have to make certain factual findings as to the knowledge of a person skilled in the art. The findings of the Court in this respect may best be considered as findings of mixed fact and law.

e) The U.K. and European Decisions as to Swiss Claims

[71] There are four decisions of the U.K. Courts and one of the European patent Office Enlarged Board of Appeal that require consideration in these proceedings. They are:

- *Bristol-Myers Squibb Company v. Baker Norton Pharmaceutics Inc.,* [1998] EWHC Patents 300 (20th, August, 1998) a decision of Jacob J. (as he then was) in the England and Wales High Court (Patents Court) - I will refer to this as the *Bristol-Myers* trial decision.
- *Bristol-Myers Squibb Company v. Baker Norton Pharmaceutics Inc.,* [2001] R.P.C. 1 (May 23, 2000) a decision of the Court of Appeal upholding the above trial decision – I will refer to this as the *Bristol-Meyers* appeal decision.
- *Actavis UK Limited v. Merck & Co. Inc.,* [2007] EWHC 1311 (6th June, 2007) a decision of Warren J. of the England and Wales High Court (Patent Court) – this case deals with a European patent that is based on the same priority application as the '457 Patent at issue here and a "Swiss" type claim that is similar but not identical to claim 5 – I will refer to this as the *Actavis* trial decision.
- *Actavis UK Ltd. v. Merck & Co. Inc*., [2008] EWCA Civ 444, [2009] 1 All ER 196 (21st May 2008) a decision of the Court of Appeal reversing the above trial decision – Jacob J.A. (the trial judge in *Bristol-Myers*) wrote the decision for the Court – I will refer to this as the *Actavis* appeal decision. As of the date that I have released these reasons I have not been informed as to whether leave to appeal has been sought in this case.

- *Kos Life Sciences,* Case No. G 0002/08 decided by the Enlarged Board of Appeal of the European Patent Office 19 February, 2010 – this is a final decision and deals with the patentability of "Swiss" type claims – I will refer to this as the *Kos* decision.

[72] The *Bristol-Myers* trial decision made by Jacob J. was upheld by the Court of Appeal, but had important things to say about "Swiss" type claims. The trial judge in *Actavis* followed the Court of Appeal in *Bristol-Myers* only to have Jacob J.A. very painstakingly distinguish the *Bristol-Myers* Court of Appeal decision and reverse the trial judge in *Actavis.* In the meantime, the European Enlarged Board of Appeals, which has the final say in respect of European Patents (the U.K. Courts can rule on European Patents which are enforceable in the U.K., but the European Court has final say as to matters such as validity) had the *Kos* case under reserve, and was considering the validity of "Swiss" type claims. The U.K. Court of Appeal in *Actavis* was asked, but declined, to stay rendering a decision until the Enlarged Board of Appeals ruled in *Kos*. As it turned out, the European Board held "Swiss" type claims, prospectively, to be invalid.

[73] The reason those cases are important is that *Actavis* deals with a "Swiss" type claim in a patent having the same genesis as the '457 Patent with wording that is similar to claim 5. The claims in *Actavis* originally read as follows as set out in paragraph 9 of the trial decision:

> *9. The Patent specification describes a "method of treating androgenic alopecia with 5α-reductase inhibitors". The actual Claims are as follows:*

> *1. The use of [finasteride] for the preparation of a medicament for oral administration of androgenic alopecia in a person and wherein the dosage amount is about 0.05 to 1.0 mg.*
>
> *2. The use as claimed in claim 1 wherein the dosage is 1.0 mg.*
>
> *3. The use as claimed in claim 1 or 2 wherein the treatment is of male pattern baldness.*

[74] The U.K. Courts permit claims to be amended during the proceedings before the Courts and those claims were amended to add the words "per day" to the dosages stated as set out in paragraph 10 of the trial decision:

> *10. Merck says that, as a matter of construction, Claim 1 of the Patent is limited to the stated dosage of finasteride per day. If the entire Patent is read, there is material in the description which supports that conclusion. However, that construction is disputed by Actavis, relying on the definition of the invention which makes no reference to dosage. However, Actavis does not oppose the amendment so that the dispute about construction is largely academic. I do not propose to decide the question of construction but instead allow the amendment for the purpose of these proceedings.*

[75] In the case now before me respecting the '457 Patent, no procedure presently exists whereby such amendment could be made in this Court. Merck, however, argues that a proper construction of claim 5 is to consider that the indicated dosage of 1 mg. is "per day".

[76] At this point, I turn to the decision of Jacob J. as a trial judge in *Bristol-Myers* in which he provided the history of "Swiss" type claims. The particular wording of such a claim is used to get around a problem presented to a person who has found a new medical use for a compound

previously known for other medical uses where the European law, appears to preclude a claim directed to that situation. Jacob J. said at paragraphs 43 to 46 of *Bristol-Myers* trial decision:

> *43. Before going further I must now say something about the general structure of the claim. I daresay that an ordinary skilled man (to whom it is notionally addressed) would find it puzzling, unless he had been initiated in some of the Byzantine logic of patent law and jurisprudence. The explanation lies in Art. 54(4) of the EPC and the decided cases. The material parts of Art. 54 read:*
>
> > *"(1) European patents shall be granted for any inventions which are susceptible or industrial application, which are new and which involve an inventive step.*
> >
> > *(4) Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, I particular substances or compositions, for use in any of these methods."*
>
> *44. By taking the form it does, the claim is trying to steer clear of two obstacles to patentability, namely the requirement of novelty and the ban on methods of treatment of the human body by therapy. The claim is, or attempts to be, in so-called "Swiss form", following a statement of practice regarding "use claims" issued by the Swiss Federal Intellectual Property Office. ([1984] OJ EPO 581). The generalized form of such a claim is "the use of compound X in the manufacture of a medicament for a specified (and new) therapeutic use". Such claims are unnecessary when X is new, for then X can be patented in itself by virtue of the last sentence of Art. 53(4). But when X is old, the Swiss form of claim is said to confer novelty and yet not be to a method of treatment. The Enlarged Board so held in Eisai. (G5/83 [1985] OJ OJEPO 64). It said:*
>
> > *"It is legitimate in principle to allow claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application, even in a case where the process of manufacture as such does not differ from known processes using the same active ingredient."*

24. So the manufacture of an old pill for use in a new treatment was considered by the Enlarged Board to be novel. The justification for novelty was the new therapeutic use. And since the claim was to the manufacture of the pill, it was not a claim to a method of treatment. How that might work so far as infringement was concerned was, so far as the Enlarged Board was concerned, not a matter to be considered. It said:

> *"It is particularly important to bear in mind that Art. 64(3) leaves questions of infringement to be dealt with by national law".*

25. Actually Art. 64(3) merely provides that "Any infringement of a European patent shall be dealt with by national law." It does not mean that questions of validity (especially novelty) or extent of protection are matters for national law. On the contrary both are specifically matters covered by the EPC (novelty in Art. 54(1) and extent of protection I Art. 69 and its Protocol). In my view it is essential for the granting authority to consider fully the implications of the claims it grants in relation to both validity and scope. It is not helpful to take a view on validity (particularly novelty) which simply leaves intractable problems for an infringement court – and for the public who need to know what they can and cannot do.

45. There are obvious difficulties with Eisai. Take a newly discovered use for aspirin (one was discovered not so long ago, namely its use to reduce risks of heart attacks). The manufacture of aspirin pills is old. So why is the manufacture rendered new because there is a new use? Or why does adding the purpose of the manufacture of aspirin to the claim make the manufacturing process any newer? The English patents Court, sitting en banc (Whitford and Falconer JJ) in Wyeth and Scherings Appns. ([1985] R.P.C. 545) had to consider Eisai. The Court formed the view that a Swiss-type claim was clearly a claim to a method of manufacture and so to an invention capable of industrial application. As the court said, it was the requirement of novelty which "provides the real difficulty". And it plainly thought that the device of putting a claim into Swiss form did not confer novelty:

> *"we think the better view would be that a claim in the Swiss form to an invention directed to the use of a known pharmaceutical to manufacture a medicament, not in itself*

> *novel, for a second or subsequent and novel medical use would not be patentable as lacking the required novelty. (p. 565)*

However, in view of the decision in Eisai and "having regard to the desirability of achieving conformity" the patents Court decided not to follow what it regarded as the better view. It followed Eisai. Before me, Mr. Thorley, did not challenge Eisai, though he reserved the right to do so on appeal. I think he was right. For me, as a judge of the first instance, to go against Eisai would involve not only refusing to follow a decision of law of the Enlarged Board of Appeal, but also refusing to follow a considered judgment of the English Patents Court. Under the present English rules of precedent I am strictly bound by neither court. But, so far as the Enlarged Board is concerned the desirability of following its decisions on points of law has been reinforced since Eisai. Lord Hoffman in Merrell Dow ([1995] RPC 76 at p.82) said that the UK courts:

> *"must have regard to the decisions of the EPO on the construction of the EPC. These decisions are not strictly binding upon the courts in the UK but they are of great persuasive authority; first because they are decisions of expert courts (the Boards of Appeal and Enlarged Board of Appeal of the EPO) involved daily in the administration of the EPC and secondly because it would be highly undesirable for the provisions of the EPC to be construed differently in the EPO from the way they are interpreted in the national courts of a Contracting State."*

26. What Lord Hoffman said has all the more force in relation to a court of first instance. If all the courts of first instance of the member states of the EPC felt able readily to differ from the questions of law decided by the Boards of Appeal (and particularly an Enlarged Board) the result would be an all too easy fragmentation of the European system of patent law. It is a matter of the utmost seriousness for any court to depart from a decision of an Enlarged Board EPO on a point of law, and, if it is to be done at all by a national court, I think it should only be done by a higher national court and not one of first instance. For the sake of coherence of the system as a whole first instance courts should exercise self-restraint, however erroneous they may think a particular decision of law of an Enlarged Board may be.

> *46. I turn back, then to this particular claim. It is not as simple as a typical claim in Swiss form because it is not simply to manufacture of a single medicament for a particular therapeutic use. Taxol and the premedication are both involved. The premedication is, as I have said, a cocktail of drugs which prevent toxic shock. Mr. Thorley submitted that the claim had a narrow construction – in substance he said it was to a kit of drugs (taxol and premed), the kit being a specially made up kit for administration. On that basis, of course, his clients did not infringe. No-one would make up special kits (e.g. in special packs with instructions). The normal form of treatment would involve administering to the patient a number of different medicines as the premedication (for instance, particularly, by telling the patient to take several different pills so many hours before the hospital treatment is due). At the hospital a dose of taxol is be made up for the particular patient, using a combination of height and weight measurements to calculate surface area. The taxol is then administered. So the premedication is separate from the taxol and the taxol is made up to be patient specific. What, asks Mr. Thorley is the "medicamentation" of this claim, if it covers medicines administered in this sort of way? Mr. Thorley says this is going further than has ever been gone by an EPO Board of Appeal. That court has allowed claims to compositions presented side-by-side to be administered simultaneously or at intervals, see Asta-Werke (T09/81 OJ EPO 1983 372). But here there is no side-by-side presentation, just administration of the premedication cocktail followed by the making up and administration of the patient specific dose of taxol. So, says Mr. Thorley, if the claim is not limited to the manufacture of a special kit, then it is in substance merely to a method of treatment and so unpatentable.*

[77] Jacob J. held the patent to be invalid for want of novelty and obviousness.

[78] The Court of Appeal in *Bristol-Myers* upheld Jacob J. It reviewed the state of the law at that time (May 2000) respecting "Swiss" claims. In short, the Court acknowledged that the Courts must recognize that the structure of the claim is necessary to get around the prohibition against second medical use imposed by European/British law, but, in interpreting the claim in considering novelty

and infringement, the Court is to ignore the structure and proceed on the basis that the claim is simply for a new use for a known medicine. At paragraphs 35 to 41, Aldous L.J. wrote:

> *35. A claim of the type considered to be legitimate by the Enlarged Board has become known as a "Swiss-type" claim.*
>
> *36. The conclusion reached in Eisai was at the time and has since been the subject of considerable discussion amongst patent lawyers. Its importance was recognized by Whitford J and Falconer J who sat in banc to decide whether it should be followed in this country. They held in John Wyeth and Brothers Ltd's Application and Schering AG's Application [1985] RPC 545 that is should be. They concluded that there could not be any objection to the patenting of inventions in the Swiss-type form, if the statutory requirement of novelty could be met. They concluded that, without regard to the position as it had developed in the courts of Convention States, the better view would be that Swiss-type claims would not be patentable as they could lack novelty under the patents Act 1977 and by parity of reasoning under the EPC. They went on to remind themselves that it was necessary to have regard to the decisions of the courts of Member States of the EPC and also decisions of the EPO, particularly the Enlarged Board. Having referred in detail to the reasoning of the Enlarged Board in Eisai, they held at page 567:*
>
> > *"The approach of the Enlarged Board of Appeal to the question of the novelty requirement in a Swiss type use claim directed to a second or subsequent medical use may be summarise, it seems, as follows:*
> >
> > *1. Because of the provisions of article 53(4) (first sentence) (which corresponds to section 4(2) of the 1977 Act), the normal type of use claim, whereby a new use of a known product may be protected, is not open to pharmaceutical inventions directed to the use of medicaments in a method of medical treatment.*
> > *2. However, no intention to exclude second (and subsequent) medical indications from patent protection, other than by a purpose-limited claim (under the provisions of article 54(5), corresponding to section 2(6) of the 1977 Act) is to be deducted from the terms of the EPC or the legislative history of the material articles thereof.*

> *3. In that regard the Swiss-type of use claim now being considered is not prohibited by article 52(4) and is capable of industrial application.*
>
> *4. As to novelty, the Board consider that in the type of claim specifically provided for in article 54(5), namely, a purpose-limited product claim to a known substance or composition for a first (and, therefore, novel) pharmaceutical use, the required novelty for the claim is to be found in the new pharmaceutical use.*
>
> *5. Similarly, in the Swiss type of use claim directed to the use of a known pharmaceutical in the manufacture of a medicament, not novel in itself, for a novel second (or subsequent) therapeutic use, the required novelty of the claimed process may be found in the new second (or subsequent) therapeutic use.*
>
> *That approach to the novelty of the Swiss type use of claim directed to a second, or subsequent, therapeutic use is equally possible under the corresponding provisions of the 1977 Act and, not withstanding the opinion expressed earlier as to the better view of the patentability of such a Swiss type claim under the material provisions of the Act considered without regard to the position, as it has developed under the corresponding provisions of the EPC, having regard to the desirability of achieving conformity, the same approach should be adopted to the novelty of Swiss-type of claim now under consideration under the material provisions of the Act."*

37. The patent judges in the John Wyeth case correctly summarised the approach of the Enlarged Board and I believe that they came to the right conclusion in the case before them.

38. Mr. Thorley rightly, in my view, emphasised that novelty in a Swiss-type claim resided in "the new second (or subsequent) therapeutic use". Mr. Waugh submitted that claim 1 did relate to a second therapeutic use, namely use of taxol for the claimed period and in amount for the reduction of neutropenia. He submitted that in any case novelty did not have to reside in a second or subsequent therapeutic use as had been made clear by the Enlarged Board in the Mobil case.

39. The difficulties that arise from the decision of the Enlarged Board in the Mobil case on infringement were referred to by Lord Hoffman in Merrell Dow. For the purposes of this case, it is necessary to appreciate what was actually decided and there is no need to become involved in the infringement difficulties. The Enlarged Board summarised their conclusions in this way in paragraph 10.3 of their decision:

> *"…with respect to a claim to a new use of a known compound, such new use may reflect a newly discovered technical effect described in the patent. The attaining of such a technical effect should then be considered as a functional technical feature of the claim (e.g. the achievement in a particular context of that technical effect). If that technical feature ahs not been previously made available to the public by any of the means set out in article 54(2) EPC, then the claimed invention is novel, even though such technical effect may inherently taken place in the course of carrying out what has previously been made available to the public."*

40. That conclusion depended upon two strands of reasoning. First, that prior use was not a ground of invalidity. Thus prior use that did not make the invention available to the public could not invalidate the invention. Similar reasoning was applied by the House of Lords in Merrell Dow. Second a purposive construction of the claim according to the protocol on Interpretation was required. Thus claims should in appropriate circumstances be interpreted as being limited to the technical effect, namely the physical activity. It followed that in the case being considered, the claim to an additive in lubricating oil for reducing friction should be interpreted as a claim to the product when used for reducing friction. Such a claim would be novel if the use had not previously been made available to the public. However it is relevant to note that similar reasoning cannot be applied in relation to a Swiss-type claim, as such a claim cannot be interpreted as relating to the product when used because that would constitute a method of treatment which is prohibited under the EPC.

41. I do not believe that the Mobil case qualifies or amplifies the conclusion reached in Eisai. The decision in Eisai was based upon the interplay between Articles 52(4) and 54(5) of the EPC; whereas Mobil depended upon purposive construction of the claims so as to limit the claims to the product when used together with an application of Article 52(2).

[79] Buxton L. J., with whom Holman J. agreed on this point, also addressed the "Swiss" claim at paragraphs 76 to 81:

> *"Swiss-type" claims and the ruling of the Enlarged Board in Eisai*
>
> *76. The respondents argued that the Board in Eisai had misinterpreted the EPC in concluding that the second medical use claims were, in principle, patentable inventions. The argument envisaged at least the possibility that even first medical use claims may be excluded from patentability if the substance used is already comprised in the state of the art; but that in any event second medical use claims were not permitted by the EPC. For reasons that I will develop, I do not think that it is open to us to act on those criticisms, even if they thought to have force; but it will usefully illuminate the terms and extent of the provisions of the EPC regarding medical use claims to consider the criticisms made of the Enlarged Board's interpretation of them in Eisai.*
>
> *77. It will be convenient first to remind ourselves of the reasoning in Eisai. The Enlarged Board recognised (at para 21) that in the normal industrial field*
>
> > *"a new use for a known product can be fully protected as such by claims directed to that use. That is in fact the appropriate form of protection in such cases as the new and non-obvious use of the known product constitutes the invention."*
>
> *78. But that direct approach might be thought to be precluded by the provisions of Article 52(4) in the case of products for use in medical treatment. The Board therefore said that*
>
> > *"Article 54(5) EPC provides an exception to this general rule, however, so far as the first use of medicaments is concerned, in respect of which the normal type of use claim is prohibited by Article 52(4) EPC. In effect, in this case the required novelty for the medicament which forms the subject-matter of the claim is derived from the new pharmaceutical use. It seems justifiable by analogy to derive the novelty for the process which forms the subject-matter of the type of use claim now being considered from the new therapeutic use of the medicament and this irrespective of the fact whether any*

> *pharmaceutical use of the medicament was already known or not."*

79. That reasoning was criticized on two grounds. First, and somewhat tentatively, the respondents said that the terms of the EPC did not envisage any sort of use-based claims at all in connection with pharmaceutical products, and therefore there was no allowable category of first medical use claims from which the allowability of second medical use claims could be derived by analogy. The premise of that argument seems ill-founded. It is difficult to see what the proviso to Article 54(5) of the EPC is talking about if it does not envisage use-based claims of some sort. Second, however, a more substantial argument was advanced in relation specifically to second medical use claims. That was that as a matter of construction of the proviso the reference to the exclusion of a case where the use of a product in "any" method of treatment is within the state of the art meant that once the product was "within the pharmacy" the doctor was free, without threat of infringement, to prescribe it for whatever treatment seemed best to him.

80. An argument in similar form appears to have attracted the Patents Court in Wyeth: see [1985] RPC at p 565, 20. For my part, however, I did not find it persuasive. It is far from clear that the wording of Article 54(5) should be read, as the argument requires, as referring to any method whatsoever. It is at least equally understandable that the reference to exclusion from the state of the art is simply to the method on the basis of which novelty is claimed. Indeed, if the aim were to exclude from further patentability any substance already used in a medical application, Article 54(5) could have simply said so: provided that its use for any other method of treatment, etc, is not already comprised in the state of the art. And once that objection is excluded, the Enlarged Board's conclusion seems, with respect, irresistible that, if a product can claim novelty on the basis of the novelty of its first medical use, then production for a novel second medical use must equally satisfy the requirements of the EPC. And since by Article 52(4) products for use in methods of medical treatment are not to be regarded, on that ground alone, as not susceptible of industrial application, it follows, as the Board said in paragraph 23 of the report in Eisai, that

> *"it is legitimate in principle to allow claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application, even in a case in which the process of*

> *manufacture as such does not differ from known processes using the same active ingredient."*
>
> *81. This may seem to be merely a roundabout way of seeking to patent a medical process, and one that only doubtfully gives proper weight to the first sentence of Article 52(4). It is not, however, in my view open to us to use such doubts as a ground for not applying Eisai at all. That is because, although the observations of the House of Lords in Merrell Dow '1996] RPC at p 82,25 as to the undesirability of departing from decisions of the EPO may strictly speaking not have been part of the ratio of that case, they are considered reasoned guidance of a unanimous House, which I do not think we are free to depart from. The same view of the standing of the decision of the Enlarged Board in Eisai was taken, though without the benefit of the guidance in Merrell Dow, by the patents Court sitting in banc in Wyeth.*

[80] Now we come to *Actavis* where the Court considered not only a "Swiss" claim, but one very like the claim at issue in these proceedings. The trial judge, Warren J., wrote as to this matter in paragraphs 11 to 17 of *Actavis*:

> ***"Swiss form" and medical use***
> *11. It will be seen that Claim 1 is in "Swiss form" (for a general description of which see Terrell on the Law of patents (16th ed) at 6-122ff). I do not embark on an explanation of the justification for upholding patents in this form. But I should mention the legislation and a bit of history.*
>
> *12. Sections 4(2) and 4(3) of the Patents Act 1977, which are derived from Article 52(4) of the Convention on the Grant of European Patents (the European Patent Convention) ("EPC"), state:*
>
> > *"(2) An invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body shall not be taken to be capable of industrial application.*
> >
> > *(3) Subsection 2 above shall not prevent a product consisting of a substance or composition being treated as capable of*

industrial application merely because it is invented for use in any such method."

13. Section 2(6) of the 1977 Act, which is derived from Article 54(5) of the EPC, states:

> *"(6) In the case of an invention consisting of a substance or composition for use in a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body, the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new if the use of the substance or composition in any such method does not form part of the state of the art."*

14. The result is that it is possible to obtain a patent for the first medical use of a k known substance or composition, where the substance or composition was not previously known to have any medical application: see Sopharma SA's Application [1983] RPC 195.

15. Owing to the prohibition on method of treatment claims in Article 52(4) of the EPC (which corresponds to sections 4(2) and 4(3) of the 1977 Act), the Enlarged Board of the European Patent Office has held that a European patent may not be granted for the use of a substance or composition for the treatment of the human or animal body by therapy.

*16. However, it has also accepted, on policy grounds, and following the practice of the Swiss Federal Intellectual Property Office, that a European patent may be granted with claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application. This gave rise to the now widely used form of the second medical use, or so-called "Swiss form" claim: see Eisai/Second Medical Indication (1985) OJEPO, 64 ("**Eisai**").*

17. Accordingly, a claim in the form: "Use of [X] for treatment of [Y]" would not be accepted, whereas a claim "Use of [X] for the manufacture of a medicament for treatment of [Y]" would be accepted.

[81] The Court of Appeal decision in Actavis was written by Jacob L.J. for the Court (he refers to himself when considering *Bristol-Myers* in the third person for instance at paragraph 10). It reversed Warren J. The arguments directed in that case closely resemble the arguments made in the present case and are summarized at paragraphs 11 and 12:

> ***[11]*** *This case is about the limits of what can be done with Swiss form claims. In outline the argument for invalidity runs as follows: (a) Finasteride as a substance is not novel; (b) Nor is its use as a medicine (for treating BPH); (c) So its use for the manufacture of a medicament for use as a medicine lacks novelty; (d) Moreover finasteride had been proposed for treating aa, but with a daily dosage of 5 mg or more (see below); (e) So its use for the manufacture of a medicament for treating aa also lacks novelty; (f) Novelty cannot be saved by specifying a particular dosage regime even if that dosage was not proposed in the prior art; (g) Even if that is wrong, this court is bound under the English rules as to precedent by its prior decision in the BMS case to hold that the patent lacks novelty and/or is in substance one for a method of treatment of the human and thus, by virtue of art 52(4) is not to be regarded as susceptible of industrial application.*
>
> ***[12] Merck's*** *counter argument runs thus: (i) Points (a) to (e) are accepted; (ii) But (f) is wrong and contrary both to the EISAI decision and EPO Board of Appeal authority subsequent to the BMS case and this court should follow that; (iii) There is no ratio decidendi of the BMS case, or at least not one clear enough, which precludes this court from so doing; (iv) Even if there is such a ratio, this court should recognise (and apply) a new exception to the general rules of precedent for this court, rules adopted long ago and summarised in Young v Bristol Aeroplane Co Ltd [1944] 2 All ER 293, [1944] KB 718.*

[82] The Court of Appeal dealt with these arguments, commencing at paragraph 11, and reviewed in detail the "Swiss" form of claims. The Court concluded that the "Swiss" form is appropriate not only for new uses for an old medicine, but also for new dosage forms of an old

medicine. The discussion is lengthy, so I reproduce only paragraphs 13 to 18; 33, 44 and 45; and 48 and 49:

> *[13] We begin by dealing with the arguments without reference to the impact of the BMS case. There are three stages: first a detailed consideration of a Swiss form claim; secondly, why such a claim is treated as novel and not for a method of treatment, a close examination of the EISAI decision; and thirdly, subsequent EPO and other cases.*
>
> *SWISS FORM CLAIMS IN MORE DETAIL*
>
> *[14] One possible view of novelty in patent law (we speak generally rather than by reference to any particular legislation) is this: that a thing is either old or is it is not. If it is old, then a claim to the thing itself cannot be made novel by qualifying it with words specifying an intended use however inventive that use may have been. This was the rule in this country prior to the new, European, patent system brought in by the EPC and the implementing Patents Act 1977.*
>
> *[15] The rule was exemplified by Adhesive Dry Mounting Co Ltd v Trapp & co (1910) 27 RPC 341. The claim was 'for carrying into practice' a process of mounting photographs on cardboard using a tissue coated with heat activatable gum on both sides. Such a tissue (called "a pellicle') was in itself old. Parker J held that adding an intended purpose did not confer novelty on an old product: So you could patent an inventive new process using the new material, but not the material 'for carrying out the process'.*
>
> *[16] This rule had the virtue of certainty when it came to infringement—a man who sold an old product could not infringe. The rule had disadvantages from the patentee's point of view. A method claim was not as effective in practice as a 'produce for' claim. The person he really wanted to sue was the seller of the product which was going to be used for his patented process. There were difficulties about this, however. Such a seller, though not guilty of infringement as such might, otherwise be liable pursuant to some doctrine of contributory infringement or inducement to infringe. The law was not clear about this (cf Innes v Short (1898) 15 RPC 449, (1898) 14 TLR 492, the criticism of this case in the Adhesive Dry mounting case and the general discussion of the problem in §3-20 of Patents for Inventions (4th edn, 1974) by TA Blanco White QC).*

[17] The rule had a more significant disadvantage in the field of medicines. For you could not get a method claim—methods of treatment were then, as they are now, precluded from patent protection. This meant that there was no patent incentive to investigate whether old substances had a medical use—not even a first medical use for an old substance would be worth researching, a fortiori a second medical use.

[18] Things are different under EPO case law as was first established in the EISAI decision in 1984. Before we examine the IISAI decision in more detail it is important to note a parallel, closely related, development which occurred a little later but outside the context of medical use. In MOBIL OIL 'III/Friction reducing additive Decision G 0002/88 [1990] OJ EPO 93, [1990] EPOR the 'use of X as a friction reducing additive in a lubricant composition' was held by an Enlarged Board new notwithstanding the fact that the use of X in such a composition for the purpose of rust inhibition was known. Novelty of purpose for use can confer novelty even if the substance is old and unpatentable as such. Lord Hoffman in Merrell Dow Pharmaceuticals Inc v HN Norton & Co Ltd, Merrell Dow Pharmaceuticals Inc v. Penn Pharmaceuticals Ltd (1995) 33 BMLR 201, [1996] RPC 76 noted the difficulties which this sort of claim may cause in respect of infringement but clearly deliberately refrained from holding a MOBIL-type use claim is invalid.

...

[33] The EPO takes the same view about the effect of the EISAI decision as us. For there is now clear Board of Appeal authority holding, as we do, that it follows from the EISAI decision that a novel dosage regime can confer novelty to a Swiss form claim. In GENENTECH/Method of administration of IFG-I Decision T 1020/03 [2006] EPOR 9 a Legal Board of Appeal specifically so held in an unusually detailed and carefully crafted reasoned opinion. It said:

'72…the Board interprets decision G 5/83 [EISAI] allowing Swiss form claims directed to the use of a composition for manufacture of a medicament for a specified new and inventive therapeutic application, where the novelty of the application might lie only in the dose to be used or the manner of application. This Board allowed such a claim, where only the manner of application was new, already eleven years ago in T 0051/93 of 8 June 1994. The

discussion in decision G 0005/83 concerning further medical indications did indeed refer to use for treating a new illness. But the Board regards this significant only of the fact that most further medical use claims will refer to a new illness, as in that case novelty and inventive step are more likely to exist than in the case of a minor modification of the treatment known for an existing illness. The logic of decision G 0005/83 allowing claims to further medical uses of known compositions, seems equally applicable to any use of such known composition for a new and inventive treatment which cannot be claimed as such because of Article 54(4) EPC first sentence.'

. . .

[44] We pause to summarise. In the EPO, Germany, and even in New Zealand, Swiss form claims whose novelty depends on a new treatment by a different dosage regime or method of administration are treated as novel and not as claims to a method of administration. This position is settled.

[45] Our courts would normally follow such settled jurisprudence. That would be in accordance with what Lord Hoffman said in Merrell Dow Pharmaceuticals Inc v HN Norton & co Ltd, Merrell Dow Pharmaceuticals Inc v. Penn Pharmaceuticals Ltd [1996] RPC 76 at 82:

'…the United Kingdom Courts…must have regard to the decisions of the European Patent Office ("EPO") on the construction of the EPC. These decisions are not strictly binding upon courts in the United Kingdom but they are of great persuasive authority; first, because they are decisions of expert courts (the Boards of Appeal and Enlarged Board of Appeal of the EPO) involved daily in the administration of the EPC and secondly, because it would be highly undesirable for the provision of the EPC to be construed differently in the EPO from the way they are interpreted in the national courts of a Contracting State.'

. . .

[48] In saying our courts would and should normally follow the settled jurisprudence of the EPO it should be understood, of course, that they are not bound do so. In the unlikely event that we are convinced that the commodore is steering the convoy towards the rocks we can steer our ship away. Technically we are not in the same position as we are in the case of decisions of the Court of Justice of

> *the European Communities (see further below). And of course if there is no clear message from the commodore or he gives mixed messages we must decide our own course anyway.*
>
> *[49] Here, for the reasons we have given and subject to the binding effect, if any, of the BMS case, we would follow he EPO and hold that a new dosage regime is enough to confer novelty on a Swiss form claim.*

[83] The Court of Appeal in *Actavis* then turned to the earlier decision of a different panel of that Court in *Bristol-Myers.* The argument made by *Actavis* is set out at paragraph 50:

> *[50] Actavis contends that we cannot follow the EPO, however, because this court's decision in the BMS case stands in the way. Many have interpreted the BMS case as deciding (1) that a novel and non-obvious dosage regime specified in a Swiss form claim cannot make it novel and (2) that such a claim is to a method of treatment. Included in that number are the Opposition Division in relation to the parallel designations of the BMS patent itself (reasons dated 22 May 2002 holding the patent lacked novelty but expressly disagreeing with the Court of Appeal about method of treatment), the Board of Appeal in the GENETECH decision itself (it was strongly critical of the Court of Appeal decision in the BMS case), Jacob J in Merck & Co Inc's Patents [2003] FSR 498 at [74] (he was also unhappy with the BMS case), the UKIPO (see above), and Warren J in this case.*

[84] Again, the discussion is lengthy; however, the Court of Appeal in *Actavis* goes to great lengths to distinguish the decision of that Court in *Bristol-Myers* as set out at paragraph 52 to paragraph 108. The result, as stated in paragraphs 107 and 108, is that the U.K. Courts can depart from an earlier view if it is satisfied that the European Boards of Appeal have formed a settled view of European patent law. For the purposes of the present case, I repeat paragraphs 69 to 73, as they bear most directly on the matters at issue in this patent case:

[69] What is revealed particularly sharply here is that if that conclusion is right, there are two kinds of novelty attacks possible against Swiss form claims. First there is what may be called the 'conventional' novelty attach—the well-known General Tire and Rubber Co v Firestone Tyre and Rubber Co Ltd [1972] RPC 457 at 485-486 clear and unmistakable direction test'. But also available would be a different test—one asks is the novelty of the claim only due to a novel dosage regime? If that is so then it doe not matter that no one has ever proposed that regime—the claim lacks novelty.

[70] We think that cannot be so—there is only one novelty test and it is the General Tire test. We do not think one can conclude that the court in the BMS case was holding that there are two tests and certainly it was not clearly doing so.

[71] Accordingly we are not satisfied that the BMS case contains a clear ration that a Swiss form claim lacks novelty if the only difference between it and the prior art is a new dosage regime for a known medical condition.

[72] As to method of treatment, Buxton LJ reasoned the same way as Aldous LJ:

In relation to the patent in suit, however, the manufacture claimed is not the use of the active ingredient, paclitaxel, in the manufacture of toxol; but the mixing in the hospital pharmacy of taxol and other ingredients to produce the medium that is injected into the patient. It is the latter process that is said to be susceptible of industrial application, under art 52(1) of the EPC. I am afraid that I found that assertion to be, at best, artificial, and one that I do not think would have been made were it not for the need to demonstrate that the invention is not of a method of treatment. We were told that the mixing process could be, and in some cases was, subcontracted outside the hospital; but that does to prevent it from being a long way away from anything that in normal parlance would be considered an industrial application; or, for that matter, as under the old English law, "manufacture". As my Lord has described, the mixing of amounts and types of premedication, and of amounts of taxol, all determined by the doctor in relation to the specific patient. It is in reality not a self-standing operation, but subordinate and incidental to the doctor's treatment of the patient. True it is that, in treating the patient, the doctor will, or at least may, administer the drugs according to the guidance contained in the patent. But that merely underlines that what the patent teaches is not how to

> *manufacture a drug for use in the treatment of the patient, which would be in form at least a Swiss-type claim, but how to treat the patient which is the teaching that the Swiss-type claim is designed to avoid.*
>
> *[73] There is a ratio here—that the claim concerned was essentially to a method of medical treatment. It is the same ratio as that of Aldous LJ. Holman J agreed. However it seems clear that the EPO would not accept it as correct. For it accepts that any Swiss form claim by its nature stops short at claiming a method of medical treatment—it does not monopolise the actual treatment of a patient.*

[85] Thus, it can be seen that the Court of Appeal in *Actavis* maintained the position that while a "Swiss" type claim was necessary for the purpose of avoiding the prohibition against a second medical use, that structure is to be ignored when dealing with issues such as novelty. In so doing, the Court of Appeal relied heavily on what it perceived as the state of the law as pronounced by the European patent courts. However, if one looks at the postscript to the Court of Appeal decision commencing at paragraph 120, that Court was asked – but declined – to reserve until the European Board of Appeals ruling in *Kos,* which was expected shortly, came out.

[86] With this lengthy background, we must turn to the decision of the European Enlarged Board of Appeals in *Kos*. That case dealt with a "Swiss" type claim directed to a known medicine for a known use where the difference was in the stated dosage as being "once per day prior to sleep". The Board of Appeals held that, because the European law had changed, the "Swiss" type claims should no longer be read. It recognized that there were many existing patents with such claims, thus the ruling was prospective only. I repeat paragraphs 7 (7.1 to 7.1.4) of that ruling. It is important to note paragraph 7.1.3, where the Board recognizes that "Swiss" claims could be objectionable in that they do not really address the features in which novelty and inventiveness are asserted to reside. In other

words, a claim saying use this particular drug to make a tablet of a certain dosage that will eventually be used to treat a certain disease will lack novelty and inventiveness if all that is being considered is the making of the tablet:

> *7. Answer to the third question*
>
> *7.1 Consequence of the new law in respect of so called Swiss-type claims*
>
> *7.1.1 Claim 1 is submitted to the referring Board of Appeal for consideration is drafted in the so-called Swiss-type format. It has been established practice under the EPC 1973 that a patent related to a further medical application of a known medicament could only be granted for a claim directed to the use of a substance or composition for the manufacture of a medicament for a specified therapeutic application (cf. G 5/83, point 2 of the Order).*
>
> *Since the medicament per se was not new the subject-matter of such a claim was rendered novel by its new therapeutic application (cf. G 5/83, points 20 and 21 of the Reasons). This praetorian approach was a "special approach to the derivation of novelty" (cf. point 21 or G 5/83) and therefore constituted a narrow exception to the principles governing the novelty requirements which was not intended to be applied in other fields of technology.*
>
> *That praetorian ruling found its cause in the fact that a claim directed to the use of the substance or composition for the treatment of the human body by therapy had to be regarded as a step of treatment (see point 18, in fine of G 5/83). A claim of that kind was forbidden. On the other hand only the first medical indication of a known composition in the form of a medicament was by virtue of Article 54(5) EPC 1973 (Article 54(4) EPC 2000) entitled to be drafted in the form of a purpose-related product claim. And since the intention of the legislator was clearly not to exclude second therapeutic indications of a known medicament from the field of patentability the so-called Swiss-type claim constituted the adequate but exceptional solution.*
>
> *7.1.2 Article 54(5) EPC now permits purpose-related product protection for any further specific use of a known medicament in a method of therapy. Therefore, as mentioned in the preparatory*

document (MR/24/00, point 139) the loophole existing in the provisions of the EPC 1973 was closed.

In other words "cessante ratione legis, cessat et ipsa lex", when the reason of the law ceases, the law itself ceases.

The cause of the praetorian approach ceasing, the effect must cease. As stated in decision T 406/06 of 16 January 2008, point 5 of the Reasons:

"The question arises whether the exception to the general novelty requirement, which was accepted in decision G 5/83 under the EPC 1973, is still justified under the new legal framework which enables the applicant to frame its claims in accordance with the provision of Article 54(5) EPC 2000 in order to obtain patent protection for a new therapeutic application of a known medicament."

7.1.3 Moreover, Swiss-type claims could be (and have been) considered objectionable as regards the question as to whether they fulfill the patentability requirements, due to the absence of any functional relationship of the features (belonging to therapy) conferring novelty and inventiveness, if any, and the claimed manufacturing process. Therefore, where the subject matter of a claim is rendered novel only by a new therapeutic use of a medicament, such claims may no longer have the format of a so called Swiss-type claim as instituted by decision G 5/83.

7.1.4 The Enlarged Board of Appeal is aware of the fact that patents have been granted and many applications are still pending seeking patent protection for claims of this type. In order to ensure legal certainty and to protect legitimate interests of applicants, the abolition of this possibility by the interpretation of the new law give by the Enlarged Board in this decision shall therefore have no retroactive effect, and an appropriate time limit of three months after publication of the present decision in the Official Journal of the EPO is set in order for future applications to comply with this new situation. In this respect the relevant date for future applications is their date of filing or, if priority has been claimed, their priority date.

f) <u>"Swiss" Claims in Canada</u>

[87] Turning to the use of "Swiss" type claims in Canada, I discussed the origin and nature of such a claim at paragraphs 18 to 24 in *Eli Lilly Canada Inc. v. Apotex Inc.*, 2008 FC 142, 63 C.P.R. (4th) 406:

> ***18*** *All 17 claims of the '356 patent, not only claims 1, 3, 15 and 17, are drafted in the "Swiss" style that is to say in a style which says:*
>
> > *The use of [an old compound] in the manufacture of a medicament for the treatment of [a new disorder].*
>
> ***19*** *Claims in a patent directed in one way or another to medicines, to make them and how to use them have at various times and in various jurisdictions, been the subject of certain restrictions and limitations. At one time for instance, Canada as well as some other countries did not permit claims for a medicine per se. As a result claims became structured in certain ways so that, indirectly, some monopoly protection could be claimed. A good brief analysis of the history of such claims in Canada was given by the late Jerome A.C.J. in Deprenyl Research Ltd. v. Apotex Inc. (1994), 55 C.P.R. (3d) 171 (aff'd (1995), 60 C.P.R. (3d) 501 (F.C.A.)) at page 175:*
>
> > *Until very recently, a medicine itself could not be patented, except when prepared by a particularly described process. Even then, however, it was essential that the medicine so produced be new or novel. If the medicine was not new, but the process producing it was, only the process could be patented. Though medicines themselves can now be patented as products, clearly a large number of patents still exist in relation to medicines when prepared by a particular process. Accordingly, there are three types of claims which can be made in a medicine patent. There may be a claim for the medicine itself, known as a "product" claim; a claim for the medicine when prepared by a particular process, known as a "process-dependent" product claim; and, a claim for*

> *the particular process that produces a medicine, known as a "process" claim.*

20 *In Europe, claims that were "susceptible of industrial application" were quite permissible but "methods of treatment of the human body...by surgery or therapy and diagnostic methods" were not, with the saving provision that "substances or compositions, for use in any of these methods" were permitted to be claimed. Thus a new medicine could be claimed, but not a new use for an old medicine. The Swiss developed a way around this issue of claiming a new use for an old medicine by characterizing the manufacture of a pill for a new use as something that was "susceptible of industrial application" thus this type of claim became known as a "Swiss claim".*

21 *Jacob J. as he then was explained Swiss claims clearly in his decision in the English Chancery (Patents) Division in Bristol-Myers Squibb Co. v. Baker Norton Pharmaceuticals Inc., [1998] EWHC Patents 300 (aff'd [2000] EWCA Civ. 169 (CA)), at paragraph 43 and following:*

> *43. Before going further I must now say something about the general structure of the claim. I daresay that an ordinary skilled man (to whom it is notionally addressed) would find it puzzling, unless he had been initiated in some of the Byzantine logic of patent law and jurisprudence. The explanation lies in Art. 54(4) of the EPC and the decided cases. The material parts of Art.54 read:*
>
> > *(1) European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.*
> >
> > *(4) Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products,*

> *in particular substances or compositions, for use in any of these methods.*
>
> ***22*** *Thus the "Swiss claim" is an additional structural form of a claim that can be added to the structures discussed in Deprenyl, supra so that presently, in Canada, claims directed to a medicine, and in particular to a previously known medicine can be structured in a variety of ways such as:*
>
> - *The use of an old medicine for the treatment of a new disorder (new use claim)*
> - *The process for making an old medicine that is to be used in the treatment of a new disorder (process claim)*
> - *The use of an old medicine when prepared by a certain process for the treatment of a new disorder (process-dependent claim)*
> - *The use of an old medicine for the manufacture of a medicament for the treatment of a new disorder (Swiss claim)*
>
> ***23*** *Each of these claims could arguably be said in "spirit" or "essence" to be directed to the new use of a known medicine, but each is structured differently.*
>
> ***24*** *At the pre-trial conference held on January 14, 2008, counsel for Apotex stated that Apotex would not be arguing whether "Swiss" type claims are appropriate for listing under the NOC Regulations nor would it be arguing whether such claims are directed to a method of medical treatment. To the extent that such arguments were raised in Apotex's Notice of Allegation or Memorandum of Argument, they have been abandoned.*

In that case, I did not have to deal with the effect of drafting the claims in a Swiss type style. In the present case I do.

[88] There are somewhat conflicting decisions in our Courts as to the construction of a “Swiss” type claim. In *Abbott Laboratories v. Canada (Minister of Health)* (2007), 59 C.P.R. (4th) 1, the

Federal Court of Appeal held that the Trial Judge was “on solid ground” when she construed such a claim not be a claim for the use of the medicine. At paragraphs 32 to 43, Noel J.A. (who dissented on other grounds) wrote:

> ***32*** *Turning to the first issue raised on appeal, claim 31 reads:*
>
> > *The use of [clarithromycin] Form 0-ethanolate in the preparation of [clarithromycin] Form II for use as an antibiotic.*
>
> ***33*** *Abbott does not dispute Heneghan J's conclusion that claim 31 is not a claim for the "medicine itself". The sole issue is whether Heneghan J. correctly held that claim 31 is not an eligible claim under the NOC Regulations because it is not (section 2) "... a claim for the use of the medicine for the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or the symptoms thereof".*
>
> ***34*** *Abbott submits that Heneghan J. erred in holding that claim 31 is not a claim for the use of the medicine. The applications judge concluded that claim 31 "claims the use of Form 0 to make something else, that is Form II" (Reasons, at para. 120). In so doing, according to Abbott, she erred by giving no meaning to the words "for use as an antibiotic" in claim 31.*
>
> ***35*** *When given a purposive construction, Abbott submits that claim 31 is a claim for the use of a medicine, thereby rendering it eligible for inclusion on the Patent List. In other words, had the phrase "for use as an antibiotic" not been disregarded, an eligible use would have been found.*
>
> ***36*** *In this respect, Abbott submits that claim 31 should be read with claim 30 which is identical to claim 31, but for the fact that the concluding words "for use as a medicine" are omitted. According to Abbott, these additional words in claim 31 must be given meaning, and Heneghan J. erred in law, in choosing to ignore them.*
>
> ***37*** *I do not believe that Heneghan J. ignored the words "for use as an antibiotic" in construing claim 31. She refers to that phrase throughout her reasons. On a fair reading of her reasons, she held that the person skilled in the art would have read claim 31 as*

claiming the use of Form 0 to make Form II and considered that the closing words were not essential to the invention claimed (Reasons, at para. 104, 120-134). The issue in this appeal is whether this conclusion was open to her. In my respectful view, it was.

38 *On a plain reading of claim 31, it makes a claim to a use of a substance (Form 0 clarithromycin) in the preparation of another substance (Form II clarithromycin). This is achieved by heating Form 0 at extreme temperatures (between 70o C and 110oC).*

39 *The 68 claims of the '361 Patent vary in scope, but all relate to Form 0 being used to make Form II. None purports to claim Form 0 clarithromycin as a medicine. Claims for Form 0 clarithromycin per se and for the use of Form 0 as an antibiotic are made in Patent 2,277,274 which was filed at the same time as the '361 Patent (Appeal Book, Vol. VI, p. 2270).*

40 *On the other hand, the use of Form II as an antibiotic is disclosed in Patent 2,258,606 which was filed before the '361 Patent and has a claim date which precedes that of the '361 Patent (ibid).*

41 *It is significant that Abbott's own expert (Dr. Byrn) omitted the phrase "for use as an antibiotic" entirely in describing what is claimed by the '361 Patent (Appeal Book, Vol. VI, pp. 2171-2172).*

In the same vein, Dr. Atwood (who also provided expert evidence on behalf of Abbott) does not qualify the words "for use as an antibiotic" as being essential to the claim (Appeal Book, Vol. VII, p. 2645).

42 *Moreover, Form II was known to have but one use, that being use as an antibiotic. Dr. Byrn indicates so much at para. 296 of his affidavit (Appeal Book, Vol. VI, p. 2333). It is true, as Counsel for Abbott point out, that the statement made by Dr. Byrn relates to clarithromycin tablets, but Dr. Byrn's evidence does not suggest that Form II from which the tablets are made, had any other use.*

> ***43*** *Although, the Court should strive to construe claims which do not bear the same words differently, Heneghan J. was on solid ground in this case, when she held that the words "for use as an antibiotic" at the end of claim 31, do not add anything to the invention claimed. At best, these words describe the*

> *utility of Form II once made in accordance with the claimed invention. The fact that clarithromycin in Form II is used as an antibiotic was well known. Saying, in effect, that an antibiotic is used as an antibiotic adds nothing to the invention.*

[89] In *Pfizer Canada Inc. v. Apotex Inc.* (2007), 61 C.P.R. (4th) 305, Mosley J. of this Court considered certain claims which he summarized at paragraph 147 so as to include, at claim 8 a "Swiss" type claim. Other claims were more directly stated to be the use of the medicine:

> ***147*** *The relevant claims with respect to this issue, as disclaimed, are set out as follows in summary form and with emphasis added:*
>
> > *1. The* ***use of a compound of formula*** *(I) [which is then defined] or a pharmaceutically acceptable salt thereof, or a pharmaceutical composition containing either entity,* ***for the manufacture of a medicament for the curative or prophylactic treatment of an erectile dysfunction in man.***
>
> *Claims 2-4 in essence claim "The use according to claim 1" and give more narrow definitions for formula (I).*
>
> > *7. The use according to claim 4 wherein the compound of formula (I) is 5-[2-ethoxy-5-(4-methyl-1-piperazinylsulphonyl)phenyl]-1-methyl-3-n-propyl-1,6-dihydro-7Hpyrazolo[4,3-d]pyrimidin- 7-one] (i.e. sildenafil) or a pharmaceutically acceptable salt thereof (i.e. sildenafil salt), [italicized notations added]*
>
> > *8. The use according to any one of claims 1 to 7 for the* ***manufacture of a medicament for the curative or prophylactic treatment of erectile dysfunction in man****.*
>
> > ***10. A pharmaceutical composition for the curative or prophylactic treatment of erectile dysfunction in man****, comprising a compound of formula (I) according to any one of claims 1 to 7, or a pharmaceutically acceptable salt thereof, together with a pharmaceutically acceptable diluent or carrier.*

> ***18. The use of a compound of formula (I) according to any one of claims 1 to 7, or a pharmaceutically acceptable salt thereof, for the curative or prophylactic treatment of erectile dysfunction in man***.
>
> ***22. The use according to any one of claims 1 to 8*** *wherein the medicament is adapted for oral treatment.*
>
> *23. A pharmaceutical composition according to claim 10 which is adapted for oral treatment.*
>
> *[Emphasis added]*

[90] In referring to these claims at paragraph 153, he referred to all of them, including the "Swiss" as directed to the use of the medicine, the manufacture of a medicament being merely secondary:

> ***153*** *To my mind, it is clear from the claims at issue that multiple forms of sildenafil, including a compound of formula (I), a pharmaceutically acceptable salt thereof, or a pharmaceutical composition containing either, are claimed as being useful for the treatment of ED in man, and that this may require the manufacture of a medicament to be achieved. The use being spoken of is therefore the use of sildenafil (which is a medicine, as defined above, i.e. "a substance") for the curative or prophylactic treatment of erectile dysfunction in man, and the manufacture of a medicament or the adaptation for oral treatment are merely secondary aspects to the essential claimed use.*

[91] Given *Bristol-Myers*, *Actavis* and *Kos*, as well as these Canadian decisions, where are we in Canada in respect of "Swiss" claims? Do we do what the British Courts and Mosley J. have done and view the structure which is drafted in terms of the manufacture of a medicament as merely secondary to the real intent in claiming a new use? The difference is important when considering validity in particular.

[92] In this case, if claim 5 is really directed simply to the manufacture of a tablet having, in this case, 1 mg. of the drug, these cannot be said to be anything novel or inventive in making a tablet at that dosage, given the prior art which shows tablets used for the same purposes with the same drug in dosages, say, at 5 mg. or more. This is what Warren J. did in the *Actavis* trial decision at paragraphs 23 to 27:

> ***Lack of Novelty***
>
> *23. Mr Thorley submits that the present case is indistinguishable from Bristol-Myers (which is of course binding on me). Dealing first with lack of novelty he says that, in order to be a valid Swiss-type claim, the novelty must lie in the new therapeutic application: novelty cannot reside in a new dosing regimen for treatment of the same disorder as previously treated. In the present case, he submits that EP 0 285 382 discloses the therapeutic application, namely, the treatment of androgenic alopecia. The fact that the dosage levels are changed cannot afford novelty. The Claim accordingly lacks novelty in the light of the reasoning in Bristol-Myers.*
>
> *24. I need to say something at this stage about that EP 0 285 382. This application was published in October 1988. It is entitled "Methods of treating androgenic alopecia with 17β-N-monosubstituted-carbomyl-4-aza-5α-androst-1-en-3-ones". One of the compounds in question is finasteride.*
>
> *25. As with the Patent, 382 begins with a reference to a number of hyperandrogenic conditions including male pattern baldness and BPH (page 2 11-13). At the foot of page 2, it refers to the new class of compounds as active ingredients and methods of inhibiting 5α-reductase and of treating androgenic sensitive conditions.*
>
> *26. Having described the underlying chemistry, the specification states as follows:*
>
> > *"Accordingly, the present invention is particularly concerned with providing a method of treating the hyperandrogenic conditions of androgenic alopecia, including male pattern alopecia, acne vulgaris, seborrhoea, and female hirsutism by topical administration, and a method of treating all of the above conditions as well as benign hypertrophy, by systemic*

> *administration, of the novel compounds of the present invention.*
>
> *The compositions containing the compounds of the present invention is [query should be "which are"] the active ingredient for use in the treatment of benign prostatic hypertrophy can be administered in a wide variety of therapeutic dosage forms in conventional vehicles for systemic administration, as for example, by oral administration in the form of tablets, capsules, solutions, or suspensions, o[r] by intravenous injection. The daily dosage of the products may be varied over a wide range varying from 5 to 2,000 mg, preferably from 5 to 200 mg."*
>
> *27. In light of that, it seems to be clear that there is no novelty in the use of finasteride as a possible treatment for MPB. It may be novel to use it in the small dosage which it is now apparent can result in successful treatment, rather than the much larger doses mentioned in EP 0 285 382. But this is simply a different dosing regime and is thus precisely the same as the situation in Bristol-Myers.*

[93] On the other hand, if we ignore the "Swiss" structure and construe the claim to be directed to the treatment of baldness with finasteride at a particular dosage, then we are in the situation as discussed by Jacob L.J. in the *Actavis* appeal decision at paragraphs 66 to 71:

> *[66] If one considers Warren J's judgment on these points it illustrates particularly vividly why it is unlikely that the BMS case actually decided that a Swiss form claim whose difference from the prior art is only in the dosage regime lacks novelty.*
>
> *[67] The judge held that claim 1 lacked novelty because the only thing that differentiated it from the prior art was the new dosage regime. Spelling that out it means he held that 'the use of finasteride for the preparation of a medicament for oral administration useful for the treatment of aa wherein the dosage is amount is about 0.4305 to 1.430 mg' lacked novelty. But no one had ever used finasteride for that purpose or ever given clear and unmistakable directions to do so. This case is not like the BMS case where Winograd had disclosed the very dosage regime of the claim and had given clear and*

> *unmistakable directions for its use and hence to use taxol for the preparation of that dosage regime.*
>
> *[68] The judge noted that 'it may be novel to use it in the small dosage which it is now apparent can result in successful treatment'. He thought it followed from the BMS case that that novelty was not enough to count as novelty for the purposes of validity.*
>
> *[69] What is revealed particularly sharply here is that if that conclusion is right, there are two kinds of novelty attacks possible against Swiss form claims. First there is what may be called the 'conventional' novelty attack—the well-known General Tire and Rubber Co v Firestone Tyre and Rubber Co Ltd [1972] RPC 457 at 485-486 clear and unmistakable direction test'. But also available would be a different test—one asks is the novelty of the claim only due to a novel dosage regime? If that is so then it doe not matter that no one has ever proposed that regime—the claim lacks novelty.*
>
> *[70] We think that cannot be so—there is only one novelty test and it is the General Tire test. We do not think one can conclude that the court in the BMS case was holding that there are two tests and certainly it was not clearly doing so.*
>
> *[71] Accordingly we are not satisfied that the BMS case contains a clear ration that a Swiss form claim lacks novelty if the only difference between it and the prior art is a new dosage regime for a known medical condition.*

[94] I will leave the matter there because, in the circumstances of this case, since it is a proceeding under the provisions of the *NOC Regulations*, I am determining, as follows, that Pharmascience is bound by the allegations as to construction of claim 5 that it made in its Notice of Allegation.

g) <u>Claim Construction – Notice of Allegation</u>

[95] The function of a Notice of Allegation served by a second party such as Pharmascience under the provisions of the *NOC Regulations* is to raise all the relevant facts and law upon which it

intends to rely in clear and unequivocal terms. I wrote *in Eli Lilly Canada Inc. v. Novoharm Ltd.,* 2009 FC 301, 76 C.P.R. (4th) 407 at paragraph 78:

> ***78*** *The jurisprudence in this Court has evolved to the point where it has established that a second party has an obligation in its Notice of Allegation to raise all the issues and relevant facts and law upon which it relies and set this out in clear and unequivocal terms such that the first party will know exactly the case that it will have to meet should it wish to commence proceedings under the NOC Regulations. In this regard I stated in Bristol-Myers Squibb Canada Co. v. Apotex Inc., 2009 FC 137 at paragraph 130 in reliance upon Stone JA. in AB Hassle v. Canada (Minister of Health and Welfare) (2000), 7 C.P.R. (4TH) 272:*
>
> > *[130] A Notice of Allegation is intended to be fulsome, putting the first party on notice as to the allegations made and the factual and legal basis for those allegations. The intent is that the entire factual basis upon which a second person relies is set out with particularity. The second person assumes the risk if the notice is incomplete. I quote from the reasons of the Federal Court of Appeal given by Stone JA. in AB Hassle v. Canada (Minister of Health and Welfare), previously referred to in these reasons when I was dealing with the disclaimer issue. He wrote at paragraph 21and 23:*
> >
> > ***21*** *In my view, all of these considerations suggest that a second person must do what, in fact, paragraph 5(3)(a) requires, i.e. set forth in the detailed statement "the legal and factual basis" for the paragraph 5(1)(b) allegation and to do so in a sufficiently complete manner as to enable the patentee to assess its course of action in response to the allegation. See Pharmacia Inc. v. Canada (Minister of National Health and Welfare) (1994), 58 C.P.R. (3d) 209 (F.C.A.), per Strayer J.A. at 216. An examination of the detailed statement in issue is thus required in order to determine whether it*
> >
> > *measures up to this requirement with respect to the allegation that the '693 and '891 Patents are not valid for obviousness.*
> >
> > *...*

23 *The respondent suggests that the list of prior art in the detailed statement was not intended to be exhaustive, hence the presence of the word "including", so that the way was left open to add to that list in the section 6 proceeding. I am of the view, however, that paragraph 5(3)(a) does not contemplate such possibility. The intent appears to be that the entire factual basis be set forth in the statement rather than be revealed piecemeal when some need happens to arise in a section 6 proceeding. This Court has cautioned persons in the position of the respondent that they assume a risk that a particular allegation may not be in compliance with the Regulations and that the deficiency cannot be cured by the Court in a section 6 proceeding. In Bayer AG v. Canada (Minister of National Health and Welfare) (1995), 60 C.P.R. (3d) 129 (F.C.A.), Strayer J.A. stated, at 133-134, in reference to the decision of this Court in Pharmacia Inc. v. Canada (Minister of National Health and Welfare) (1994), 58 C.P.R. (3d) 207:*

The order appealed from here was made before this court had had occasion to clarify certain issues arising out of the Regulations. In particular, this court in Pharmacia Inc. v. Canada (Minister of National Health and Welfare)...[since reported at 58 C.P.R. (3d) 207]...stated the following [at p. 209]:

It seems to us that while a notice of allegation does play an important role in the ultimate outcome of litigation of this nature, it is not a document by which the judicial review application may be launched under s. 6 of the regulations. That document was put in as a piece of evidence by the appellants; it originated with the application filed before the Minister. Because it is not a document that was filed with the court but with the Minister, in our view the notice of allegation is beyond the reach of the court's jurisdiction in a judicial review proceeding. That being so, the court, in our opinion, lacks jurisdiction to strike out the notice of allegation.
This clearly means that the court has no jurisdiction to make orders concerning the filing of notices of allegation or requiring them to be perfected in some way. The principle is that, by the scheme of the Regulations, the notice of allegation precedes the institution of prohibition proceedings in this court. It forms part of the background to that

> *proceeding, perhaps what one might loosely refer to as part of the "cause of action". A court cannot order that a cause of action be created, or that it be created at a certain time, or in a certain way. It can only deal with it after it is created or allegedly created. Those who fail to file notices of allegation,*
>
> *or adequate notices of allegation, must assume their own risk when it comes to attacks on the adequacy of such allegations once prohibition proceedings are commenced before the court.*

[96] In this sense, the Notice of Allegation is like a pleading. Once a second party has taken a position as to fact or law, it cannot be seen to resile from that position. This is particularly so since a Notice of Allegation cannot be amended once Court proceedings have been commenced.

[97] In the present case, Pharmascience characterized the ’457 Patent, including claim 5, not as being directed to the manufacture of a tablet; rather, it took the position that it was directed to a particular dosage. It said at pages 2 and 3 of its “Detailed Statement”:

> ***C. Canadian Patent No. 2,173,457***
>
> *1) Subject Matter of the ’457 Patent*
>
> *The ’457 Patent is directed to the treatment of androgenic alopecia, including both female and male pattern baldness, and other hyperandrogenic conditions by administering a low daily dosage of a 5α-reductase 2 inhibitor, in particular, 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, i.e., finasteride, wherein the dosage is 0.05 to 3.0 mg per day.*
>
> *2) Summary of the Claims in the ’457 Patent*
>
> *a) Claims 1 to 5 of the ’457 Patent*
>
> *Claim 1 of the ’457 Patent is a broad, independent claim, directed to the use of a 5α-reductase 2 inhibitor for the preparation*

> *of a medicament adapted for oral administration useful for the treatment of androgenic alopecia in a person, wherein the dosage amount is about 0.05 to 3.0 mg.*
>
> *Claim 2 is dependent on claim 1, wherein the 5α-reductase 2 inhibitor is limited to finasteride.*
>
> *Claim 3 is dependent upon claim 2, wherein the dosage claimed is about 1.0 mg.*
>
> *Claim 4 is dependent upon claim 3, wherein the dosage claimed is about 1.0 mg.*
>
> *Claim 5 is dependent upon claim 4, wherein the androgenic alopecia is male pattern baldness.*

[98] Furthermore, each of Pharmascience's witnesses, Doctor Taylor at paragraphs 108 to 115 of his affidavit, and Doctor Steiner at paragraph 123 of his affidavit, took the position that the claims, including claim 5, were really directed to the use of finasteride in a particular dosage to treat male baldness.

[99] Thus, for purposes of the present proceedings, I shall deal with the construction of claim 5 on the basis that the "Swiss" type construction should not be taken literally. Rather it is to be considered that the claim is directed to the use of finasteride at a particular dosage in oral form to treat male baldness.

h) Construing Claim 5

[100] Having gone the long way around, I return to the construction of claim 5, which I repeat in the form incorporating the earlier claims and substituting finasteride for the complex chemical formula:

> *5. The use of finasteride for the preparation of a medicament adopted for oral administration useful for the treatment of male baldness pattern and wherein the dosage is about 1.0 mg.*

[101] Given the discussion previously set out including the position taken by Pharmascience as to the "Swiss" type claim, I construe this claim as having the following essential elements:

- a medicament
- prepared using finasteride
- for oral administration
- to treat male baldness
- having a dosage at about 1.0 mg.

[102] Two items of controversy have been raised by Pharmascience.

1. does the claim contemplate finasteride alone as the active ingredient
2. is the dosage a daily dosage

[103] As to the first, is claim 5 properly construed, directed to the use of finasteride alone as the active ingredient? The claim does not say "alone" or "only". The description of the '457 Patent at

page 5 states that the drug such as finasteride *"can be used in combination with a potassium channel opener, such as minoxidil"*.

[104] Pharmascience's witnesses, Doctor Taylor (paragraph 152 of his affidavit) and Doctor Steiner (paragraphs 81 and 82 of his affidavit), take the view that claim 5 is not limited to finasteride alone. Merck's witness, Doctor Russell, in cross-examination, in answer to questions 378, 379 and 382 was of the view that there was nothing in claim 5 to exclude another active ingredient such as minoxidil.

[105] In *AstraZeneca AB v. Apotex Inc.* (2007), 60 C.P.R. (4th) 199, at paragraphs 21 to 25, and 32 and 33 (aff'd 61 C.P.R. (4th) 97 (FCA)) at paragraphs 22 and 23, Barnes J. of this Court, in dealing with very similar claims, held that such claims were not limited to the use of the named drug alone.

[106] In the present case in particular, given the specific reference in the description of the '457 patent to the inclusion of other active drugs, I conclude that, on a proper construction, claim 5 is not limited to the use of finasteride alone as an active drug.

[107] The second issue is directed to whether the reference to the 1.0 mg. dosage is a daily dosage. I note that all the experts for each party in their evidence understand that the dosage is a daily dosage. (Doctor Russell in cross-examination, questions 162 to 170; Doctor Shapiro in cross-examination, page 42, lines 34 to 41; Doctor Taylor in his affidavit, paragraphs 108 to 109; Doctor Steiner in his affidavit, paragraph 33).

[108] The ’457 Patent, in the description at pages 3a and 5 refer to the dosages as daily dosages. I conclude, in particular, with reference to this description, that a proper construction of claim 5 is that the 1.0 mg is a daily dosage.

5. Method of Medical Treatment

[109] Pharmascience attacks the validity of claim 5 on the basis that it is, in reality, simply directed to a method of medical treatment which, it alleges, is not valid subject matter for a patent in Canada.

[110] First, being a “Swiss” type claim, if we allow it to be read in that fashion, claim 5 is not directed to a method of medical treatment; rather, it is directed to a vendible product; namely, a medicament. The reasoning used in the U.K. cases and in the earlier European cases, is the same reasoning as would apply here such that the claim would not be considered to be directed to a method of medical treatment.

[111] If, on the other hand, the claim is to be construed as directed to the use of a medicament for treatment of a human condition at a particular dosage, then the Canadian jurisprudence must be considered, particularly in light of the fact that claim 5 is restricted to a particular fixed dosage and not a dosage range in which it is left to the physician to make a final determination as to dosage. I refer to the careful and thorough analysis given by Justice Harrington of this Court in considering

claims directed to a dosage range in *Axcan Pharma Inc. v. Pharmascience Inc*. (2006), 50 C.P.R. (4th) 321 at paragraphs 45 to 51:

> ***45*** *Pharmascience does not dispute that a new use for an old compound is patentable, as held in* Shell, supra. *However, as noted by Mr. Justice Binnie in* Apotex, supra, *and* Shell, supra, *an invention relating to the area of professional skill is not patentable. This issue was considered by Mr. Justice Dubé in Visx Inc. v. Nidek Co. et al*, *3 C.P.R. (4th) 417, affirmed by the Federal Court of Appeal at 16 C.P.R. (4th) 251. That case dealt with an apparatus for performing laser eye surgery. One submission was that the patent was invalid as relating to surgical procedures. The argument was that the claim did not relate to an "art or process" within the statutory definition of an invention Mr. Justice Dubé rejected the argument. He said:*
>
> > *[173] In my view, the Professional Skill Defence is not available to attack the validity of the three patents in issue. These patents do not teach professional skills to surgeons. They deal with an apparatus, a machine, a combination of several components. In that sense, the apparatus is similar to other medical equipment, as x-ray machines, dentist drills, scalpels, all of which are patentable if they teach an invention. The invention in the Visx patents does not pose a limitation upon the surgeons' skills. On the contrary, it is meant to assist a surgeon in his operation on the human eye. It focuses, directs and shapes the beam. It determines and controls a circular area of exposure and does the ablation. All the surgeon does is prepare the patient and enter the basic measurements into the computer. He then steps on the pedal to start the machine. Moreover, in accordance with Dr. Sher's evidence, myopia, hypermyopia and astigmatism are not diseases, they are human conditions.*
>
> ***46*** *The invention claimed here is quite different. It is up to the physician based on his or her knowledge of the patient's rate of metabolism and other factors to determine the appropriate daily dosage. I cannot, for a moment, contemplate that Axcan could claim exclusive property in the dosage and sue a physician for prescribing Ursodiol for the treatment of PBC at a dosage less than 13 mg/kg/day or greater than 15 mg/kg/day. In fact, Dr. Shaffer, who was called by Axcan, stated during cross-examination*

that he has at times prescribed Ursodiol at dosages greater than those set out in the patent.

47 *A case very much on point is the decision of Mr. Justice Mosley in Merck & Co., Inc. et al. v. Apotex Inc. et al. (2005), 41 C.P.R. (4th) 35. That case also dealt with the PM (NOC) Regulations. Merck had long marketed Alendronate tablets in a 10 mg daily dosage form for the treatment of osteoporosis. This required a strict dosing regime to which a number of patients did not adhere, to their detriment. There were significant adverse side-effects. The alleged invention asserted that a larger once weekly dose had fewer adverse effects. Mr. Justice Mosley held that the invention was obvious and therefore invalid. However, he also addressed the issue of medical treatment at paragraphs 133 and following. Apotex argued that the patent was invalid as it simply provided instructions to the physician to alter the dosage regime. Merck, however, argued that the claim was for a vendable product having economic value in trade, industry and commerce, and was distinguishable from the work of the physician, which work required the exercise of specialized skill. The how and when of administration was not part of the patent.*

48 *Contrary to the position taken by the U.K. Courts, Mr. Justice Mosley found that the patent was for a vendable product having real economic value, and was not for an unpatentable method of treatment. However, in this case the number of capsules to prescribe is a matter between the patient and her doctor, and does not form part of a monopoly protected by Letters Patent. Therefore, the patent is invalid because it claims a method of medical treatment.*

49 *Another case of some interest is the decision of Mr. Justice Heald of the Federal Court of Appeal in Imperial Chemical Industries Ltd. v. Canada (Commissioner of Patents), [1986] 3 F.C. 40, 67 N.R. 121. The Commissioner had rejected a patent application in so far as it related to method claims. The invention claimed a method of cleaning teeth by applying an aqueous composition. The application was rejected as being a treatment of the human body not patentable in virtue of* Tennessee Eastman, supra. *The method was not a "process" in the economic sense. The appellant argued that* Tennessee Eastman *only prohibited the patentability of medical methods which utilized materials produced by chemical processes as per Section 41(1) of the Patent Act, a section repealed before Dr. Poupon's application. However, Mr.*

Justice Heald, like the Supreme Court in Apotex v. Wellcome Foundation, supra, held that Tennessee Eastman was authority for the broader proposition that methods of medical treatments, as such, are not patentable.

50 *After analyzing the decision of Mr. Justice Kerr in first instance in Tennessee Eastman, Mr. Justice Heald said:*

> ***para.*** *11 Coming now to the decision of the Supreme Court of Canada, Mr. Justice Pigeon delivered the Court's decision. He commences his reasons by setting out the agreed statement of facts and issues. At pages 114-115 S.C.R.; at page 204 of the C.P.R., he reproduces, with approval, that portion of the reasons of Kerr J. set out supra. It is true that he does discuss the impact of section 41, presumably since that case was a subsection 41(1) case. However, after that discussion, at page 119 S.C.R.; at page 207 of the C.P.R., he states:*
>
> > *Having come to the conclusion that methods of medical treatment are not contemplated in the definition of "invention" as a kind of "process", the same must, on the same basis, be true of a method or surgical treatment.*
>
> *In my opinion, this is a clear and unequivocal statement that "methods of medical treatment are not contemplated in the definition of 'invention' as a kind of 'process', ..". That was the sole issue before the Court and it is here answered in unmistakable and unambiguous language. Accordingly, in my view, the force of that pronouncement cannot be restricted merely to factual situations where subsection 41(1) of the Act applies. It follows, therefore, that the Commissioner did not err in considering himself bound by the ratio of Tennessee Eastman.*

51 *There is a distinction between the dosage in a capsule and a dosage range based on the patient's weight. As I read the claim, the emphasis is on the dosage range, and a dosage range is not a vendable product.*

[112] In *Axcan*, Harrington J. found the claim to be invalid because it was directed to a dosage range in which it was left to the physician to make on appropriate selection. In the present case, there is no such range; there is a fixed dosage claimed. The case is similar to that decided by Justice Mosley of this Court in *Merck & Co. Inc. v. Apotex Inc*. (2005), 41 C.P.R. (4th) 35 where he held that such a claim was directed to a vendible product at paragraphs 134 to 138:

> ***134*** *In Tennessee Eastman, a method of surgical treatment was found not to be patentable because such subject matter does not fall within the definition of "process" or "art" as those terms are understood under the Patent Act: Tennessee Eastman Co. v. Canada (Commissioner of Patents) (1974), 8 C.P.R. (2d) 202 at 207 (S.C.C.).*
>
> ***135*** *Apotex argues that the impugned claims in the '595 Patent are essentially methods of medical treatment in that they simply provide instructions to the physician to alter the dosage regime, as found by the Australian court and the U.K. Court of Appeal: Arrow Pharmaceuticals Ltd. v. Merck &Co. Inc., supra at para. 89; Instituto Gentili SpA v. Teva Pharmaceutical Industries Ltd., supra at para. 69.*
>
> ***136*** *Merck submits that where the claims of a patent are for a vendible product having economic value in trade, industry and commerce and are distinguishable from the work of a physician, which requires the exercise of specialized skill, the patent is taken out of the realm of Tennessee Eastman. The how and when of administration is not a part of the patent. The inventors provide a new product which physicians may choose to use in treating patients, based on their own skill and judgment: Apotex Inc. v. Wellcome Foundation Ltd. [2001] 1 F.C. 495 (C.A.); Merck & Co. v. Apotex Inc. (1994), 59 C.P.R. (3d) 133 at 176 (T.D.); Apotex v. Wellcome Foundation Ltd., [2002] 4 S.C.R. 153.*
>
> ***137*** *I find that the patent is for a vendible product having real economic value, as demonstrated by its immediate success in the market, and is, therefore, not for an unpatentable method of treatment. I note, however, that this is contrary to the position reached by the U.K. courts. But for the decision of the Court of Appeal in Bristol Myers Squibb v. Baker Norton [2001] R.P.C. 1, Justice Jacob would have held that it was not a method of*

> *treatment patent. The words of Holman J. (at para. 111) in Bristol Myers were adapted by counsel for the claimant in that case by substituting alendronate for taxol, the drug in question in that case, in the following manner;*
>
> > *In the present case, however, the drug alendronate is exactly the same; the method of administration, orally, is exactly the same; and the therapeutic application or purpose, namely the attempt to treat osteoporosis is exactly the same. The only difference is the discovery that if the drug is administered in a unit dosage form of 70mg once weekly rather than 10mg once daily an undesirable side effect, adverse GI effects, is less than it otherwise would be, whilst the therapeutic effect remains. No previously unrecognized advantageous properties in the chemical compound have been discovered ... All that has been discovered ... is that if the compound is administered once a week rather than daily, one of its disadvantageous side effects will be less than it otherwise would be.*
>
> ***138*** *Consequently, Jacob J. found that the claim was in substance a method of treatment of the human body by therapy, which finding was upheld by the Court of Appeal: [2003] All E.R. (D) 62.*

[113] I do not find the decision of *Re Allergan* (2009), 79 C.P.R. (4th) 161, decided by the Patent Appeal Board, to be any different than *Axcan* as the claims there were also directed to a range of dosages within which a physician was to make a selection.

[114] I note, as explained in paragraph 50 of *Axcan*, *supra*, that Justice Heald of this Court has found that the decision of the Supreme Court of Canada in *Tennessee Eastman* the case that is considered to be the basis of arguments as to method of medical treatment, is not to be distinguished on the basis that there were express statutory prohibitions at the time, now repealed. However, a distinction must be made between claims that rely upon the skill and judgment of a medial

practitioner and those that deal with a vendible product, be it a scalpel, X-ray machine or 1 mg tablet that are to be used or prescribed for use by such practitioner. In the present case, we have a 1.0 mg tablet taken as a daily dose. No skill or judgment is brought to bear. It is a vendible product and not a method of medical treatment.

6. Double Patenting

[115] Canadian law has developed a concept whereby a patent will be invalid if it is found to be "double patenting" having regard to an earlier patent granted to the same patentee. This concept is based on the premise that a person is entitled to "a" patent for each invention and should not be able to gain a second monopoly for what is, in reality, the same thing. One cannot "evergreen" the patent monopoly. This concept was stated clearly by the Supreme Court of Canada in *Whirlpool Corp v. Camco Inc.,* [2000] 2 S.C.R. 1067 where Binnie J., for the Court, wrote at paragraph 63:

> ***63*** *The prohibition against double patenting relates back to the "evergreen" problem mentioned at the outset. The inventor is only entitled to "a" patent for each invention: Patent Act, s. 36(1). If a subsequent patent issues with identical claims, there is an improper extension of the monopoly. It is clear that the prohibition against double patenting involves a comparison of the claims rather than the disclosure, because it is the claims that define the monopoly. The question is how "identical" the claims must be in the subsequent patent to justify invalidation*

[116] The question of double patenting was again addressed by the Supreme Court of Canada in *Sanofi-Synthelabo Canada Inc. v. Apotex Inc.*, [2008] 3 S.C.R. 265 where Rothstein J. for the Court, wrote at paragraphs 95 and 97:

> ***95*** *There may only be one patent covering an invention* (*Whirlpool Corp. v. Camco Inc.*, *[2000] 2 S.C.R. 1067, 2000 SCC*

> *67, at para. 63). Apotex says that a selection patent claims the same invention as the original class or genus patent and as a result, the selection patent cannot be valid.*
>
> ...
>
> ***97*** *Evergreening is a legitimate concern and, depending on the circumstances, strategies that attempt to extend the time limit of exclusivity of a patent may be contrary to the objectives of the Patent Act. The Act aims to promote inventiveness by conferring exclusivity for a limited period of time while providing for public disclosure of the invention to enable others to make or use it after expiry of the period of exclusivity.*

[117] As stated by Binnie J. in *Whirlpool*, *supra*, at paragraph 63, what a Court must do is compare the claims of the earlier patent with those of the later patent and determine whether they are "identical or co-terminus" or whether they are "obvious" having regard to the earlier claims. This is addressed by Binnie J. at paragraphs 65 to 67 of *Whirlpool*:

> ***65*** *This branch of the prohibition on double patenting is sometimes called "same invention" double patenting. Given the claims construction adopted by the trial judge it cannot be said that the subject matter of the '734 patent is the same or that the claims are "identical or conterminous" with those of the '803 patent.*
>
> ***66*** *There is, however, a 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 substance 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. [Emphasis added.]*
>
> ***67*** *In Consolboard, supra, Dickson J. referred to Farbwerke Hoechst as "the main authority on [page1106] double patenting" (p. 536) which stood for the proposition that a second patent could not be justified unless the claims exhibited "novelty or ingenuity" over the first patent:*
>
> *Judson J. for the Court said that the second process involved no novelty or ingenuity, and hence the second patent was unwarranted.*

[118] In *Whirlpool*, the Supreme Court found that the claims of the patent at issue were not identical or co-terminus with the claims of an earlier patent and that, on the trial judge's finding on the evidence, the latter were not obvious in light of the former.

[119] In *Sanofi*, where an argument as to double patenting was dealt with briefly, the Supreme Court found that the claims of the latter patent were patentably distinct and not obvious over the claims of a prior patent because they constituted a valid "selection" patent over the first. In the present case Merck's Counsel expressly stated to this Court that the '457 Patent at issue was not to be treated as a selection patent.

[120] In *Bristol-Myers Squibb Canada Co. v. Apotex* (2009), 74 C.P.R. (4th) 85, 2009 FC 137, I summarized double patenting at paragraphs 173 to 175 as follows:

> ***173*** *Double patenting, put simply, involves the concept that a person cannot get a second patent for the same thing for which*

> *they already have received a patent. A patent is a monopoly for a limited period of time and that period should not be extended by the expedient of getting a subsequent patent for the same thing.*
>
> ***174*** *Double patenting only applies when dealing with the same person getting two or more patents. If some other person has received an earlier patent, then the second patent is to be considered in the context of anticipation and obviousness or, in the case of pre-October 1989 patent applications, the first to invent.*
>
> ***175*** *Even when the same person has received two patents the test for distinguishing one from the other is like anticipation or obviousness. One asks whether the second patent is claiming the same thing as the first (literal or co-terminus) or is the second patent claiming something that is obviously within the scope of the first. The Supreme Court of Canada has accepted both approaches as sound: see Whirlpool Inc. v. Camco Inc., [2000] 2 S.C.R. 1067 at paragraphs 63 to 75.*

[121] The concept of double patenting does not seem to have arisen in Great Britain, and certainly was not discussed in the *Actavis* case. In Australia, there are statutory provisions respecting what is described as double claiming. A good discussion by the Federal Court of Australia can be found in *Arbitron v. Telecontrol A/G*, [2010] FCA 302 at paragraphs 140 to 159.

[122] In the United States, there is both statutory law and judicial jurisprudence respecting double patenting. A good overview can be found in *Boehringer Ingelheim International GMBH v. Barr Laboratories Inc*, 592 F.3d 1340 (2010), a decision of the United States Court of Appeals for the Federal Circuit (CAFC). In the United States, invalidity of the second patent can sometimes be avoided by invoking statutory provisions to make the later patent terminate at the same time as the

earlier patent that is, to make a "terminal disclaimer". Linn, Circuit Judge, wrote for the Court at page 1346:

> *A Retroactive Terminal Disclaimer*
>
> *Because [HN1] 35 U.S.C. 101 "states that an inventor may obtain a patent for an invention," the statute "permits only one patent to be obtained for a single invention." In re Lonardo, 119 F 3d 960, 965 (Fed. Cir. 1997) (emphasis added). [HN2] "A* ***double patenting*** *rejection precludes one person from obtaining more than one valid patent for either (a) the 'same invention', or (b) an 'obvious' modification of the same invention." In re Longi, 759 F.2d 887, 892 (Fed. Cir. 1985).*
>
> *Obviousness-type* ***double patenting*** *is a "judicially created doctrine grounded in public policy (a policy reflected in the patent statute)" that "prevent[s] the extension of the term of a patent, even where an express statutory basis for the rejection is missing, by prohibiting the issuance of the claims in a second patent not patentably distinct from the claims of the first patent." Id.*
>
> *The purpose for the doctrine of obviousness-type* ***double patenting*** *is well established.*
>
> > *(HN3) The doctrine of double patenting is intended to prevent a patentee from obtaining a time-wise extension of patent (rights) for the same invention or an obvious modification thereof.*
>
> *Lonardo, 119 F.3d at 965; see also Eli Lilly & co. v. Barr Labs., Inc., 251 F.3d 955, 967 (Fed. Cir. 2001) [HN4] ("The judicially-created doctrine of obviousness-type* ***double patenting*** *cements [the]legislative limitation [of 101] by prohibiting a party from obtaining an extension of the right to exclude through claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent.")*
>
> *[HN5] The doctrine of obviousness-type* ***double patenting*** *is an important check on improper extension of patent rights through the use of divisional and continuation applications, at least for patents issued from applications filed prior to the amendment of 35 U.S.C. 154 to create twenty-year terms running from the date of the earliest related application. See 35 U.S.C. 154; Uruguay Round Agreements*

> *Act, Pub. L. No. 103-465, 108 Stat. 4809 (1994); see also In re Fallaux; 564 F.3d 1313, 1318 (Fed. Cir. 2009)* ***[**13]*** *(discussing rationales for obviousness-type* ***double patenting*** *rejections for patents issued from applications filed both before and after the amendment of the Patent Act). "The policy underlying a* ***double patenting*** *rejection is an important policy because it precludes the improper extension of the statutory term of patent protection for an invention." Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc., 98 F.3d 1563, 1577 (Fed. Cir. 1996).*
>
> > *[HN7] A patentee, whether of the whole or any sectional interest therein, may, on payment of the fee required by law, make disclaimer of any complete claim, stating therein the extent of his interest in such patent…*
> >
> > *In like manner any patentee or applicant may disclaim or dedicate to the public the entire term, or any terminal part of the term, of the patent granted or to be granted.*
>
> *[HN8] "[A] terminal disclaimer may restrict the slight variation to the term of the original patent and cure the* ***double patenting*** *rejection." Geneva Pharms., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1378 (Fed. Cir. 2003).*

[123] Thus it can be seen that the United States concept of double patenting, with the exception of the ability to make a terminal disclaimer, is not very different from the Canadian concept as expressed in *Whirlpool* and *Sanofi.*

[124] What is important to keep in mind is that the exercise required in the inquiry as to whether there is double patenting is that the claims of the earlier patent owned by the same patentee as the latter must be compared with the claims of the latter to see if they are "identical or co-terminus", or whether the latter is "obvious" in view of the former. Therefore, the exercise is somewhat different than that of dealing with obviousness of a patent having regard to the art that would have been known to a person skilled in the art as of the relevant time. The exercise respecting double patenting

is to present the notional person skilled in the art with the claims of the first patent and inquire whether what is claimed in the second patent was "identical or co-terminus" with the first or would have been obvious in light of the earlier patent. The inquiry must not bother with any inquiry as to whether the earlier patent would have come to the attention of the notional person skilled in the art. Nor does the inquiry extend to the validity or otherwise of the claims of the earlier patent. Nor does the inquiry extend to "prior art" beyond the earlier patent, as Binnie J. wrote at paragraph 67 of *Whirlpool*, the inquiry is whether a second patent can be justified unless the claims exhibit "novelty or ingenuity" over the first patent. As the Supreme Court of Canada, Binnie J. said in another case, *Apotex Inc. v. AstraZeneca Canada Inc.,* [2006] 2 S.C.R. 560 at paragraph 39, there is an evident (and entirely understandable) commercial strategy of the innovative drug companies to evergreen their products by adding bells and whistles to a pioneering product even after the original product for that patent has expired. This is the "evergreening" problem discussed in *Whirlpool, supra*.

[125] In the present case, Merck & Co. Inc received a first patent – Canadian Patent 1,302,277 (the '277 patent) – which, as stated at page 1 of that patent, in the Background section, is directed to a range of compounds, of which finasteride is one and the use of such compounds for the treatment of androgenic alopecia, including male pattern baldness, with finasteride.

[126] The '277 patent contains a lengthy discussion as to the preparation of the compounds, including finasteride, and their composition. At pages 11 and 12, there is a discussion respecting the oral administration of the drug in a daily dosage "over a wide range, varying from 5 to 2000 mg., preferably from 5 to 200 mg. and "well below the toxic dose".

> *The compositions containing the compounds of the present invention as the active ingredient can be administered in a wide variety of therapeutic dosage form in conventional vehicles for systemic administration, as, for example, by oral administration in the form of tablets, capsules, solutions, or suspensions, of by intravenous injection. The daily dosage of the products may be varied over a wide range varying from 5 to 2,000 mg, preferably from 5 to 200 mg.*
>
> *The compositions are preferably provided in the form of scored tablets containing 5, 10, 25, 50, 100, 150, and 500 milligrams of the active ingredient for this symptomatic adjustment of the dosage to the patient to be treated. An effective amount of the drug is ordinarily supplied at a dosage level from about 0.1 mg. to about 50 mg./kg. of body weight per day. Preferably the range is from about 0.1 mg. to 7 mg./kgs. of body weight per day and more preferably from about 0.1 to about 3 mg/kg of body weight per day. These dosages are well below the toxic dose of the product.*

[127] It is to be noted that the tablets can be scored, i.e. broken. For a person weighing 70 kg (160 lbs) the minimum daily dosage would be about 7 mg.

[128] There are 23 claims at the end of the ’277 patent. Those that are relevant here are claims 14, 15 and 19, which read:

> *14. The use of 17*β*-(N-t-butylcarbamoyl)-4-aza-5*α*-androst-1-ene-e-one for treating androgenic alopecia.*
>
> *15. The use according to claim 11, 12, 13, 14, wherein the androgenic alopecia is male pattern alopecia.*
>
> . . .
>
> *19. The use of 17*β*-(N-t-butylcarbamoyl)-4-aza-5*α*-androst-1-ene-e-one, for the manufacture of a medicament for the treatment of androgenic alopecia*

[129] Translating those claims into the language that has been used in these proceedings, they read:

> *14. The use of finasteride for treating androgenic alopecia.*
>
> *15. The use according to claim 14 wherein the androgenic alopecia is male pattern baldness.*
>
> . . .
>
> *19. The use of finasteride for the manufacture of a medicament for the treatment of androgenic alopecia.*

[130] As can be seen, the claims of the ’277 patent are not limited to any particular dosage or dosage range. A dosage range is discussed in the descriptive portion of the ’277 patent, but not in the claims.

[131] The ’457 Patent which is at issue here, describes the ’277 patent this way at page 2, lines 15 to 20:

> *“Finasteride’s utility in the treatment of androgenic alopecia…is…disclosed in…Canadian Patent No. 1,302,277… The specific dosages exemplified in the above-noted disclosures varied from 5 to 2000 mg. per patent per day.”*

[132] At page 7 of the description, the ’457 Patent at issue here makes it clear that:

> *“A physician or veterinarian of ordinary skill can readily determine and prescribe the effective amount of the drug required to prevent, counter, arrest or reverse the progress of the condition.”*

[133] The only difference between claim 5 and the ’457 Patent at issue and claims 14, 15 and 19 of the ’277 earlier patent is that claim 5 specifies 1 mg/day. Is claim 5 “identical or co-terminus”, to use the *Whirlpool* language, with those earlier claims of the ’277 patent?

[134] Counsel for Merck argues that claim 5 is not “identical or co-terminus” because, it is argued, the earlier claims 14, 15 and 17 must be read together with the description and, in being so limited, are to be restricted to a dosage range of between 5 and 2000 mg. I disagree. First, as the ’277 patent at issue here says, and I agree, that the range of 5 to 2000 “exemplifies” the dosage; it does not say that it limits or restricts it. Second, there is nothing in the ’277 patent that clearly states that the dosage range of 5 to 2000 mg are the limits of the range to be administered. At best, it states that 2000 mg is still below the toxic level. Nothing is said about restricting the lower limit to 5 mg. Thirdly, the ’457 patent itself states that the dosages can be readily determined by a physician of ordinary skill.

[135] Simply to attach a number to the dosage level, even if that number is outside the range “exemplified” in the earlier patent, does not mean that claim 5 is not (to use a double negative) “identical or co-terminus” with the claims of the earlier patent. I find claim 5 to be invalid for that reason.

[136] In the event that a further Court may wish to consider the issue of double patenting, I will also address the issue of “obviousness” double patenting. In so doing, I will follow the “best case” presented in favour of Merck.

[137] Merck argues, for instance, at paragraph 51 of its Memorandum of Argument, that the inventive concept is that finasteride is particularly useful in the treatment of male pattern baldness at the low daily dosage of 1 mg.

[138] Pharmascience argues, just as Actavis argued in the U.K. case, that given the prior art such as the equivalent of the '277 patent before the U.K. Court, and other art, Merck accepted in the U.K. court that the "invention" of the use of low dosages of finasteride would be obvious. Merck argued, however, to use the colourful language of the U.K. case, that there was a "lion in the path" in the form of two papers; one by Harris, et al.; the other by Thigpen, et al, (both Merck scientists) that would radically change the view of the ordinary person skilled in the art and dissuade them from pursuing a low dosage inquiry. These papers were published after the publication of relevant prior art, but before the filing of the application for the patent at issue. The arguments were set out by the Court of Appeal in *Actavis, supra*, at paragraphs 110, 111 and 113 as follows:

> ***[110]*** *In more detail Actavis's case ran as follows (1) It had already been proposed to treat aa with finasteride but with a dosage of '5 to 2000 mg preferably from 5 to 200 mg' (Merck patent appn 0285,382A published on 5 October 1988); (2) It was obvious to follow this up-and to investigate suitable doses. One would thereby learn that the lower does of the patent in suit would do. Hence it was obvious to manufacture finasteride for the manufacture of a medicament for the treatment of as with such lower doses. (3) The Sudduth review paper of August 1993 ('Finasteride" The First 5α-Reductase Inhibitor') reinforces this. It says:*
>
> > *"DHT appears to be the active androgen in the balding scalp. Thus preventing DHT formation by inhibiting 5α-reductase may be a viable treatment option.*

> *And (after summarising a report of some small scale experiments with balding monkeys in a paper by Diani):*
>
> *'Results from this study suggest a role in reversing established baldness. It also appears that the combination of finasteride and minoxidil may be more effective than either agent alone. Development of a topical finasteride treatment would allow local treatment of baldness without significant systemic alteration of androgens. Clinical trials in humans are planned to establish the drug's role as either single-agent therapy or in combination with minoxidil in the treatment of MPB'.*
>
> ***[111]*** *Given just these matters (all of which are accepted as being material which the skilled man would know) Merck accept that the invention would indeed be obvious. Indeed Merck accepts that if Sudduth could fairly be taken alone. But, Merck submits that the skilled man would, at the priority date of the patent, know more. In particular by then he would know that there is no detectable Type 2 in the scalp. Since finasteride was known only to inhibit Type 2 he would think there would be no point in trying it at all for aa. He would never get to investigate suitable dosage forms for he would think there are none.*
>
> . . .
>
> ***[113]*** *Merck says that the state of knowledge of the skilled man was radically changed by two documents which it accepted the skilled man would have read at the priority date. They are Thigpen et ors ('Tissue Distribution and Ontogeny of Steroid 5α-Reductase Isozyme Expression), published in August 1993 and Harris et ors ('Identification and selective inhibition of an isozyme of steroid 5α-reductase in Human Scalp'}, published November 1992. Merck says these documents clearly point to Type 1 as the culprit responsible for baldness, for instance Harris says: '5α-reductase 1-type activity appears to be the major reductase activity in the scalp. And Thigpen reported that Type 2 could not be detected in any region of the balding scalp – in experiments which were quite sensitive.*

[139] Merck's arguments prevailed in the U.K. The Court of Appeal found that while the "invention" may have been "obvious" at an earlier time, it was not obvious at a later time; (the critical time for determining invention is the same date that is to be used in the present case) because

of the "change of one's perspective" brought about by Harris and Thigpen. The Court of Appeal acknowledged that the conclusion was "a bit odd" and explained itself at paragraph 119 of *Actavis*, *supra* as follows:

> ***[119]*** *We add a small postscript: superficially one might think this conclusion is a bit odd given that the invention was once obvious – one might assume that when an invention becomes obvious it must remain so thereafter. But such an assumption would be wrong: obviousness must be determined as of a particular date. There is at least one other well-known example showing how an invention which might be held obvious on one date, would not be so held at a later date. That is where there has been commercial success following a long-felt want. Time can indeed change one's perspective. The perspective the court must bring to bear is that of the skilled man at the priority date and not any earlier time.*

[140] The difference between that discussion as to "obviousness" and the discussion as to double patenting undertaken here is that, as instructed by the Supreme Court in *Whirlpool, supra*, we are dealing with a different type of "obviousness" when it comes to double patents. As set out in paragraph 66 of *Whirlpool,* we are to compare the earlier patent with the later patent to determine if the claims of the later are "patentably distinct" from the earlier. The example given is particularly interesting:

> ***66*** *There is, however, a 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 substance 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. [Emphasis added.]*

[141] Thus, for obviousness type double patenting under Canadian law, Harris and Thipgen do not exist; the "lion in the path" is nonexistent as far as this inquiry is concerned.

[142] Therefore, claim 5 is invalid for double patenting because it is "identical or co-terminus" with the claims of the earlier '277 patent. As well, it is invalid for obviousness double patenting having regard to the '277 patent.

7. Novelty and Obviousness

a) General

[143] I have started the discussion as to novelty and obviousness by addressing them together. There is no question that for a claim of a patent to be valid, it must encompass that which is both novel and inventive or, to use the other language often associated with this exercise, the claim must encompass that which is both not anticipated and not obvious.

[144] The two are similar but require somewhat different approaches. Anticipation, or lack of novelty, means that the public is already in possession of what is claimed as an invention; regardless as to how inventive the concept may be. A person cannot purchase a monopoly with something the public already has. On the other hand, inventiveness means that the invention has gone beyond what

the public already has by going farther than the ordinary person skilled in the art would have been expected to go in providing something new and useful or dispelling an old preconception.

[145] A patent is not something simply to be acquired as of right. It is a monopoly voluntarily sought by an applicant seeking a time-limited but state-supported exclusivity. The applicant must fulfill the statutory requirements in order to acquire the monopoly. I quote de Montigny J. at paragraph 46 of *M-Systems Flash Disk Pioneers Ltd. v. Commissioner of Patents*, April 23, 2010, 2010 FC 441:

> *[46] That being said, however, I fail to see how the grant of a patent can be said to be a right for the Applicant. Quite the contrary, a patent has been described as a bargain voluntarily entered into by the patentee. It is a quid pro quo agreement in which the patentee obtains time-limited but state-supported exclusivity for his invention in return for his disclosure of it to the public: Smith, Kline & French Laboratories Ltd. v. Canada (Attorney General), [1987] 2 F.C. 359, at p. 389 (F.C.A.). If an applicant does not fulfill his part of the bargain and does not fulfill the requirements of the statute, he cannot claim the exclusivity conferred by a patent.*

[146] While there he was dealing with a procedural matter, the statement is equally true respecting substantive matters.

b) <u>The ’457 Patent</u>

[147] Turning first to what the ’457 Patent says as to novelty and invention, one starts at the beginning of page 1 to understand that the invention deals with the treatment of male pattern baldness with finasteride:

> *The present invention is concerned with the treatment of androgenic alopecia, including male pattern baldness, with compounds that are 5-alpha reductase isozyme 2 inhibitors.*

[148] At the bottom of page 1, and over to page 2, we are told that a culprit named DHT, which causes problems, is found in certain organs of the male body such as the prostate, and the DHT is formed by something called testosterone-5α-reductase. We are further told that there are two testosterone-5α-reductases, type 1 and type 2; and that type 1 is principally found in the skin, and type 2 in the prostate:

> *The principal mediator of androgenic activity in some target organs, e.g. the prostate, is 5α—dihydrotestosterone ("DHT"), formed locally in the target organ by the action of testosterone-5α-reductase. Inhibitors of testosterone-5α-reductase will serve to prevent or lessen symptoms of hyperandrogenic stimulation in these organs. See especially united States Patent No. 4,377,584 assigned to Merck & Co., Inc., issued March 22, 2983. It is now known that a second 5α-reductase isozyme exists, which interacts with skin tissues, especially in scalp tissues. See, e.g., G. Harris, et al., Proc. Natl. Acad. Sci. USA, Vol. 89, pp. 10787-10791 (Nov. 1992). The isozyme that principally interacts in skin tissues is conventionally designated as 5α-reductase 1 (or 5α-reductase type 1), while the isozyme that principally interacts within the prostatic tissues is designated as 5α-reductase 2 (or 5α-reductase type 2).*

[149] Next, on page 3, the reader is told that finasteride is a known compound sold commercially for prostate treatment. We are also told that several patents and published applications disclose the use of finasteride to treat both baldness and prostate issues with dosages "exemplified" from 5 to 2000 mg per day:

> *Finasteride (17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, which is marketed y Merck & Col, Inc. under the tradename PROSCAR®, is an inhibitor of 5α-reductase 2 and is known to be useful for the treatment of hyperandrogenic conditions. See e.g., U.S. Patent No. 4,760,071. Finasteride is currently marketed in the*

> *United States and worldwide for the treatment of benign prostatic hyperplasia. Finasteride's utility in the treatment of androgenic alopecia and prostatic carcinoma is also disclosed in the following documents: EP 0 285,382, published 5 October 1988; EP 0 285 383, published 5 October 1988; Canadian Patent no. 1,302,277; and Canadian Patent no. 1,302,276. The specific dosages exemplified in the above-noted disclosures varied from 5 to 2000 mg per patient per day.*

[150] The last paragraph at page 3 states the desirability of administering the lowest possible dosage to treat baldness, and that the inventors have *"surprisingly and unexpectedly*" discovered: that a low dosage of finasteride is "particularly useful" in treating baldness.

> *In the treatment of androgenic alopecia, which includes both female and male pattern baldness, and other hyperandrogenic conditions, it would be desirable to administer the lowest dosage possible of a pharmaceutical compound to a patient and still maintain therapeutic efficacy. Applicants have surprisingly and unexpectedly discovered that a low daily dosage of a 5α-reductase 2 inhibitor is particularly useful in the treatment of androgenic alopecia. Furthermore, a low daily dosage of a 5α-reductase 2 inhibitor may also be particularly useful in the treatment of hyperandrogenic conditions of acne vulgaris, seborrhoea, female hirsutism, and polycystic ovary syndrome.*

[151] Example 4, beginning at page 12, describes a test for measuring hair growth – essentially taking photographs over a period of time. That example concludes at page 14 in stating that the test has been used to show that the administration of finasteride, at dosages of 1 mg/day or 0.2 mg/day, are useful in treating baldness.

> *Using the above-described methodology, it can be shown that administration of 5α-reductase 2 inhibitors, including finasteride, I dosages below 5 mg/day per patient, for example, 1 mg/day or 0.2 mg/day, are useful in the treatment of androgenic alopecia, and promote hair growth in patients with this condition.*

[152] We must be careful to note that this is all the information that has been given to support the statement at page 3 that there was a "surprising and unexpected" discovery that a low dosage would be "particularly useful" in treating baldness. Example 5 only tells us that DHT was reduced significantly with the previously exemplified dosage, and presumably, also with dosages of 0.2 mg/day and 1.0 mg/day. No relative data between the three dosages is given; no information linking DHT reduction to improvement in baldness is given. No reason is given as to why any of the three dosages, including the previously exemplified dosage would give "surprising and unexpected" results.

[153] I repeat claim 5 in the form often referred to herein:

> *5. The use of finasteride for the preparation of a medicament adapted for oral administration useful for the treatment of male pattern baldness in a person and wherein the dosage is about 1.0 mg.*

[154] The last example of the '457 patent, Example 5, tells the reader that some kind of test was conducted at the previously exemplified dosage of 5 mgs/day, as well as two other dosages of 0.2 mg/day and 1 mg/day; and the results of the test showed significant reduction of DHT in the scalp tissue:

EXAMPLE 5

> *In another test, finasteride was orally administered for 6 weeks to men with male pattern baldness at doses of 0.2 mg/day, 1.0 mg/day and 5.0 mgs/day. The results of this test showed a significant reduction in DHT content in scalp tissue of the test participants.*

c) The Prior Art

[155] Pharmascience relies on some of the prior art recited at page 2 of the patent as well as a published patent application filed by Upjohn, a competitor of Merck, in which disclosures of work conducted by Diani, et al. is disclosed. Referring to them in order of date of publication:

i) US Patent 4,760,071 ('071 patent)

This patent, issued in 1988 to Merck (and its Canadian equivalent 1,314,541, issued in March 1993) are relied upon by Pharmascience to show which has been acknowledged at page 2 of the '457 Patent; namely, that finasteride was a known compound shown to be useful in treating prostate conditions. At column 3 of the '071 patent, there is a disclosure that the drug can be taken in tablet or capsule form, preferably at dosage levels of 5 to 500 mg. The dosage level is ordinarily about 1 mg to 50 mgs/kg per day; that is, for a 70 kg (160 lb) person, about 7 to 3500 mg/day.

Merck acknowledges all of the foregoing, through Doctors Russell and Shapiro, but says that there is no disclosure that finasteride is useful in treating male baldness, nor can it be effectively administered in low dosages.

The claims of these two patents are more broadly stated than the previous discussion would indicate. The '071 patent in claim 3

claims the use of finasteride in inhibiting testosterone-5α-reductase by using a "therapeutically effective amount". Claim 17 of the Canadian 1,314,541 patent claims use for treating a hyperandrogenic condition with a "therapeutically effective" amount of finasteride.

ii) European Patent Application 0 285 382

European Patent Application 0 285 382, published in October 1988, is also a Merck document and is mentioned at page 2 of the '457 Patent.

At page 1, this patent application acknowledges that finasteride is a known compound and has been said to be useful in treating hyperandrogenic conditions. The invention stated in this application is the use of finasteride as a highly potent testosterone-5α-reductase inhibitor. At page 6, the treatment of male pattern alopecia is specifically identified. A novelty of forms of administration, including tablets, capsules and solutions, are indicated. Preferable, it is said, are scored tablets, ranging in dosages from 5 mg to 500 mg, with dosage levels ordinarily said to be from 0.1 mg/kg to 50 mg/kg per day (7 to 3500 mg/day for a 70 kg person). Claims 6 and 7 state, in effect:

6. The use of finasteride for the manufacture of a medicament useful for arresting and reversing male pattern alopecia

7. As per claim 6, where the medicament contains 0.1% to 15% of the total.

Merck, through Doctors Russell and Shapiro, state that this patent application does not disclose, nor would be taken to disclose, dosages in the order of 1.0 mg/day.

iii) European Patent Application WO 92/02225 (Diani)

European Patent Application WO 92/02225 was published 20 February 1992. The applicant is the Upjohn Company, and Diani and others are named as inventors. This application discloses the "concomitant administration" of two medicines such as minoxidil and finasteride to promote hair growth. At page 2, the use of the two medicines together is said to have a synergistic effect. The dosage of finasteride administered is set out at page 3 as from about 0.001 to about 10 mg/kg body weight (for a 70kg person, that would be about 0.7 to 700 mg). Also at page 3, it is stated that one drug can be administered orally and the other topically. Thus, we have the

disclosure of the oral administration of finasteride in the dosage usage of claim 5 of the ’457 patent, but always in combination of minoxidil. Pharmascience points out that at page 5 of the ’457 Patent, specifically describes the use of finasteride in combination with minoxidil and argues that claim 5 is not limited to the use of finasteride alone.

Merck, through Doctors Russell and Shapiro, states that the dosage range of 0.001 to 10 mg/kg is a vast range and, without further guidance, a skilled person would not know how to narrow that range. Doctor Russell also states that Diani’s conclusions are based on studies conducted on few monkeys and that the results cannot necessarily be translated into human use, and further, that the dosages administered to monkeys were outside the low dosage ranges claimed in the ’457 Patent. Merck argues that the teaching of Diani must be limited to a use of the combination of minoxidil and finasteride.

iv) Canadian Patent 1,302,277

Canadian Patent 1,302,277 was issued and granted to Merck in June 1992. This patent was discussed again when considering double patenting. As described at page 2 of the ’457 Patent, this

patent discloses the use of finasteride to treat male baldness; the dosages exemplified are from 5 to 2000 mg/day. The claims, particularly 15, 19 and 23 are directed to such use and the manufacture of a medicament for such use without any limitation as to dosage. Pharmascience argues that this is an adequate enabling disclosure of what is contained in claim 5 of the '457 Patent. Merck argues that this patent discloses and enables dosages only from 5 mg and upward, and not the dosage of claim 5.

v) The Harris Paper

A scientific paper by Harris et al. (Merck employees) entitled "Identification and selective inhibition of an isozyme of steroid 5α-reductase in human scalp" was published in August 1992 in *Biochemistry.* This paper is referred to at page 2 of the '457 Patent. This paper reports the existence of two forms of 5α-reductase, which, during these proceedings, were called type 1 and type 2. The paper concludes in stating that the inhibitors effective against one type may not be suitable as against the other. At page 10790, it concludes:

The results reported in this paper may not have important implications in pursuing steroid 5α-reductase as a therapeutic target. An inhibitor of 5α-reductase has been shown to be useful in the treatment of benign prostatic hyperplasia (34). Reductase inhibitors may also be useful in treating male pattern baldness, acne, and hirsutism, as these disorders also appear to be DHT dependent. However, the results of our study indicate that a single inhibitor may not be suitable, given the differences in the enzymes. We have shown

that it is possible to identify scalp-selective, prostate-selective, and dual-active inhibitors.

Merck argues that this paper constitutes a "lion on the path" and would dissuade a researcher from using finasteride in low dosages for treatment of conditions related to the scalp, such as baldness. Pharmascience argues that the paper is inconclusive, and does not say that finasteride would be ineffective, or at what dosage it would be ineffective.

vi) The Thigpen Paper

A scientific paper by Thigpen, et al. (University of Texas) entitled "Tissue Distribution and Ontogeny of Steroid 5α-Reductase Isozyme Expression" was published in August 1993 in the Journal of Clinical Investigation. It deals with type 1 and type 2 5α-reductase isozymes. This paper is not referred to in the '457 Patent.

This paper speculates as to the occurrence of type 1 and type 2 in the scalp and the influence on hair regression. At page 909, it states:

...Since 5α-reductase type 2-deficient subjects have less temporal hair regression (1-5), the pulse of type 2 expression in the scalp may influence the development of baldness later in life.

In support of this speculation regarding type 2 expression, we could find no qualitative difference in the steady state levels of

> *5α-reductase type 1 in the scalps of balding and nonbalding men (Fig. 9), nor were any regional expression differences detected in the balding scalp (Fig. 8). Thus, at the level of resolution afforded by these studies, no evidence for abnormal expression of the type 1 isozyme as a feature of male pattern baldness was found. The interpretation of these results must be tempered by the qualitative nature of the findings. We cannot rule out low levels of expression that are below the sensitivity of detection by our antibodies (as clearly demonstrated by the mRNA and enzyme activity studies (Fig. 3, Table I), nor can we assess changes in cell type specific expression It remains to be seen whether similar results will be obtained I hirsutism (35, 36) and acne (37), two disorders that are manifest together with the reappearance of 5α-reductase type 1 expression in the skin at puberty.*

The arguments of each of Merck and Pharmascience respecting Thigpen are the same as for Harris. Merck argues that the combination of Thigpen and Harris prove a formidable "lion in the path".

d) Viewing the Prior art Through the Eyes of the Person of Ordinary Skill in the Art (POSITA)

[156] Given this prior art, the Court must consider it through the eyes of a person skilled in the art (POSITA). All parties are agreed that the relevant date for considering each of novelty and inventiveness is the "claim date", which is the date of the filing of the priority application upon which the '457 application is based; namely, October 15, 1993. All the prior art referred to above predates that date.

[157] The prior art clearly shows that finasteride has been used for the treatment of baldness. The prior art patents directed to finasteride alone do not claim a specific dosage or dosage range. A range of 5 mg/day to 2000 mg/day is "exemplified". A lower dosage from about 0.7 mg/day is indicated by Diani, but only when finasteride is used with minoxidil. The papers published by Harris and Thigpen raise doubts as to the effectiveness of finasteride in treating male baldness, although dosages and dosage ranges are not discussed.

[158] The first indication as to the skill expected of a POSITA is stated in the '457 Patent itself at page 7. Such a person is expected to select dosages having regard to a variety of factors:

> *The dosage regimen utilizing the compounds of the present invention is selected in accordance with a variety of factors including type, species, age, weight, sex and medical condition of the patient; the severity of the condition to be treated; the route of administration; the renal and hepatic function of the patient; and the particular compound thereof employed. A physician or veterinarian of ordinary skill can readily determine and prescribe the effective amount of the drug required to prevent, counter, arrest or reverse the progress of the condition. Optimal precision in achieving concentration of drug within the range that yields efficacy without toxicity requires a regimen based on the kinetics of the drug's availability to target sites. This involves a consideration of the distribution, equilibrium, and elimination of a drug.*

[159] Doctor Russell, for Merck, concludes at paragraph 130 of his affidavit that a skilled person would not have thought that it would be more or less self-evident that low dosages of finasteride would work and that, based on Harris and Thigpen, such person would conclude that finasteride would be ineffective in treating male baldness. Doctor Shapiro says much the same at paragraphs 71 to 85 of his affidavit.

[160] Pharmascience relies on the cross-examination of Doctor Russell (pages 76 and 77) and Doctor Shapiro (page 68) to argue that the prior art, particularly the ’277 Patent, claims that which falls within claim 5 of the ’457 Patent and that the Harris and Thigpen papers do not present any formidable dissuasive considerations (Russell, pages 176-7, 184; Shapiro, pages 91-92, 95). Pharmascience also relies on Doctor Taylor (paragraphs 161, 196) and Doctor Steiner (paragraph 124) to argue that dosage selection was well within the expected skill of a person of ordinary skill in the art.

e) <u>Conclusions as to the Factual Evidence Respecting Novelty and Inventiveness</u>

[161] Having reviewed all of the evidence, including the evidence summarized above, I have reached the following conclusions as to the facts relevant to an inquiry as to novelty and inventiveness:

1. The relevant date for considering such an inquiry is October 15, 1993 – the “claim date”.

2. As of the claim date finasteride was a known drug.

3. As of the claim date finasteride was sold commercially for prostate treatment.

4. Prior patents, particularly the ’277 Patent, state that finasteride is useful in treating male baldness. They state that finasteride can be taken in oral dosage form. These

patents exemplify, but do not restrict themselves, to a dosage range of between 5 to 2000 mg/day. No patent suggests that a lower dosage will not work.

5. The Diani patent application discloses the use of finasteride in a dosage range that includes 1 mg/day to treat male baldness, but only in combination with minoxidil. The finasteride could be taken orally, while the minoxidil is rubbed on topically. The '457 Patent also describes the fact that the two drugs can be used as a combination.

6. The Harris and Thigpen papers would cause a researcher to consider looking elsewhere rather than pursuing further research into the use of finasteride to treat male pattern baldness.

[162] Given these factual findings, I turn to the law respecting novelty and inventiveness, much of which has been recently considered by the Supreme Court of Canada in *Sanofi-Synthelabo Canada Inc. v. Apotex Inc*., [2008] 3 S.C.R. 265, 2008 SCC 61 (*Sanofi*). The decision of the Supreme Court was given by Rothstein J.

f) Novelty

i) The Law

[163] The Supreme Court of Canada, in *Sanofi*, based much of its consideration as to novelty on the decision of the House of Lords, per Lord Hoffman, in *Synthon BV v. Smithkline Beecham plc,* [2006] 1 All E.R. 685, [2005] UKHL 59. In *Synthon BV*, Lord Hoffman stated that in considering

prior art in respect of novelty, the prior art must both disclose and enable that which is claimed in the patent under consideration. In *Synthon BV,*, Lord Hofman wrote at paragraphs 32 and 33:

> ***[32]*** *Likewise, the role of the person skilled in the art is different in relation to disclosure and enablement. In the case of disclosure, when the matter relied upon as prior art consists (as in this case) of a written description, the skilled person is taken to be trying to understand what the author of the description meant. His common general knowledge forms the background to an exercise in construction of the kind recently discussed by this House in Kirin-Amgen Inc v Hoechst Marion Roussel Ltd; Hoechst Marion Roussel Ltd v Kirin-Amgen [2004] UKHL 46, [2005] 1 All ER 667. And of course the patent itself must be construed on similar principles. But once the meanings of the prior disclosure and the patent have been determined, the disclosure is either of an invention which, if performed, would infringe the patent, or it is not. The person skilled in the art has no further part to play. For the purpose of enablement, however, the question is no longer what the skilled person would think the disclosure meant but whether he would be able to work the invention which the court has held it to disclose.*
>
> ***[33]*** *There is also a danger of confusion in a case like Merrell Dow Pharmaceuticals Inc v HN Norton & Co Ltd (1995) 33 BMLR 201, [1996] RPC 76, in which the subject matter disclosed in the prior art is not the same as the claimed invention but will, if performed, necessarily infringe. To satisfy the requirement of disclosure, it must be shown that there will necessarily be infringement of the patented invention. But the invention which must be enabled is the one disclosed by the prior art. It makes no sense to inquire as to whether the prior disclosure enables the skilled person to perform the patented invention, since ex hypothesis in such a case the skilled person will not even realise that he is doing so. Thus in the Merrell Dow case the question of enablement turned on whether the disclosure enabled the skilled man to make terfenadine and feed it to hay fever sufferers, not on whether it enabled him to make the acid metabolite.*

[164] In considering *Synthon BV*, and the requirements of enablement and disclosure, Rothstein J. in *Sanofi* wrote at paragraphs 25 to 27:

> ***25*** *He explains that the requirement of prior disclosure means that the prior patent must disclose subject matter which, if performed, would necessarily result in infringement of that patent, and states, at para. 22:*
>
> > *If I may summarise the effect of these two well-known statements [from General Tire and Hills v. Evans], the matter relied upon as prior art must disclose subject matter which, if performed, would necessarily result in an infringement of the patent... . It follows that, whether or not it would be apparent to anyone at the time, whenever subject matter described in the prior disclosure is capable of being performed and is such that, if performed, it must result in the patent being infringed, the disclosure condition is satisfied.*
>
> *When considering the role of the person skilled in the art in respect of disclosure, the skilled person is "taken to be trying to understand what the author of the description [in the prior patent] meant" (para. 32). At this stage, there is no room for trial and error or experimentation by the skilled person. He is simply reading the prior patent for the purposes of understanding it.*
>
> ***26*** *If the disclosure requirement is satisfied, the second requirement to prove anticipation is [page280] "enablement" which means that the person skilled in the art would have been able to perform the invention (para. 26). Lord Hoffmann held that the test for enablement for purposes of anticipation was the same as the test for sufficiency under the relevant United Kingdom legislation. (Enablement for the purposes of sufficiency of the patent specification under the Canadian Patent Act, s. 34(1)(*b*) of the pre-October 1, 1989 Act, now s. 27(3)(*b*), is not an issue to be decided in this case and my analysis of enablement is solely related to the test for anticipation. The question of whether enablement for purposes of sufficiency is identical in Canada is better left to another day.)*
>
> ***27*** *Once the subject matter of the invention is disclosed by the prior patent, the person skilled in the art is assumed to be willing to make trial and error experiments to get it to work. While trial and error experimentation is permitted at the enablement stage, it*

> *is not at the disclosure stage. For purposes of enablement, the question is no longer what the skilled person would think the disclosure of the prior patent meant, but whether he or she would be able to work the invention.*

[165] Rothstein J. then considered other authorities and, at paragraph 37 of *Sanofi,* concluded as to novelty:

> ***37*** *Drawing from this jurisprudence, I am of the opinion that the following factors should normally be considered. The list is not exhaustive. The factors will apply in accordance with the evidence in each case.*
>
> 1. *Enablement is to be assessed having regard to the prior patent as a whole including the specification and the claims. There is no reason to limit what the skilled person may consider in the prior patent in order to discover how to perform or make the invention of the subsequent patent. The entire prior patent constitutes prior art.*
>
> 2. *The skilled person may use his or her common general knowledge to supplement information contained in the prior patent. Common general knowledge means knowledge generally known by persons skilled in the relevant art at the relevant time.*
>
> 3. *The prior patent must provide enough information to allow the subsequently claimed invention to be performed without undue burden. When considering whether there is undue burden, the nature of the invention must be taken into account. For example, if the invention takes place in a field of technology in which trials and experiments are generally carried out, the threshold for undue burden will tend to be higher than in circumstances [page284] in which less effort is normal. If inventive steps are required, the prior art will not be considered as enabling. However, routine trials are acceptable and would not be considered undue burden. But experiments or trials and errors are not to be prolonged even in*

> *fields of technology in which trials and experiments are generally carried out. No time limits on exercises of energy can be laid down; however, prolonged or arduous trial and error would not be considered routine.*
>
> *4. Obvious errors or omissions in the prior patent will not prevent enablement if reasonable skill and knowledge in the art could readily correct the error or find what was omitted.*

ii) Applying the Law to the Facts of this Case - Novelty

[166] The prior art, particularly the ’277 Patent, discloses the use of finasteride to treat male pattern baldness. It may be administered in a number of forms, including oral dosage. A range of dosages, from 5 mg/day to 2000 mg/day are disclosed as examples. Neither the disclosure nor the claims are limited to such dosages. Clearly, if one were to make a medicament in accordance with claim 5 of the ’457 Patent, a number of claims of the ’277 Patent would be infringed.

[167] It would be within the expected skill of a person skilled in the art, as the ’457 Patent itself acknowledges, to determine an appropriate dosage for a given person. There is no “undue burden” to use the words of paragraph 37(3) of *Sanofi* in determining an appropriate dosage.

[168] I find that the prior art in particular the ’277 patent, discloses and enables that which is claimed in claim 5 of the ’457 Patent, including the dosage.

[169] What then of Harris and Thigpen? They were published later in time than the prior art such as the ’277 Patent. Merck relies heavily on what was found by the Court of Appeal in the U.K. in *Actavis*, at paragraph 23:

> *[23] In the course of argument Rimer L.J. noted that the Board considered that a new dosage form would be enough to confer novelty. Mr. Prescott seized upon that, submitting that the Board clearly contemplated that a new dosage—even for treating a disease previously treated with the same substance in a different dosage was regarded as novel. We agree. A claim to a pill containing a l mg dose of finasteride would be a claim to a new thing. No one had made or proposed such a thing, so why should it not be novel? Whether it would obvious is a quite different matter. Since the patent in fact has*
>
> *no claim to a pill with a 1 mg dose it is not necessary to pursue this further, though in view of our conclusion on obviousness it may be that such a claim would have stood as valid on its own.*

[170] Also, Merck cites Jacob L.J. in another case, *Pozzoli SPA v. BDMO SA* [2007] EWCA Civ 588 at paragraphs 26 to 29:

> ***[26]*** *I put it this way in Union Carbide v BP [1998] RPC 1, 13: “Invention can lie in finding out that that which those in the art thought ought not be done, ought to be done. From the point of view of the purpose of patent law it would be odd if there were no patent incentive for those who investigate the prejudices of the prior art.”*
>
> ***[27]*** *Patentability is justified because the prior idea which was thought not to work must, as a piece of prior art, be taken as it would be understood by the person skilled in the art. He will read it with the prejudice of such a person. So that which forms part of the state of the art really consists of two things in combination, the idea* and *the prejudice that it would not work or be impractical. A patentee who contributes something new by showing that, contrary to the mistaken prejudice, the idea will work or is practical has shown something new. He has shown that an apparent “lion in the path” is merely a paper tiger. Then his contribution is novel and non-obvious and he deserves his patent.*

> ***[28]*** *Where, however, the patentee merely patents an old idea thought not to work or to be practical and does not explain how or why, contrary to the prejudice, that it does work or is practical, things are different. Then his patent contributes nothing to human knowledge. The lion remains at least apparent (it may even be real) and the patent cannot be justified.*
>
> ***[29]*** *This analysis does not require a different way of looking at the inventive concept depending on whether or not the patentee has shown the prejudice is unjustified as the Judge thought at 67. It is simply that in the former case the patentee has disclosed something novel and non-obvious, and in the latter not. The inventive concept, as I have said, is the essence of what is in the claim and not dependent on any question about a prejudice being overcome.*

[171] Merck also relies on Jacob L.J. in *Dr. Reddy's Laboratories (UK) Limited v. Eli Lilly and Company Limited* [2009] EWCA Civ 1362 at paragraphs 26 to 30:

> *26. First then, the a priori considerations apart from case-law. An old question and answer runs as a follows: "Where does a wise man hide a leaf? In a forest." It is, at least faintly, ridiculous to say that a particular leaf has been made available to you by telling you that it is in Sherwood Forest. Once identified, you can of course see it. But if not identified you know only the generality: that Sherwood Forest has millions of leaves.*
>
> *27. The contention has no logical stopping place. If there is disclosure of olanzapine here, why would one not regard an even more general disclosure as a disclosure of it. Suppose the prior art had merely been of "3-ringed organic compounds?" Such a description would encompass much bigger numbers than the 1019 of formula I. Yet the logic of the argument would be the same – that there is a disclosure of each and every member of the class.*
>
> *28. I would add that I would regard the listing out of a great number of compounds as opposed to the use of a Markush formula in the same way. To say a particular book is identified by saying "the books in the Bodleian" is no different from saying it is identified by providing access to the catalogue of the Bodleian.*
>
> *29. Similarly it makes no sense to say that a generalised prior description discloses a specific matter falling within in. The Judge's*

> *example illustrates the point. A prior disclosure of "fixing means" is not a disclosure of a particular fixing means e.g. welding or riveting even though you could list out a whole number of ways of fixing things together which would include these means.*
>
> *30. Thus logic dictates rejection of the argument that a disclosure of a large class is a disclosure of each and every member of it. So also does EPO case-law. Mr Carr accepted that was so, so I can take the matter quite shortly, going to just one case, Hoescht Enantiomers T 0296/87 which effectively sums up earlier cases. It said:*
>
> *6.1 Here the Board is guided by the conclusions it reached in its "Spiro compounds" decision T 181/82 (OJ EPO 1984, 401) concerning the novelty of chemical entities within a group of substances of known formula. With regard to products of the reaction of specific spiro compounds with a (C1-C4)-alkyl bromide defined as a group, the Board drew a sharp distinction between the purely intellectual content of an item of information and the material disclosed in the sense of a specific teaching with regard to technical action. Only a technical teaching of this kind can be prejudicial to novelty. If any such teaching is to apply in the case of a chemical substance, an individualised description is needed."*
>
> *So what one must look for by way of an anticipation is an "individualised description" of the later claimed compound or class of compounds. This case is miles from that. It is noteworthy that the Board's application of that principle in that case to enantiomers was specifically followed by this Court in Generics v. Lundbeck [2008] EWCA Civ 311; [2008] RPC 19 per Lord Hoffmann at [9].*

[172] Justice Heneghan recently heard arguments respecting this decision in *Pfizer Canada Inc. v. Apotex Inc.*, 2010 FC 447, at paragraphs 115 to 134, but she found that she did not need to decide upon it.

[173] Pharmascience argues that Merck itself has advanced the opposite argument in this Court in *Merck & Co. Inc. v. Apotex Inc*. (1994), 59 C.P.R. (30) 133, where the argument made by Merck

was accepted that the selection of an appropriate dosage was within the skill of a person skilled in the art. MacKay J. dealt with this argument at pages 179 – 180:

> *The second major argument of the defendant in regard to claims 8, 9 and 10 is that the Merck patent specification does not set out what constitutes an effective amount of the specified compounds, the active ingredients in the composition claims. In this regard the reference in the description to "a dosage range of 5 to 500 mg per patient" (animal and human) "giving a total daily dose of from 5 to 2000 mg per day", ignores Merck's own production of tablet of 2.5 mg of active ingredient in VASOTEC, and that the upper range suggested for daily dosage may be virtually toxic in the view of one witness. Yet, I am persuaded that the specification in its terms includes more than Merck's VASOTEC products for human consumption, for it describes a range of dosage for several compounds claimed, some more active than others, for use in treating hypertension, not only in humans but in animals as well, including large animals like horses. On this point, I accept the evidence of Drs. Patchett and Schwartz that to the person skilled in the art for whom the specification is written, here a combination of clinical physician and industrial pharmaceutical chemist at least in regard to producing finished product for human consumption, once a product has been discovered and its intended use established, determination of an effective amount to be included in a delivery system, a dosage amount, is not an inventive step even if it requires some experimental work by persons of experience and skill, extrapolating from other known products for similar uses and from experimental work with animals and clinical trials with human subjects.*

[174] Further, Pharmascience relies upon the decision of this Court in *Ratiopharm Inc. v. Pfizer Limited* (2009), 76 C.P.R. (4th) 241, 2009 FC 711 at paragraphs 177 to 180 in arguing that all that the '457 Patent does is to use adjectives such as "unexpected" or "surprising" and offers no solid foundation for distinguishing itself from the prior art, nor distancing itself from any previous prejudices:

> ***177*** *To address these criteria in this particular case we must determine if the besylate salt of amlodipine has a "special*

> *advantage" in respect of a "quality of special character" unique to besylate.*
>
> ***178*** *The use of words like "unexpectedly" and "unique" and "outstandingly suitable" by the person or persons drafting the application that resulted in the'393 Patent becomes clearly apparent.*
>
> ***179*** *However, adjectives and adverbs without solid foundation cannot create a "selection patent" where none in fact exists. As reviewed in the evidence, it is difficult from the face of the patent and unsupportable from the evidence to state that besylate is sufficiently superior to the other salts, for instance tosylate and mesylate so as to make it "unique" or "outstanding" or "particularly suitable".*
>
> ***180*** *If a category of "selection" patent exists, besylate salt of amlodipine does not merit being a member of that category. The '393 Patent is invalid for this reason as well.*

[175] Further, Pharmascience relies on the decision of the European Board of Appeals in *Kos,* discussed elsewhere as being decided after *Actavis*, and the other decisions relied on by Merck. Pharmascience argues that *Kos*, particularly at paragraph 6.3, requires that a subsequent invention that comes within broader disclosures in the prior art must distinguish itself so as to provide "a particular technical effect as compared with the known state of the art" and, in considering dosage selected from a prior broader disclosure a "new technical effect" must be considered.

> *Furthermore, assuming for the sake of argument that the claimed modalities of the dosage regime would only consist in a mere selection within the teaching of a broader prior disclosure in the state of the art, then novelty could only be acknowledged if the criteria developed in the jurisprudence of the boards of appeal with respect to selection inventions would be fulfilled. One typical issue in such kinds of cases is whether the dosage regime defined in the claim has been shown to provide a particular technical effect as compared with what was known in the state of the art.*

> *In the past, a whole body of jurisprudence developed concerning the question as to when a technical effect of a claimed therapeutic application not previously described in the state of the art can be recognized as conferring novelty on said application and this jurisprudence continues to be applicable to the assessment of the individual cases under consideration (see in particular T 290/86, OJ EPO 1992, 414; T 1020/03, OJ EPO 2007, 204; T 836/01 of 7 October 2003; T 1074/06 of 9 August 2007).*
>
> *Furthermore, if the distinguishing feature of a claim seeking patent protection for a known medicament to be used for a different treatment of the same illness is a dosage regime and is something else than a mere selection from a prior broader disclosure, a new technical effect caused by said feature shall e considered when examining inventive step under Article 56 EPC.*

[176] I find, given the state of the law in Canada as set out in *Sanofi*, in particular, that the use of finasteride in an oral composition to treat male baldness has been disclosed, and that the selection of a dosage range was within the skill of an ordinary person skilled in the art. Claim 5 of the ’457 Patent does nothing more than confirm that it works at a dosage of 1 mg/day. No new technical feature has been disclosed or claimed. To the extent that Harris and Thigpen suggest that finasteride may not work, there is no clear teaching that it will not work. In the absence of Harris and Thigpen, claim 5 has no novelty. With Harris and Thigpen, the ’457 Patent, including claim 5, is merely confirmatory, without undue experimentation, as to what was already known.

[177] Claim 5 of the ’457 Patent is not novel.

g) Obviousness (Inventive)

i) Law

[178] To determine whether what is claimed as an invention is truly an invention, and not obvious to a person skilled in the art, the Court is to place itself in the position of such a person at the relevant time, here the "claim date" October 15, 1993. This issue was considered at length in *Sanofi*. I repeat what Rothstein J. wrote at paragraphs 67 to 70:

> ***67*** *It will be useful in an obviousness inquiry to follow the four-step approach first outlined by Oliver L.J. in Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd., [1985] R.P.C. 59 (C.A.). This approach should bring better structure to the obviousness inquiry and more objectivity and clarity to the analysis. The Windsurfing approach was recently updated by Jacob L.J. in Pozzoli SPA v. BDMOSA, [2007] F.S.R. 37 (p. 872), [2007] EWCA Civ 588, at para. 23:*
>
> *In the result I would restate the Windsurfing questions thus:*
> *(1) (a) Identify the notional "person skilled in the art";*
>
> *(b) Identify the relevant common general knowledge of that person;*
>
> *(2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;*
>
> *(3) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;*
>
> *(4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention? [Emphasis added].*
>
> *It will be at the fourth step of the Windsurfing/Pozzoli approach to obviousness that the issue of "obvious to try" will arise.*
> *i. When Is the "Obvious to Try" Test Appropriate?*
>
> ***68*** *In areas of endeavour where advances are often won by experimentation, an "obvious to try" test might be appropriate.*

> *In such areas, there may be numerous interrelated variables with which to experiment. For example, some inventions in the pharmaceutical industry might warrant an "obvious [page294] to try" test since there may be many chemically similar structures that can elicit different biological responses and offer the potential for significant therapeutic advances.*
>
> *ii. "Obvious to Try" Considerations*
>
> ***69*** *If an "obvious to try" test is warranted, the following factors should be taken into consideration at the fourth step of the obviousness inquiry. As with anticipation, this list is not exhaustive. The factors will apply in accordance with the evidence in each case.*
>
> *1. 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?*
>
> *2. 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?*
>
> *3. Is there a motive provided in the prior art to find the solution the patent addresses?*
>
> ***70*** *Another important factor may arise from considering the actual course of conduct which culminated in the making of the invention. It is true that obviousness is largely concerned with how a skilled worker would have acted in the light of the prior art. But this is no reason to exclude evidence of the history of the invention, particularly where the knowledge of those involved in finding the invention is no lower than what would be expected of the skilled person.*

[179] To this discussion must be added the decision of the Federal Court of Appeal in *Apotex Inc. v. Pfizer Canada Inc.* (2009), 72 C.P.R. (4th) 141, 2009 FCA 8, as to motivation. It distinguishes between "obvious to try" and "more or less self-evident" at paragraphs 43 to 45:

> ***43*** *The reasoning advanced by Mr. Justice Laddie and approved by the English Court of Appeal is that where the motivation to achieve a result is very high, the degree of expected success becomes a minor matter. In such circumstances, the skilled person may feel compelled to pursue experimentation even though the chances of success are not particularly high.*
>
> ***44*** *This is no doubt the case. However, the degree of motivation cannot transform a possible solution into an obvious one. Motivation is relevant in determining whether the skilled person has good reason to pursue "predictable" solutions or solutions that provide "a fair expectation of success" (see respectively the passages in* KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007) at page 1742 and* Angiotech Pharmaceuticals Inc. v. Conor Medsystems Inc.*, [2008] UKHL 49, at paragraph 42, both of which are referred to with approval in* Sanofi-Synthelabo, supra*, at paragraphs 57 and 59).*
>
> ***45*** *In contrast, the test applied by Mr. Justice Laddie appears to be met if the prior art indicates that something may work, and the motivation is such as to make this avenue "worthwhile" to pursue (*Pfizer Ltd., supra*, para. 107, as quoted at para. 42 above). As such, a solution may be "worthwhile" to pursue even though it is not "obvious to try" or in the words of Rothstein J. even though it is not "more or less self-evident" (*Sanofi-Synthelabo, supra*, para. 66). In my view, this approach which is based on the possibility that something might work, was expressly rejected by the Supreme Court in* Sanofi-Synthelabo*, at paragraph 66.*

[180] In addition to the law already discussed in respect of novelty, the decision of the U.K. Court of Appeal in *Actavis* should be noted. It found the invention not to be obvious. That Court reviewed in detail the evidence of Doctor Russell and the prior art at paragraphs 109 to 118, and concluded that the evidence showed that the effect of Harris and Thigpen was enough to conclude that the person skilled in the art would put expectations of success respecting the use of finasteride to treat baldness so low that one would never start inquiries in that area. At paragraph 119, the Court

admitted that its conclusion was a "bit odd" in that, once a person has been put in a position of thinking a matter to be obvious, subsequently, they may be discouraged:

> *[119] We add a small postscript: superficially one might think this conclusion is a bit odd given that the invention was once obvious—one might assume that when an invention becomes obvious it must remain so thereafter. But such an assumption would be wrong: obviousness must be determined as of a particular date. There is at least one other well-known example showing how an invention which might be held obvious on one date, would not be so held at a later date. That is where there has been commercial success following a long-felt want. Time can indeed change one's perspective. The perspective the court must bring to bear is that of the skilled man at the priority date and not any earlier time.*

ii) Applying the Law to the Facts - Obviousness

[181] In the present case before me, I find, on the evidence, particularly that of Doctor Russell, that because of the Harris and Thigpen papers, a researcher would be discouraged from pursuing research in that area. In other words, the "motivation" would be lost. Thus, it has been proven that the allegation that claim 5 of the '457 Patent was obvious was not justified.

[182] I can understand that at first glance the finding that claim 5 lacks novelty may be at odds with the finding that it is inventive. This is not unlike the finding of the trial judge in *Actavis*. The difference lies in the legal test for novelty and obviousness. Novelty invokes a consideration as to whether the public is already possessed of what is claimed. It does not matter whether it is invented or not. Here I have found that, within the tests as set out in *Sanofi,* the public was already in possession of what is claimed in claim 5 of the '457 Patent. The fact that any suspicion or discouragement raised by Harris and Thigpen would have to be dispelled is irrelevant.

8. Sound Prediction/Overbreadth

[183] Pharmascience argues, in its Memorandum of Argument at paragraphs 116 to 120, that claim 5 is invalid for overbreadth and lack of sound prediction. I repeat paragraphs 119 and 120 of the Memorandum:

> *119. To the extent, therefore, that it was not simply obvious that a 5α-Reductase 2 inhibitor at low doses would provide effective treatment for male pattern baldness, the inventors of the '457 Patent provided no further information on which that conclusion could be reached, and set out no new information establishing or allowing a prediction that 1.0 mg of the finasteride is effective in actually treating male pattern baldness (the "arresting and/or reversing of androgenic alopecia, and the promotion of hair growth"). Therefore, if claim 5 is not considered obvious, then it is invalid for overbreadth and lack of sound prediction.*
>
> *120. Further, if what the inventors invented was the use of finasteride alone to treat male pattern baldness, as Merck now apparently asserts, claim 5 is broader than that invention, as it captures the use of finasteride either alone or in combination with other medicines. Merck cannot assert that the invention is the use of finasteride alone (to avoid anticipation by Diani) and avoid the conclusion that claim 5 is overbroad.*

[184] Merck, citing my decision in *Eli Lilly Canada Inc. v. Apotex Inc.,* (2008), 63 C.P.R. (4th) 406, at paragraph 58, which had been previously set out in those Reasons, states that Pharmascience has an obligation to put these allegations "in play" in its Notice of Allegation and has not done so and cannot do so now.

[185] Furthermore, Merck points out that Pharmascience has not in its evidence, namely the affidavits of Doctors Taylor and Steiner, put in any evidence to support these allegations.

[186] Pharmascience points out that Merck must have understood that these allegations were in play since its own witness, Doctor Russell, in his affidavit, purports to address these allegations at paragraphs 194 and 195:

> ***PART VII SOUND PREDICTION, UTILITY AND CLAIMS BROADER***
>
> ***X. Low doses of finasteride to treat male pattern baldness***
>
> *194. Dr. Taylor and Dr. Steiner both state that Example 5 in the patent does not teach anything about effectiveness of finasteride to treat male pattern baldness because the results of the DHT/scalp study were not disclosed and also because the patent does not actually assess whether the dosage amounts reversed baldness or promoted hair growth. Despite these observations, both Dr. Taylor and Dr. Steiner state that Merck inventors nonetheless did have a basis upon which to predict that low doses of finasteride would be effective in treating in male pattern baldness. They assert, however, that the basis for this "prediction" merely arises from the fact that they deem it obvious that low doses of finasteride are effective in treating male pattern baldness. Finally, they assert that to the extent that the patent is not obvious there was no basis to make this prediction.*
>
> *195. I have been asked to respond to these points and to comment on the examples in the patent. I have also been asked whether*
>
> *(i) there was a factual basis for the "prediction" that the claimed compounds are effective in treating male pattern baldness;*
>
> *(ii) the inventor had at the date of the patent application an articulable and "sound" line of reasoning from which the desired result can be inferred from the factual basis and*
>
> *(iii) there was proper disclosure of the factual basis and the line of reasoning.*

[187] I have carefully reviewed Pharmascience's Notice of Allegation and agree with Merck that the Notice does not address these issues with respect to claim 5. These issues are raised with respect to other claims and not with respect to claim 5. The evidence of Doctor Russell is directed to the matters raised with respect to those other claims.

[188] I find that Pharmascience cannot raise this issue now with respect to claim 5. It had an obligation to raise the issue clearly in its Notice of Allegation. It cannot now rely on general statements or general evidence directed to other claims in an effort to redirect those statements and evidence to claim 5.

[189] In the absence of a clear meeting of the minds between the parties to have the issue determined, notwithstanding that a matter was not raised in the Notice of Allegation, I am not prepared to allow Pharmascience to address such issue now.

CONCLUSION AND COSTS

[190] I have concluded that Pharmascience's allegation that claim 5 of the '457 Patent is invalid is justified within the provision of section 6(2) of the NOC Regulations. I do so on the basis that the claim lacks novelty and constitutes double patenting having regard to the '277 patent.

[191] At the hearing, counsel for the parties were agreed that costs should be awarded to the successful party. Counsel indicated that they probably could agree as to the quantum, failing which

they could return to me for a ruling in that regard within a reasonable period of time. No costs will be awarded for or against the Minister.

[192] The application will be dismissed with costs payable to Pharmascience by Merck.

JUDGMENT

THIS COURT ORDERS AND ADJUDGES that:

1. The application is dismissed; and

2. Pharmascience is entitled to costs to be paid by Merck. If these parties cannot agree as to quantum within a reasonable time, either one of them may apply to me for a ruling as to costs. No costs are awarded to or against the Minister.

"Roger T. Hughes"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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