T-677-99

2001 FCT 770

SmithKline Beecham Pharma Inc. and **SmithKline Beecham p.l.c.** (*Applicants*)

v.

Apotex Inc. and **The Minister of Health** (*Respondents*)

INDEXED AS: SMITHKLINE BEECHAM PHARMA INC. V. APOTEX INC. (T.D.)
Trial Division, Gibson J.—Ottawa, May 22 and July 6, 2001.

Patents — Infringement — Application for order prohibiting Minister of Health from issuing notice of compliance to Apotex until expiry of applicants' 637 patent for formulation of paroxetine into tablets without using water — Beecham also owner of 060 patent for crystalline paroxetine hydrochloride hemihydrate formulated by conventional methods of admixture, i.e. wet granulation, dry granulation, direct compression — 637 patent result of research to solve problem of pink hue caused by wet formulation method — Apotex filing notice of new drug submission, alleging non-infringement, invalidity of 637 patent — (1) Patent Act, s. 28.2 providing subject-matter must not have been disclosed more than one year before filing date — Test for anticipation met — Person of ordinary skill, knowledge in field would be able to look at prior, single publication (060 patent) and find in it all information needed to produce invention of 637 patent without exercising inventive skill — Logical next step to determine whether alternative formulation methods disclosed by 060 patent would solve "pink hue problem" — That 637 patent anticipated by 060 patent supported by unanimous view of experts that potential source of "pink hue problem" wet formulation — SmithKline not discharging persuasive, legal burden of establishing allegation of invalidity not justified — Test for obviousness set out in s. 28.3 — Authorities holding solution posed must be "crystal clear", "plain as day", not require experimenting, serious thought or research, and where "worth a try" test inappropriate — SmithKline met burden to establish on balance of probabilities allegation of obviousness not justified — To constitute invention, art or improvement must be new, useful — Lessening of pink hue problem useful — SmithKline met burden of establishing allegation of lack of utility not justified — (2) Apotex adding film-coating using water only after paroxetine tablets prepared using formulation process in which water absent — Pith and marrow of alleged invention taken — Allegation of non-infringement not justified — S. 32 permitting inventor to obtain patent for improvement, but not thereby obtaining right to use original invention — Assuming Apotex' film-coating using water as solvent improvement, not conferring on Apotex right to use original invention — (3) McGillis J. previously holding Minister not erring in including 637 patent in Register — Dispositive of issue of eligibility for listing of 637 patent.

Patents — Practice — Respondent alleging invalidity of patent in notice of allegation — (i) Evidential burden on respondent to put each of issues raised in notice of allegation "in play" — Persuasive or legal burden then on applicant (patent owner) to disprove allegations in notice of allegation, not to negative claims for declarations of validity, non-infringement — Entitled to rely on presumption of validity created by Patent Act, s. 43(2) — (ii) As to construction of patent, reliance on words of specification outside claims very limited — Should be resorted to only where words of claims ambiguous — (iii) Expert's personal interest in achieving solution to problem created by formulation method, precluded Court from treating him as expert witness — Court could not consider prior art introduced through experts' statements — Respondent limited to relying on prior art listed in detailed statements made pursuant to Regulations, s. 5(3)(a) in support of allegations certain Canadian patents invalid for anticipation, obviousness.

This was an application for an order prohibiting the Minister of Health from issuing a notice of compliance to the respondent, Apotex Inc., in connection with paroxetine hydrochloride tablets until after the expiration of Canadian letters patent No. 2,178,637 (the 637 patent). The applicant, SmithKline Beecham p.l.c., is the owner of the 637 patent for the invention of formulating paroxetine into tablets without using water. The Beecham Group also owns the 060 patent for the invention of crystalline paroxetine hydrochloride hemihydrate, the disclosure for which indicated formulation thereof by conventional methods of admixture, which would be understood by persons skilled in the art to include wet granulation, dry granulation and direct compression. The wet granulation process resulted in some tablets developing a pink hue, which caused substantial concern as it would lead to the product not meeting the specification for the colour of the uncoated tablet, thus leading to supply, and possibly regulatory, problems. In the course of research to overcome this problem, it was discovered that using a formulation process in which water was absent to prepare the paroxetine tablets solved the pink hue problem. This led to the filing of the application for the 637 patent, which was entitled “Paroxetine Tablets and Process to Prepare Them”. The respondent Apotex filed a new drug submission and notice of allegation in which it alleged that no claim for the medicine paroxetine, or for the use of the medicine, would be infringed by the making, constructing, using or selling by it of 10, 20 or 30 mg tablets containing paroxetine hydrochloride. Its paroxetine tablets were prepared using a formulation process in which water was absent, after which a film-coating using water was added to the tablets. Apotex alleged that the patent claims were limited to a formulation process in which water is absent, and undertook to only sell tablets using a process in which water is present. It further alleged that the 637 patent was invalid.

The issues were: (1) whether the 637 patent was valid in light of alleged anticipation or lack of novelty, alleged obviousness, and alleged inutility; (2) whether the 637 patent would be infringed by the drug formulation disclosed in Apotex’ new drug submission; and (3) whether the 637 patent was properly listed in the patent register.

Held, the application should be dismissed.

Some preliminary issues were dealt with, including: (i) the burden of proof; (ii) construction of the 637 patent; and (iii) evaluation of the expert testimony.

(i) There was an “evidential burden” on Apotex to put each of the issues raised in its notice of allegation “in play”, after which the persuasive or legal burden was with SmithKline to disprove the allegations in the notice of allegation. It was not required to justify declarations of validity and infringement or conversely to negative claims for declarations of invalidity and non-infringement. Assuming that the issue of the validity of the 637 patent was in play, SmithKline would be entitled to rely on the presumption of validity of the patent created by *Patent Act*, subsection 43(2).

(ii) As to construction of the 637 patent, reliance on the words of the specification outside the claims must be very limited and should be resorted to only where the words of the claims themselves are ambiguous.

(iii) One of SmithKline’s experts, Dr. Robin Roman, had been employed by a SmithKline-related company since 1983. He was the director of a group charged with the responsibility of finding a solution to the “pink hue problem”. His personal interest in achieving that solution, and thus in the issues before the Court with respect to the 637 patent, precluded the Court from treating him as an expert in relation to those issues, at least in so far as his opinions were other than merely confirmatory of the opinions of other experts whose statements were before the Court.

Apotex introduced prior art in the form of patents and excerpts from textbooks to support allegations that the invention claimed by the 637 patent was anticipated and obvious through its experts’ statements. Such additional prior art could not be taken into account. A respondent is

limited to relying on those documents of prior art listed in the detailed statements made pursuant to paragraph 5(3)(*a*) of the Regulations in support of its allegations that certain Canadian patents were invalid for anticipation and/or obviousness.

(1) *Patent Act*, section 28.2 provides that the subject-matter must not have been disclosed more than one year before the filing date. The anticipation alleged in the notice of allegation is by the 060 patent which issued July 30, 1991. The 637 patent was filed on December 14, 1994, and a patent issued on June 22, 1995. The sole matter disclosed in the 637 patent that was not disclosed in the 060 patent was that one or more of the "conventional methods of admixture" namely, "a formulation process" in which water is absent, is less likely to give rise to the "pink hue problem" than wet granulation. Having determined that a wet formulation of paroxetine tablets gives rise to a "pink hue problem", a problem of significant enough magnitude to cause a skilled person to seek out at least a partial solution to the problem, a logical first step for a person skilled in the art would be to turn to the alternative formulation methods disclosed by the 060 patent and to determine whether each or any of those alternative formulation methods would solve the problem. Such an enquiry would not involve any inventive step or skill, but would simply involve application of the invention taught by the 060 patent. The 060 patent contained so clear a direction that a skilled person reading and following it would in every case and without possibility of error be led to the claimed invention. Thus the prior art that was before the Commissioner of Patents at all relevant times, the 060 patent, taught a practising of the alternative conventional methods of formulation to be practicable. That the 637 patent was anticipated by the 060 patent was supported by the unanimous view of the experts that one of the potential sources of the "pink hue problem" would be formulation in the presence of water. SmithKline failed to discharge the persuasive or legal burden of establishing that the allegation of invalidity was not justified.

The test for obviousness is set out in section 28.3. Against the authorities indicating that the test for obviousness is difficult to satisfy, that to be obvious, the solution to the problem posed must be "plain as day" or "crystal clear" without the necessity of having to do any experimenting or serious thought or research, and where the "worth a try" test is inappropriate, while Apotex met its initial evidentiary burden with respect to "obviousness" and thus put obviousness in issue, SmithKline in turn met its burden to establish on a balance of probabilities that the allegation of obviousness was not justified.

To constitute an invention, the art or improvement in any process, machine, manufacture or composition of matter must be new and useful. The claimed utility of the 637 patent was a formulation process that was less likely to develop a pink hue than a formulation process in which water was present. All of Apotex' experts agreed that the pink hue problem was a serious problem. All of SmithKline's experts attested that the lessening of the pink hue problem disclosed in the 637 patent was useful. SmithKline met the burden on it to establish that the allegation of lack of utility was not justified.

(2) The claim in the notice of allegation to non-infringement was spurious, assuming the validity of the 637 patent. The addition of a film-coating was not part of the claimed tablet formulation process in the 637 patent and was superfluous to that process. Apotex proposed to take the pith and marrow of the alleged invention. The superadding of ingenuity in the form of a film-coating did not make the operation justifiable. Section 32 permits an inventor to obtain a patent for an improvement, but he does not thereby obtain the right to use the original invention. Assuming that Apotex' film-coating made using water as the solvent was an improvement, it did not confer on Apotex the right of using the original invention.

(3) McGillis J. concluded that the Minister did not err in including the 637 patent on the Register in *Apotex Inc. v. Canada (Minister of Health)*, and that decision has been affirmed on appeal. That decision was wholly dispositive of the issue of the propriety of listing of the 637 patent. If an issue in

that regard was not raised, it is too late to raise it now. If it was raised before McGillis J. and her reasons do not address it, the appropriate forum in which to have dealt with that concern was the Court of Appeal.

STATUTES AND REGULATIONS JUDICIALLY CONSIDERED

Federal Court Rules, 1998, SOR/98-106, Tariff B.

Food and Drug Regulations, C.R.C., c. 870, s. C.08.004 (as am. by SOR/95-411, s. 6).

Patent Act, R.S.C., 1985, c. P-4, ss. 2 "claim date" (as enacted by S.C. 1993, c. 15, s. 26), "invention", 28.1 (as enacted *idem*, s. 33), 28.2(1) (as enacted *idem*), 28.3 (as enacted *idem*), 32, 43(2) (as am. *idem*, s. 42), 55.2(4) (as enacted by S.C. 1993, c. 2, s. 4).

Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, s. 4(1) (as am. by SOR/98-166, s. 3), 5(3)(*a*), 6 (as am. *idem*, s. 5), 7(1)(*e*) (as am. *idem*, s. 6).

CASES JUDICIALLY CONSIDERED

APPLIED:

Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare) (1994), 55 C.P.R. (3d) 302; 169 N.R. 342 (F.C.A.); *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] 1 S.C.R. 504; (1981), 122 D.L.R. (3d) 203; 56 C.P.R. (2d) 145; 35 N.R. 390; *Nekoosa Packaging Corp. v. AMCA International Ltd.* (1994), 56 C.P.R. (3d) 470; 172 N.R. 387 (F.C.A.); *Free World Trust v. Électro Santé Inc.*, [2000] 2 S.C.R. 1024; (2000), 194 D.L.R. (4th) 232; 9 C.P.R. (4th) 165; 263 N.R. 150; *Whirlpool Corp. v. Camco Inc.*, [2000] 2 S.C.R. 1067; (2000), 194 D.L.R. (4th) 193; 263 N.R. 88; *AB Hassle v. Canada (Minister of National Health and Welfare)* (1998), 78 C.P.R. (3d) 489 (F.C.T.D.); *AB Hassle v. Canada (Minister of National Health and Welfare)* (2000), 7 C.P.R. (4th) 272; 256 N.R. 172 (F.C.A.); revg [1999] F.C.J. No. 1653 (T.D.); *Beloit Can. Ltée/Ltd. v. Valmet Oy* (1986), 8 C.P.R. (3d) 289; 64 N.R. 287 (F.C.A.); *Apotex Inc. v. Wellcome Foundation Ltd.* (1998), 79 C.P.R. (3d) 193; 145 F.T.R. 161 (F.C.T.D.); vard *Apotex Inc. v. Wellcome Foundation Ltd.*, [2001] 1 F.C. 495 (2000), 10 C.P.R. (4th) 65; 262 N.R. 137 (C.A.); leave to appeal to S.C.C. granted, [2000] S.C.C.A. No. 610 (QL); *Bayer Aktiengesellschaft v. Apotex Inc.* (1995), 60 C.P.R. (3d) 58 (Ont. Gen. Div.); *Cabot Corp. v. 318602 Ontario Ltd.* (1988), 20 C.P.R. (3d) 132; 17 F.T.R. 54 (F.C.T.D.); *Wenham Gas Co., Ltd. v. Champion Gas Lamp* (1891), 9 R.P.C. 49; *Apotex Inc. v. Canada (Minister of Health)* (1999), 87 C.P.R. (3d) 271; 165 F.T.R. 42 (F.C.T.D.); affd (2001), 11 C.P.R. (4th) 538 (F.C.A.).

DISTINGUISHED:

Warner-Lambert Canada Inc. v. Canada (Minister of Health), [2001] F.C.J. No. 801 (QL); 2001 FCT 514 (T.D.).

CONSIDERED:

McPhar Engineering Co. of Canada Ltd. v. Sharpe Instruments Ltd. et al., [1956-60] Ex. C.R. 467; (1960), 35 C.P.R. 105; *Bayer AG v. Canada (Minister of National Health and Welfare)* (1993), 51 C.P.R. (3d) 329; 163 N.R. 183 (F.C.A.); *Bayer AG v. Apotex Inc.* (1998), 84 C.P.R. (3d) 23; 156 F.T.R. 303 (F.C.T.D.); *Beecham Canada Ltd. et al. v. Proctor & Gamble Co.* (1982), 61 C.P.R. 1; 40 N.R. 313 (F.C.A.).

REFERRED TO:

Shell Oil Co. v. Commissioner of Patents, [1982] 2 S.C.R. 536; (1982), 142 D.L.R. (3d) 117; 67 C.P.R. (2d) 1; 44 N.R. 541; *Pfizer Canada Inc. v. Apotex Inc.* (1997), 77 C.P.R. (3d) 547 (F.C.T.D.); *Diversified Products Corp. v. Tye-Sil Corp.* (1991), 35 C.P.R. (3d) 350; 125 N.R. 218 (F.C.A.); *Bayer Aktiengesellschaft v. Apotex Inc.* (1998), 82 C.P.R. (3d) 526; 113 O.A.C. 1 (Ont. C.A.); leave to appeal to S.C.C. denied, [1998] S.C.C.A. No. 563 (QL).

APPLICATION for an order prohibiting the Minister of Health from issuing a notice of compliance to Apotex Inc. in connection with paroxetine hydrochloride tablets until after the expiration of Canadian letters patent No. 2,178,637. Application dismissed.

APPEARANCES:

Anthony George Creber and *James E. Mills* for applicants.

Harry B. Radomski, *Andrew R. Brodkin* and *Ivor M. Hughes* for respondent Apotex Inc.

No one appearing for respondent Minister of Health.

SOLICITORS OF RECORD:

Gowling Lafleur Henderson LLP, Ottawa, for applicants.

Goodmans LLP, Toronto, for respondent Apotex Inc.

Deputy Attorney General of Canada for respondent the Minister of Health.

The following are the reasons for order rendered in English by

GIBSON J.:

INTRODUCTION

[1] These reasons arise out of an application by the applicants pursuant to subsection 55.2(4) of the *Patent Act*[1] (the Act) and section 6 of the *Patented Medicines (Notice of Compliance) Regulations*[2] (the Regulations) for an order in accordance with subsection 6(1) of the Regulations prohibiting the respondent the Minister of Health from issuing a notice or notices under section C.08.004 of the *Food and Drug Regulations*[3] to the respondent Apotex Inc. (Apotex) in connection with paroxetine hydrochloride tablets until after the expiration of Canadian letters patent No. 2,178,637 (the 637 patent). In addition to the order of prohibition, the applicants seek their costs of the application and such further and other relief as the Court considers just.

[2] The applicant, SmithKline Beecham p.l.c., is the owner of the 637 patent and was joined as a party to the application in accordance with subsection 6(4) of the Regulations. SmithKline Beecham Pharma Inc. included the 637 patent in patent lists submitted pursuant to subsection 4(1) [as am. by SOR/98-166, s. 3] of the Regulations in connection with notices of compliance issued to it for tablets of its PAXIL brand of the

drug paroxetine hydrochloride. The applicants will be jointly referred to in these reasons as “SmithKline”.

[3] SmithKline’s application followed a notice of allegation pursuant to the Regulations in which the respondent Apotex alleged that no claim for the medicine paroxetine and no claim for the use of the medicine would be infringed by the making, constructing, using or selling by it of tablets for oral administration containing paroxetine hydrochloride 10 mg, 20 mg or 30 mg. In the notice of allegation, the legal and factual basis for it is described in the following terms:

> 1. The claims of this patent are limited to a paroxetine formulation prepared on a commercial scale into tablets using a formulation process in which water is absent. We [Apotex] hereby undertake that the formulation made and sold by us will be prepared only using a formulation process in which water is present. More specifically, the only formulation that we will make and sell will be film-coated tablets made using water as the solvent for the film-coating part of the process, and we will include pigments in the film coating to cover any pink hue generated by the effect of the water on the paroxetine. Accordingly, we will not infringe any claim.
>
> 2. In addition or in the alternative, with respect to the tablets to be made and sold by us, the claims in this patent are not claims for the medicine itself or the use of the medicine. This is because the tablets which we will make and sell will be made as aforesaid using water, and the claims of the patent relate only to tablets made by a process in which water is absent.

Apotex further alleges in its notice of allegation that the 637 patent is invalid in that the claims of the 637 patent are anticipated or devoid of novelty by reason of the disclosure of Canadian patent No. 1,287,060 (the 060 patent), the patent is devoid of inventiveness or is obvious and is not directed to any new and useful composition of matter, and is devoid of utility. Finally, Apotex alleges that the 637 patent was not eligible for listing in the Patent Register maintained under the Regulations.

[4] SmithKline’s application was heard by the Court on May 22, 23, 24, 2001. The 24 month period during which the Minister of Health is prohibited from issuing a Notice of Compliance to Apotex following the filing of SmithKline’s application, pursuant to paragraph 7(1)(*e*) [as am. *idem*, s. 6] of the Regulations, was extended by four months by consent order of the Court so that it now expires on August 16, 2001.

[5] The Minister of Health filed no materials on the application and did not appear at the hearing of the application.

BACKGROUND

[6] The 060 patent entitled Crystalline Paroxetine HCL issued to Beecham Group p.l.c. on July 30, 1991. The abstract of the 060 patent is in the following terms:

> The invention provides crystalline paroxetine hydrochloride hemihydrate, processes for its preparation, compositions containing the same and its therapeutic use.

[7] The disclosure of the 060 patent indicates that paroxetine was, at the date of the application for the patent, a known substance. The disclosure includes the following statements:

> In general, the hydrochloride salt of a basic compound [such as paroxetine] is preferred for therapeutic use because of its physiological acceptability.
>
> …
>
> It has now been discovered that paroxetine hydrochloride can be produced in crystalline form in a manner reproducible on a commercial scale.
>
> …
>
> Paroxetine hydrochloride hemihydrate is stable and non-hygroscopic.
>
> …
>
> In its preferred aspect the present invention provides paroxetine hydrochloride hemihydrate in pharmaceutically acceptable form.
>
> The present invention also provides a pharmaceutical composition comprising crystalline paroxetine hydrochloride hemihydrate and a pharmaceutically acceptable carrier.
>
> The compositions of this invention are usually adapted for oral administration, but formulations for dissolution for parenteral administration are also within the scope of this invention.
>
> …
>
> Preferred unit dosage forms include tablets or capsules.
>
> The composition of this invention may be formulated by conventional methods of admixture such as blending, filling and compressing.

It was not in dispute before me that conventional methods of admixture or formulation would be understood by persons skilled in the art to include wet granulation, dry granulation and direct compression.

[8] Dr. Robin Roman, for some 16 years when he swore his first expert affidavit filed in this matter on May 27, 1999, an employee of SmithKline Beecham Corporation, a wholly-owned subsidiary of SmithKline Beecham p.l.c., attests that, as part of his responsibilities in the 1991 to 1993 time period, he was in charge of the development of formulations of paroxetine hydrochloride (paroxetine). In his first expert affidavit filed in this matter, Dr. Roman attests:

> While I worked at SmithKline Beecham p.l.c. on the formulation of tablets of paroxetine hydrochloride in the 1991 to 1993 time frame, commercial paroxetine hydrochloride tablets were manufactured using a wet granulation process. Commercial paroxetine hydrochloride tablets manufactured in the absence of water were not sold prior to the filing of either the 637 Patent or the priority patent application upon which the 637 Patent is based….

…

> In the 1991-1992 time frame, a major concern to SmithKline was the development of a pink hue or coloration by some of the commercial paroxetine tablets. Not all tablets developed a pink hue and of those tablets that developed a pink hue, not all of them developed the pink hue to the same degree.
>
> The development of a pink hue was of major concern as it would lead to the product not meeting the specification for the color of the uncoated tablet and would result in the batches having the pink colouration being rejected and disposed of. The commercial consequences of this would be an inability to supply product to the marketplace and the concomitant financial consequences. The batch to batch variation of the pink hue was also indicative of a potential variability in the tablet manufacturing process which could have led to a major regulatory problem where the manufacturing process may have been deemed to be "out of control" and a prohibition placed on further sales until the problem was explained to the satisfaction of the regulatory authorities.
>
> Work was undertaken to overcome this problem. Many scientific groups worked in parallel to solve this problem. The pink hue could have been caused by one of the steps in the manufacturing process of the formulated product or by an impurity in one of the excipients or in the active ingredient, the paroxetine hydrochloride. It was unexpectedly found by two members of my formulation group that using a formulation process in which water is absent to prepare the paroxetine tablets solved the pink hue problem.[4]

This "unexpected" discovery led to the filing of the application for the 637 patent with a priority date of December 15, 1993 based upon the equivalent British patent.

[9] The 637 patent is entitled "Paroxetine Tablets and Process to Prepare Them". The following extracts are drawn from the disclosure of the 637 patent:

> The present invention relates to novel formulations and to the use of the formulation in the treatment and/or prevention of certain disorders.
>
> …
>
> This compound [paroxetine] has been approved for human use and is being sold in many countries around the world as an anti-depressant agent.
>
> It has been noticed that tablets of paroxetine often develop a pink hue which is highly undesirable.
>
> To date, all tablets which have been sold have been formulated using an aqueous granulation process. It has surprisingly been found that formulation of paroxetine into tablets can be carried out reliably and on a commercial scale using a formulation process in which water is absent, such as by direct compression or by dry granulation.
>
> It has also been surprisingly found that paroxetine formulated into a tablet using a process in which water is absent, is much less likely to develop a pink hue.
>
> Accordingly, the present invention provides paroxetine which is formulated into tablets using a formulation process in which water is absent.
>
> Examples of such a formulation process are dry direct compression of paroxetine or dry

> granulation of paroxetine followed by compression into tablets. The present invention therefore provides a formulation comprising direct compressed paroxetine admixed with dry excipients in the form of a tablet and a formulation comprising dry granulated and compressed paroxetine admixed with dry excipients in the form of a tablet.
>
> It should be appreciated that the term "dry" means substantially "dry" as opposed to the wholesale addition of water which was previously employed in the wet granulation process.
>
> Direct compression techniques are generally known in the art of pharmaceutical science. For example, paroxetine is conventionally admixed with dry excipients and compressed into tablets.
>
> Dry granulation techniques are generally also known in the art of pharmaceutical science. For example, paroxetine is conventionally admixed with dry excipients and compressed into large slugs or roller compacted into ribbon-like strands. The compacted material is then suitably milled to produce a free flowing powder which is then compressed into tablets.
>
> …
>
> Paroxetine when incorporated into the above-mentioned tablets is suitably, present as the hydrochloride hemi-hydrate form which may be prepared according to the procedures outlined in US Patent 4,721,723.[5]

The four claims of the 637 patent, as modified by a Certificate of Correction issued in respect of the 637 patent on May 13, 1999, read as follows:

1. A paroxetine formulation which is prepared on a commercial scale into tablets using a formulation process in which water is absent.

2. A formulation according to claim 1 in which the process is a dry direct compression of paroxetine followed by compression into tablets or a dry granulation of paroxetine followed by compression into tablets.

3. A formulation according to claim 1 or 2 in which the process for preparing it comprises the step of admixing paroxetine with dry excipients.

4. A formulation according to any one of claims 1 to 3 in which the paroxetine used in the process is in the form of the hydrochloride hemihydrate.[6]

[10] It is against the foregoing context that Apotex' new drug submission and the related notice of allegation earlier referred to in these reasons were respectively filed and issued.

THE ISSUES

[11] As earlier indicated in these reasons, Apotex' notice of allegation raises the following issues on this application: first, the validity of the 637 patent in the light of alleged anticipation or lack of novelty, alleged obviousness, and alleged inutility; secondly, whether the 637 patent would be infringed by the bringing into practice of the drug formulation disclosed in Apotex' new drug submission; and finally, the propriety of the listing of the 637 patent pursuant to the Regulations.

ANALYSIS

(a) Preliminary Issues

(i) Burden of Proof

[12] Subsection 43(2) [as am. by S.C. 1993, c. 15, s. 42] of the Act creates a presumption of validity of the 637 patent. That subsection reads as follows:

> **43.** …
>
> (2) After the patent is issued, it shall, in the absence of any evidence to the contrary, be valid and avail the patentee and the legal representatives of the patentee for the term mentioned in section 44 or 45, whichever is applicable.

In *McPhar Engineering Co. of Canada Ltd. v. Sharpe Instruments Ltd. et al*[7], President Thorson wrote at page 492:

> It must follow from the provision of the Act [a predecessor provision to the same effect as subsection 43(2)] that a patent granted under it "shall thereafter be *prima facie* valid" and avail its grantee and his legal representatives for the term of the patent that the onus of showing that it is invalid lies on the person attacking it, no matter what the ground of attack may be, and that until it has been shown to be invalid the statutory presumption of its validity remains.
>
> This does not mean that the patent is immune from attack or that the patentee is free from the obligations that are incumbent on him by way of consideration for the grant of the patent monopoly to him, but it seems clear that, since Parliament has deliberately endowed a patent granted under the Act with a presumption of validity, the onus of showing that such a patent is invalid is not an easy one to discharge.

[13] Counsel for Apotex urged that the foregoing must be read in light of the statutory and regulatory scheme here underlying the application which, he noted, provides for an extraordinary remedy in the nature of a presumptive interlocutory injunction for a term of 24 months, subject to variation, effective immediately on the commencement of the proceeding. In *Bayer AG v. Canada (Minister of National Health and Welfare)*,[8] Mr. Justice Mahoney, for the Court, wrote at page 337:

> By merely commencing the proceeding, the applicant obtains what is tantamount to an interlocutory injunction for up to 30 months [now 24 months] without having satisfied any of the criteria a court would require before enjoining issuance of a NOC. In particular, no liability as to damages arises from the application as would be imposed by the undertaking any court would require before making an interlocutory injunction. The liability for damages created by s. 8 of the Regulations pertains only to those incurred as a result of the NOC not issuing until after the patent has expired. That is by no means coextensive with the liability that arises on an undertaking exacted when an injunction is issued.

In *Bayer AG v. Apotex Inc.*,[9] I wrote at paragraphs 16-18:

> In *Hoffmann-La Roche Ltd. v. Canada (Minister of National Health and Welfare)*, Mr. Justice Stone wrote:

2. The initiator of a section 6 proceeding [a proceeding such as these [*sic*]], being the person having the carriage of the litigation, bears "the initial burden of proof" which is a difficult burden because "it must be to disprove some or all of the allegations in the notice of allegation which, if left unchallenged, would have allowed the Minister to issue a notice of compliance"…

3. This burden, known in a civil case as either the "persuasive burden" or the "legal burden", is the burden of establishing a case to the civil standard of proof. By contrast, the "evidential burden" consists of the burden of putting an issue in play and means that a party has the responsibility to ensure that there is sufficient evidence of the existence or non-existence of a fact or an issue on the record to pass the threshold for that particular fact or issue… [Citations omitted.]

Here, against the foregoing principles, the initial "persuasive" or "legal" burden of proof falls on Bayer to establish that Bayer Germany was entitled to the grant of the Canadian patents and that, contrary to the allegations made by Apotex, the patents are not invalid. Bayer is entitled to rely on the presumption of validity earlier referred to. Regarding both entitlement and validity, the issue here put in play by Apotex' notices of allegations is the novelty of the inventions disclosed by the Canadian patents. By adducing in evidence the Chilean patent and the Spanish patent supported by expert evidence to which I will refer later to the effect that those patents claim the inventions of the Canadian patents, Apotex has, I conclude, adduced "sufficient evidence of the existence … of an issue on the record to pass the threshold for that particular … issue".

Thus, the "initial burden of proof" is restored and lies upon Bayer. [Citation omitted.]

[14] Against the foregoing, I conclude that while an "evidential burden" lies on Apotex to put each of the issues raised in its notice of allegation "in play", if it is successful in doing so, the "persuasive burden" or "legal burden" then lies with SmithKline. Assuming Apotex to be successful in putting the issue of validity of the 637 patent "in play", SmithKline is entitled to rely on the presumption of validity of the patent created by subsection 43(2) of the Act.

[15] The "persuasive burden" or "legal burden" that lies with SmithKline in the circumstances described in the preceding paragraph is, however, impacted by the nature of the proceeding here before the Court. In *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)*,[10] Mr. Justice Hugessen, for the Court, wrote at pages 319-320:

As I understand the scheme of the regulations, it is the party moving under s. 6, in this case Merck, which, as the initiator of the proceedings, has the carriage of the litigation and bears the initial burden of proof. That burden, as it seems to me, is a difficult one since it must be to disprove some or all of the allegations in the notice of allegation which, if left unchallenged, would allow the Minister to issue a notice of compliance….

…

In this connection, it may be noted that, while s. 7(2)(*b*) [of the Regulations] seems to envisage the court making a declaration of invalidity or non-infringement, it is clear to me that such declaration could not be given in the course of the s. 6 proceedings themselves. Those proceedings, after all, are instituted by the patentee and seek a prohibition against the Minister; since they take the form of a summary application for judicial review, it is

> impossible to conceive of them giving rise to a counterclaim by the respondent seeking such a declaration. Patent invalidity, like patent infringement, cannot be litigated in this kind of proceeding.

Thus, the burden on SmithKline is only to disprove the allegations in the notice of allegation, not to justify declarations of validity and infringement or conversely to negative claims for declarations of invalidity and non-infringement.

(ii) Construction of the 637 Patent

[16] In a classic statement of the principles regarding interpretation of a patent, Mr. Justice Dickson, as he then was, for the Supreme Court of Canada, in *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*[11] wrote at pages 520-521:

> We must look to the whole of the disclosure and the claims to ascertain the nature of the invention and methods of its performance …, being neither benevolent nor harsh, but rather seeking a construction which is reasonable and fair to both patentee and public. 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, … "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 Lightning Company*. He said the patent should be approached "with a judicial anxiety to support a really useful invention". [Citations omitted.]

[17] Counsel for Apotex urged that the foregoing was qualified in its references to the whole of the specification in *Beecham Canada Ltd. et al. v. Proctor & Gamble Co.*[12] where Mr. Justice Urie, for the Court, wrote at page 11:

> … in construing the claims in a patent recourse to the remainder of the specification is (a) permissible only to assist in understanding terms used in the claims; (b) unnecessary where the words of the claim are plain and unambiguous; and (c) improper to vary the scope or ambit of the claims.

[18] Later, in *Nekoosa Packaging Corp. v. AMCA International Ltd.*,[13] Mr. Justice Robertson, after citing the foregoing quotation from *Consolboard*, wrote at page 482:

> As Hayhurst … cautions … "Terms 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…". [Citations omitted.]

[19] While I am satisfied that the foregoing quotation from *Beecham* places a gloss on the principles enunciated in *Consolboard*, that gloss is very limited. It in turn must be read in the context of the quotation from the learned author cited by Mr. Justice Robertson.

[20] The Supreme Court of Canada has recently commented at some length on the interpretation of a patent in the context of infringement issues. In *Free World Trust v. Électro Santé Inc.*,[14] Mr. Justice Binnie, for the Court, wrote at paragraph 31:

> The appeal thus raises the fundamental issue of how best to resolve the tension

between “literal infringement” and “substantive infringement” to achieve a fair and predictable result. There has been considerable discussion of this issue in Canada and elsewhere, which I will discuss briefly in support of the following propositions:

(a) The *Patent Act* promotes adherence to the language of the claims.

(b) Adherence to the language of the claims in turn promotes both fairness and predictability.

(c) The claim language must, however, be read in an informed and purposive way.

(d) The language of the claims thus construed defines the monopoly. There is no recourse to such vague notions as the “spirit of the invention” to expand it further.

(e) The claims language will, on a purposive construction, show that some elements of the claimed invention are essential while others are non-essential. The identification of elements as essential or non-essential is made:

(i) on the basis of the common knowledge of the worker skilled in the art to which the patent relates;

(ii) as of the date the patent is published;

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

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

(v) without, however, resort to extrinsic evidence of the inventor’s intention.

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

After reviewing Canadian jurisprudence against the foregoing propositions, Mr. Justice Binnie continues at paragraph 39:

The English courts have also engaged in a debate about the proper reach of a patent monopoly. In *Clark v. Adie* … James L.J. spoke of “an essence or substance of the invention underlying the mere accident of form; and that invention, like every other invention, may be pirated by a theft in a disguised or mutilated form”. On the other hand, in *Electric & Musical Industries Ltd. v. Lissen Ltd.* … Lord Russell stated …

A patentee who describes an invention in the body of a specification obtains no monopoly unless it is claimed in the claims …. [T]here is no such thing as infringement of the equity of a patent ….

The primacy of the language of the claims was emphatically affirmed in the celebrated case of *Catnic Components Ltd. v. Hill & Smith Ltd.,* … . The *Catnic* approach has been accepted in New Zealand … and in Australia …. The *Catnic* decision has its critics, of course, particularly among those who feel its subsequent application under the *European Patent Convention* denies the patentee the higher level of protection for patentees afforded

in continental Europe. For some critics, the claims should more properly be treated not as a "fence" but as a "guidepost" ….

The primacy of the claims language was already rooted deeply in our jurisprudence and should, I think, be affirmed again on this appeal. [Citations omitted.]

At paragraphs 44-45, Mr. Justice Binnie continued:

(c) The Claims Must Be Construed in an Informed and Purposive Way

The courts have traditionally protected a patentee from the effects of excessive literalism. The patent is not addressed to an ordinary member of the public, but to a worker skilled in the art described by Dr. Fox as:

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

…

It is the "common knowledge" shared by competent "ordinary workers" that is brought to bear on the interpretation …. The present appeal does not raise great subtleties of interpretation. The experts called by the parties here more or less agreed on the significance of what is stated in the claims. The electro-magnetotherapy is to be controlled by "circuit means". The present appeal turns on the scope of the legal protection that arises out of that fact.

(d) The Language of the Claims Thus Construed Defines the Monopoly. There is No Recourse to Such Vague Notions as "Spirit of the Invention" to Expand It Further

There appears to be a continuing controversy in some quarters as to whether there are two approaches to infringement (literal and substantive) or only one approach, namely infringement of the claims as written but "purposively" construed. [Citations omitted.]

Mr. Justice Binnie concluded on this aspect of his reasons at paragraphs 50-51 to the following effect:

I do not suggest that the two-stage [the literal and substantive] approach necessarily ends at a different destination than the one-stage [purposive] approach, or that the two-stage approach has resulted in abuse. I think we should now recognize, however, that the greater the level of discretion left to courts to peer below the language of the claims in a search for "the spirit of the invention", the less the claims can perform their public notice function, and the greater the resulting level of unwelcome uncertainty and unpredictability. "Purposive construction" does away with the first step of purely literal interpretation but disciplines the scope of "substantive" claims construction in the interest of fairness to both the patentee and the public. In my view its endorsement by the Federal Court of Appeal in *O'Hara* was correct.

…

> This point [purposive construction showing that some elements of invention are essential while others are non-essential] is addressed more particularly in *Whirlpool Corp. v. Camco Inc*., … and *Whirlpool Corp. v. Maytag Corp.*, … released concurrently. The involvement in claims construction of the skilled addressee holds out to the patentee the comfort that the claims will be read in light of the knowledge provided to the court by expert evidence on the technical meaning of the terms and concepts used in the claims. The words chosen by the inventor will be read in the sense the inventor is presumed to have intended, and in a way that is sympathetic to accomplishment of the inventor's purpose expressed or implicit in the text of the claims. However, if the inventor has misspoken or otherwise created an unnecessary or troublesome limitation in the claims, it is a self-inflicted wound. The public is entitled to rely on the words used *provided* the words used are interpreted fairly and knowledgeably. [Citations omitted.]

[21] While I do not read the foregoing guidance provided by the Supreme Court of Canada as eliminating a court's reference to elements of the specification of a patent outside the claims in order to arrive at a purposive construction, there can be no doubt that the reliance on the words of the specification outside the claims must be very limited and should be resorted to only where the words of the claims themselves are ambiguous. I am satisfied that my conclusion in this regard is supported by the following brief quotation from the reasons of Mr. Justice Binnie at paragraph 52, in *Whirlpool Corp. v. Camco Inc.*:[15]

> 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.

(iii) Evaluation of the Expert Testimony

[22] SmithKline put before the Court the expert statements of three highly qualified persons while Apotex put forward the statements of an equal number highly qualified persons. Indeed, I did not hear the submissions before me as being contradictory of a view that all six experts were overqualified as persons skilled in the art to which the 637 patent relates which is to say, skilled drug formulators.

[23] As earlier noted, one of SmithKline's experts, Dr. Robin Roman, as at the time his first expert statement was sworn, May 27, 1999, had been employed by a SmithKline-related company since 1983. Indeed, he attests that in 1991, he was seconded to the United Kingdom to work for SmithKline Beecham p.l.c. where he was head of a SmithKline research and development facility where one of the inventors named on the 637 patent reported directly to him and the other reported indirectly to him. In the course of his cross-examination on his expert statements he acknowledged that the work being done to solve the "pink hue problem" was work for which he had overall responsibility.[16]

[24] In *AB Hassle v. Canada (Minister of National Health and Welfare)*,[17] Mr. Justice Noël, then of the Trial Division of this Court, commented on an expert opinion there before him on behalf of a respondent to the following effect at paragraphs 59-60:

> Although Dr. Slemon purported to give evidence as an expert, he offered his opinion with respect to the process which he devised himself with the view of avoiding the claims made in the 158 patent. He was therefore opining on the question as to whether he was successful in his efforts to bypass the 158 patent.
>
> It is clear to me that Dr. Slemon lacks the necessary independence to be treated as an expert in the present proceeding. Dr. Slemon was committed to developing a non-infringing process and having it upheld by the Court. … As he was an inventor, it is not surprising that he had more to say about the process than [certain other experts]. I accept his evidence insofar as it serves to establish facts of relevance. However, his personal interest in this matter and the circumstances in which he became involved preclude me from treating him as an expert. To the extent that the opinions he expressed were considered to be essential to the respondent's case, they should have been advanced by someone else.

[25] I reach a similar conclusion here. While Dr. Roman was not an inventor named on the 637 patent, he was the director of the group, or at least a group, charged with the responsibility of finding a solution to the "pink hue problem". His responses on cross-examination on his expert statements clearly indicated that the solution identified by persons reporting to him were, in his opinion, important to his employer. I am satisfied that his personal interest in achieving that solution, and thus in the issues before this Court with respect to the 637 patent, preclude me from treating him as an expert in relation to those issues, at least in so far as his opinions are other than merely confirmatory of the opinions of other experts whose statements are before the Court.

[26] Through its experts' statements, Apotex introduced into this proceeding prior art in the form of patents and excerpts from textbooks allegedly, in the submission of counsel for SmithKline, to support allegations by Apotex that the invention claimed by the 637 patent was anticipated and obvious.

[27] In *AB Hassle v. Canada (Minister of National Health and Welfare)*,[18] the Federal Court of Appeal considered an appeal from the Trial Division [[1999] F.C.J. No. 1653 (QL)] dismissing a motion for an order that a respondent in a proceeding such as this be limited to relying on those documents of prior art listed in the respondent's detailed statement made pursuant to paragraph 5(3)(*a*) of the Regulations in support of its allegations that certain Canadian patents were invalid for anticipation and/or obviousness.

[28] In allowing the appeal, Mr. Justice Stone wrote at paragraph 17:

> Indeed, this Court has recognized that the detailed statement must be such as to make the patentee fully aware of the grounds for claiming that the issuance of an NOC would not lead to infringement of a listed patent for, otherwise, the patentee would be unable to decide whether or not to initiate a section 6 [of the Regulations] proceeding.

[29] At paragraphs 19-21, 23, 24, Mr. Justice Stone continued:

> The detailed statement is not a pleading *per se* but represents a pivotal step in the process leading up to the issuance of an NOC. By taking that step the second person puts the patentee on notice of the grounds on which he or she considers that the making, constructing, using or selling of the drug will not infringe the second person's patent rights

during the unexpired term of the patent….

> While it is true that the detailed statement is not filed in a section 6 proceeding, it nevertheless casts a long shadow over that proceeding. Indeed, it is upon the content of that statement that the patentee must decide whether or not to commence a section 6 proceeding and to assess its chances of success or failure. In this sense the allegation and detailed statement assist in an important way in framing the issues and facts to be determined in the section 6 proceedings for in seeking prohibition the patentee is obliged to show that, contrary to what is stated in the detailed statement, the patentee's patent right will be infringed if an NOC for the drug is issued prior to the expiration of the listed patent.
>
> 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…. 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 … Patents are not valid for obviousness.
>
> …
>
> 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 my view, this reasoning applies equally to a deficiency in a detailed statement of a second person. [Citations omitted.]

[30] On the basis of the foregoing authority, the additional prior art cited in the experts' statements filed on behalf of Apotex will not be taken into account in considering the allegations that the 637 patent is invalid and that formulation of Apotex' paroxetine tablets would not infringe the 637 patent.

[31] Counsel for SmithKline urged that Apotex's experts erred in their approach on the question of obviousness in two fundamental ways: first, in that they did not ask whether using a dry formulation technique was the obvious solution to the intermittent pink hue problem but rather answered the very different question whether it would be easy to make a dry granulation formulation of paroxetine based upon their knowledge of the art; and secondly in that they approached the question of obviousness after they had read the 637 patent and learned that water was associated with the pink hue problem. Counsel for Apotex urged the converse position, that is to say, that SmithKline's experts approached the question of obviousness in a manner that was in error.

[32] In addressing the issue of “the right question” to which experts should address their minds in approaching the question of obviousness, counsel for SmithKline relied on the decision of the Supreme Court of Canada in *Shell Oil Co. v. Commissioner of Patents*.[19] I find little guidance in the *Shell Oil* decision that I regard as useful on this issue. Subject to what I have previously said regarding the expert statements of Dr. Roman, I regard the advice from the experts on both sides as to the issue of obviousness to be of equal value.

[33] Finally as to the expert statements filed by both sides, I find it to be of significant value that all are in agreement that, in addressing the “pink hue problem”, all would identify a number of potential causes, most of which they agreed upon. In particular, they all agreed that formulation in the presence of water was a potential source of the problem. Counsel for Apotex urged that all identified the presence of water as the most likely cause. While I would not go so far as I was urged to go in this regard by counsel for Apotex, I find it very significant that all experts identified the presence of water as a potential problem and a number of them identified it high on the list of potential sources of the problem.

(b) Invalidity

(i) Anticipation or Lack of Novelty

[34] The relevant portion of subsection 28.2(1) [as enacted by S.C. 1993, c. 15, s. 33] of the Act reads as follows:

> **28.2** (1) The subject-matter defined by a claim in an application for a patent in Canada (the “pending application”) must not have been disclosed
>
> (*a*) more than one year before the filing date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant, in such a manner that the subject-matter became available to the public in Canada or elsewhere;

The filing date of the 637 patent, as earlier noted, was December 14, 1994. The anticipation alleged in the notice of allegation is by the 060 patent which issued July 30, 1991 to Beecham Group p.l.c. which, I am satisfied, was a predecessor of the applicant for the 637 patent. There can be no question that the invention disclosed by the 060 patent became available to the public in Canada or elsewhere when the 060 patent issued.

[35] In *Beloit Can. Ltée/Ltd. v. Valmet Oy*,[20] Mr. Justice Hugessen, for the Court, wrote at page 297:

> It will be recalled that anticipation, or lack of novelty, asserts that the invention has been made known to the public prior to the relevant time. The inquiry is directed to the very invention in suit and not, as in the case of obviousness, to the state of the art and to common general knowledge. Also, as appears from the passage of the statute quoted above, anticipation must be found in a specific patent or other published document; it is not enough to pick bits and pieces from a variety of prior publications and to meld them together so as to come up with the claimed invention. One must, in effect, be able to look at

> a prior single publication and find in it all the information which, for practical purposes, is needed to produce the claimed invention without the exercise of any inventive skill. The prior publication must contain so clear a direction that a skilled person reading and following it would in every case and without possibility of error be led to the claimed invention. Where, as here, the invention consists of a combination of several known elements, any publication which does not teach the combination of all the elements claimed cannot possibly be anticipatory.

It is to be noted that Mr. Justice Hugessen, in the foregoing quotation, was commenting on anticipation or lack of novelty under the terms of a previous version of the Act but it was not in dispute before me that the foregoing quotation is relevant in the context of the current Act.

[36] In *Pfizer Canada Inc. v. Apotex Inc.*,[21] Mr. Justice Richard as he then was, after reciting the foregoing quotation from *Beloit*, as adopted by Mr. Justice Décary in *Diversified Products Corp. v. Tye-Sil Corp.*,[22] commented on the reasons of Mr. Justice Décary, concurred in by Justices Marceau and Pratte, otherwise than on the issue of obviousness, to the following effect at page 553 of the *Pfizer* decision:

> He [Mr. Justice Décary] added… that when prior knowledge or use is alleged, "evidence of this character should be subjected to the closest scrutiny" and "anyone claiming anticipation on that basis assumes a weighty burden".
>
> He [Mr. Justice Décary] cited the following principles which should be applied to determine whether the prior use or prior art anticipated the invention:
>
> 1) does it teach the combination of all the elements claimed;
>
> 2) does it give the same knowledge as the specifications of the invention itself;
>
> 3) does it contain clear and unmistakable directions so to use it;
>
> 4) whatever is essential to the invention or necessary or material for its practical working and real utility must be found substantially in the prior publication; and
>
> 5) an impractical and inoperable device cannot be an anticipation.

[37] In *Free World Trust v. Électro Santé Inc.*,[23] Mr. Justice Binnie, before affirming the test for anticipation from *Beloit*, *supra*, as one that is "difficult to meet", wrote at paragraph 26:

> The legal question is whether the Solov'eva article [here the 060 patent] contains sufficient information to enable a person of ordinary skill and knowledge in the field to understand, without access to the two patents, "the nature of the invention and carry it into practical use without the aid of inventive genius but purely by mechanical skill" … . In other words, was the information given by Solov'eva "for [the] purpose of practical utility, equal to that given in the patents in suit"? *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.* … or as was memorably put in *General Tire & Rubber Co. v. Firestone Tyre & Rubber Co.* …
>
> A signpost, however clear, upon the road to the patentee's invention will not suffice. The prior inventor must be clearly shown to have planted his flag at the precise destination before the patentee. [Citations omitted.]

[38] Referring back to the brief analysis of the 637 patent and the 060 patent set out earlier in these reasons, the sole matter disclosed in the 637 patent that is not disclosed in the 060 patent is that one or more of the "conventional methods of admixture such as blending, filling and compressing" for formulation, on a commercial scale, of paroxetine tablets, namely, "a formulation process" in which water is absent, "a dry granulation" of paroxetine or comprising "the step of admixing paroxetine with dry excipients", is less likely to give rise to the "pink hue problem" than is wet granulation. It is worthy of note that this particular advantage flowing from certain of the "conventional methods of admixture" disclosed in the 060 patent is not referred to in the claims of the 637 patent. That being said, even adopting a generous interpretation of the 637 patent that would bring the advantage of reduction of the "pink hue problem" within a broad interpretation of the claims of the 637 patent, I conclude that the test for anticipation is here met.

[39] Against the terms of the *Beloit* test, I am satisfied that a person of ordinary skill and knowledge in the field would, on the evidence before me, be able to look at a prior, single publication, the 060 patent, and find in it all the information which, for practical purposes, would be needed to produce the invention of the 637 patent without the exercise of any inventive skill. The 060 patent contains so clear a direction that a skilled person reading and following it would in every case and without possibility of error be led to the claimed invention.

[40] Having determined that a wet formulation of paroxetine tablets gives rise to a "pink hue problem", a problem of significant enough magnitude to cause a skilled person to seek out at least a partial solution to the problem, I am satisfied that a logical first step for a person skilled in the art would be to turn to the alternative formulation methods disclosed by the 060 patent and to determine whether each or any of those alternative formulation methods would solve, or at least partially solve, the problem. Such an enquiry would, I am satisfied, involve no inventive step or skill. It would simply involve application of the invention taught by the 060 patent.

[41] As previously noted, the application for the 637 patent was filed in Canada on December 14, 1994. The 637 patent issued on June 22, 1995. Thus, the prior art that was before the Commissioner of Patents at all relevant times, the 060 patent, taught a practising of the alternative conventional methods of formulation to be practicable.

[42] The disclosure of the 637 patent states:

> It has surprisingly been found that formulation of paroxetine into tablets can be carried out reliably and on a commercial scale using a formulation process in which water is absent, such as by direct compression or by dry granulation.
>
> It has also been surprisingly found that paroxetine formulated into a tablet using a process in which water is absent, is much less likely to develop a pink hue. [My emphasis.]

I conclude that the only "surprising" finding was that a certain formulation method contemplated by the 060 patent, wet formulation, resulted in a pink hue problem. That another method of formulation taught by the same patent was less likely to produce the problem, was not, I conclude on the expert evidence before me, at all surprising.

[43] I find my conclusion that the 637 patent is anticipated by the 060 patent to be supported by the unanimous view of the experts who filed statements in this proceeding that one of the potential sources of the "pink hue problem" would be formulation in the presence of water.

[44] In summary then, I conclude that a person skilled in the art, on the basis of the cited prior art, namely, the 060 patent, and the existing common knowledge at the relevant time, would, in every case and without possibility of error, have arrived at the formulation claimed in the 637 patent. There was no innovative step disclosed by the claims of that patent read in a generous manner. SmithKline has simply failed, on the evidence before me, to discharge the "persuasive burden" or "legal burden" borne by it to establish that the allegation of invalidity is not justified.

(ii) Obviousness

[45] The test for obviousness is set out in section 28.3 [as enacted by S.C. 1993, c. 15, s. 33] of the Act. That section reads as follows:

> **28.3** The subject-matter defined by a claim in an application for a patent in Canada must be subject-matter that would not have been obvious on the claim date to a person skilled in the art or science to which it pertains, having regard to
>
> (*a*) information disclosed more than one year before the filing date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant in such a manner that the information became available to the public in Canada or elsewhere; and
>
> (*b*) information disclosed before the claim date by a person not mentioned in paragraph (*a*) in such a manner that the information became available to the public in Canada or elsewhere.

[46] The test for obviousness was characterized by Mr. Justice Hugessen in *Beloit Can. Ltée/Ltd. v. Valmet Oy*[24] in the following terms at page 294:

> The test for obviousness is not to ask what competent inventors did or would have done to solve the problem. Inventors are by definition inventive. The classical touchstone for obviousness is the technician skilled in the art but having no scintilla of inventiveness or imagination; a paragon of deduction and dexterity, wholly devoid of intuition; a triumph of the left hemisphere over the right. The question to be asked is whether this mythical creature (the man in the Clapham omnibus of patent law) would, in the light of the state of the art and of common general knowledge as at the claimed date of invention, have come directly and without difficulty to the solution taught by the patent. It is a very difficult test to satisfy.

Referring to section 28.3 of the Act quoted above, on the facts of this matter the reference in the foregoing quotation to "at the claimed date of invention" should now be to the claim date [as enacted by S.C. 1993, c. 15, s. 26], defined in section 2 of the Act to mean the date of a claim in an application for a patent in Canada, as determined in accordance with section 28.1 [as enacted *idem*, s. 33] of the Act.

[47] In *Apotex Inc. v. Wellcome Foundation Ltd.*,[25] Mr. Justice Wetston, at paragraph 245, wrote:

> The general question to be resolved is whether or not the alleged invention required the exercise of inventive ingenuity: *Windsurfing International Inc. v. Trilantic Corp…* . That is, was the invention "plain as day" or "crystal clear" to a technician skilled in the art at the date of the invention: *Bayer v. Apotex Inc.* … . Something is said to be obvious when it would occur directly to the ordinary person skilled in the relevant art searching for something novel without serious thought, research or experiment: G.F. Takach, *Patents, A Canadian compendium of law and practice* … . Where the alleged invention is the product of a collaborative research effort, the contribution of each notional member should be assessed separately, attributing to each the requisite level of skill required of a person fulfilling that function: *Re Genentech Inc.'s Patent*, … . [Citations omitted.]

[48] In *Bayer Aktiengesellschaft v. Apotex Inc.*,[26] Mr. Justice Lederman of the Ontario General Division wrote at pages 80 and 81:

> There appears, however, to be a significant difference in the abilities of the English hypothetical skilled technician and the Canadian one. Indeed, making inquiries or testing, seems to be something outside the ken of the notional Canadian skilled technician. In *Cabot Corp. v. 318602 Ontario Ltd…* . Rouleau J. [of this Court] quoted H.G. Fox in *Canadian Law and Practice Relating to Letters Patent for Inventions*… as stating in part:
>
> > "In order that a thing shall be `obvious', it must be something that would directly occur to someone who was searching for something novel, a new manufacture, or whatever it might be, *without the necessity of his having to do any experimenting* or serious thought, or research, whether the research be in the laboratory or amongst literature."
>
> (My emphasis). Thus, although one would normally imagine that this mythical person's laboratory is filled with mythical test tubes and Petri dishes and that his or her daily life is spent in experimentation, for the purposes of this legal exercise, no research of any kind can be contemplated. So, although it may have been logical to an actual skilled person at the time, based on the state of the art, to conduct certain testing, that is not open to the mythical skilled technician. The mythical researcher cannot have an inquiring or thinking mind which ultimately would lead him or her to the answer but rather he or she is expected to instantly and spontaneously exclaim, without more, "I already know the answer and it is obvious". Nor is it appropriate to say that there were significant telltales which pointed the way for the mythical expert or that there were sufficient clues which made the invention "worth a try". In *Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning v. Halocarbon (Ontario) Ltd…* ., Collier J. [of this Court] in rejecting the "worth a try" test stated:
>
> > Using the magnifying spectacles of hind-sight (a half borrowed phrase), it is easy to say that any experiment, if time and expense are unlimited … is or was worth a try.
>
> On appeal, the Supreme Court of Canada affirmed this position … and stated at p. 155:
>
> > Very few inventions are unexpected discoveries. Practically all research work is done by looking in directions where the "state of the art" points. On that basis and with hindsight, it could be said in most cases that there was no inventive ingenuity in the new development because everyone would then see how the previous accomplishments pointed that way.

> Presumably, that is why Hugessen J. stated that the question he posed in *Beloit* …, about the mythical creature is "a very difficult test to satisfy". [Citations omitted.]

[49] Against the foregoing authorities indicating that the test for obviousness is difficult to satisfy, that to be obvious, the solution to the problem posed must be "plain as day" or "crystal clear", without the necessity of having to do any experimenting or serious thought or research, and where the "worth a try" test is inappropriate, I conclude that, while Apotex has met its initial evidentiary burden with respect to "obviousness" and thus has put obviousness in issue, SmithKline has in turn met its burden to establish on a balance of probabilities that the allegation of obviousness is not justified.

[50] In his expert statement on behalf of SmithKline,[27] Dr. McGinity attested at paragraphs 26 and following:

> The first comment that I should make is that if I had been asked to solve the problem of the pink hue that had arisen in an intermittent fashion with the SmithKline product, I would have to first of all point out that I would expect to encounter considerable difficulty in solving this problem. The solution could not be achieved without any difficulty and indeed the major challenge would be to ascertain what caused the problem. Indeed, once the cause of the problem is solved it is often easy to correct the problem but what is difficult is to identify what factors created the problem.
>
> Therefore if I were to attempt to address the problem, I would investigate a number of potential causes:
>
> [There follows a list of three (3) potential causes, none of which is formulation in the presence of water although Dr. McGinity subsequently acknowledged that this was a potential cause.]
>
> In summary, therefore, it is my opinion that considerable time and effort would be required to solve this problem. Based on the three patents referred to above as well as my experience and common general knowledge in pharmaceutical technology, I was unable to identify the cause or suggest a solution to the intermittent pink hue problem. In order to try to solve the problem, a number of carefully designed experiments would have to be conducted.
>
> Therefore, in trying to solve the problem … and without the benefit of hindsight, I was unable to come directly and without difficulty to the solution of the intermittent pink hue problem. I honestly could not have come directly to the solution to this problem as there are a number of possible causes. Without knowing the cause of the problem, the solution is far from clear or plain.
>
> In addition, I cannot say that the solution would be found without some difficulty.

[51] While counsel for Apotex urged on a number of grounds that I should disregard the expert statement of Dr. McGinity, I decline to do so. Indeed, I find the foregoing quotation persuasive. While among the three patents to which Dr. McGinity refers in the foregoing paragraphs was the 060 patent, that patent certainly did not disclose the "cause' of the pink hue problem. While, as previously noted, I am satisfied that the allegation that the 060 patent anticipated the 637 patent was justified, I am satisfied that

SmithKline met the burden on it to establish that the allegation that the invention disclosed by the 637 patent was obvious was not justified.

(iii) Utility

[52] To constitute an invention, the art, process, machine, manufacture or composition of matter or improvement in any art, process, machine, manufacture or composition of matter must not only be new but it must also be useful.[28]

[53] In *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*,[29] Mr. Justice Dickson, as he then was, for the Supreme Court of Canada, wrote at page 525:

> There is a helpful discussion in *Halsbury's Laws of England*, 3rd ed.), vol. 29, p. 59, on the meaning of "not useful" in patent law. It means "that the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do". There is no suggestion here that the invention will not give the result promised. The discussion in *Halsbury's Laws of England*, *ibid*, continues:
>
> > … the practical usefulness of the invention does not matter, nor does its commercial utility, unless the specification promises commercial utility, nor does it matter whether the invention is of any real benefit to the public, or particularly suitable for the purposes suggested… .
>
> and concludes [at p. 60]:
>
> > … it is sufficient utility to support a patent that the invention gives either a new article, or a better article, or a cheaper article, or affords the public a useful choice.

[54] The disclosure of the 637 patent notes:

> It has also been surprisingly found that paroxetine formulated into a tablet using a process in which water is absent, is much less likely to develop a pink hue.

Thus, the claimed utility of the 637 patent is a formulation process that is less likely to develop a pink hue than a formulation process in which water is present, or is a "dry formulation process" where "dry" means substantially "dry" as opposed to a process where the wholesale addition of water is involved.

[55] All of Apotex' experts agree that the pink hue problem is a serious problem. Paragraphs 2 and 5 of the detailed statement forming part of Apotex's notice of allegation provide as follows:

> 2. The claims are not directed to any new and useful composition of matter, because, at the end of the process, a formulation made by a process in which water is absent is indistinguishable from formulations made by a process in which water is present, which the disclosure acknowledges were prior art.
>
> …
>
> 5. The claimed invention is devoid of utility. In the disclosure, it is said to be useful to avoid development of a pink hue; but, even if true, a pink hue is irrelevant to the utility

> of the tablets. The disclosure specifically states that all tablets which have been sold have been formulated using an aqueous granulation and there has been no problem whatsoever in relation to the production and sale of such tablets.

[56] All of SmithKline's experts attest that the lessening of the pink hue problem disclosed in the 637 patent is useful. Dr. Roman attests in his statement that until the pink hue problem was solved, to the extent that it was solved by the formulation process disclosed in the 637 patent, the launch of the paroxetine tablet product in the United States was delayed and some batches had to be discarded.

[57] Taking into account the evidence before the Court in its totality, I am satisfied that SmithKline has met the burden on it to establish that the allegation of lack of utility is not justified.

(c) Infringement

[58] In its notice of allegation, Apotex alleges that no claim for the medicine itself, and no claim for the use of the medicine, would be infringed by the making or constructing in the manner proposed, or by the using or selling by it of tablets for oral administration containing paroxetine hydrochloride 10 mg, 20 mg, or 30 mg that are so made or constructed. The legal and factual basis for the allegation is stated to be the following:

> 1. The claims of this patent are limited to a paroxetine formulation prepared on a commercial scale into tablets using a formulation process in which water is absent. We hereby undertake that the formulation made and sold by us will be prepared only using a formulation process in which water is present. More specifically, the only formulation that we will make and sell will be film-coated tablets made using water as the solvent for the film-coating part of the process, and we will include pigments in the film coating to cover any pink hue generated by the effect of the water on the paroxetine. Accordingly, we will not infringe any claim.
>
> 2. In addition or in the alternative, with respect to the tablets to be made and sold by us, the claims in this patent are not claims for the medicine itself or the use of the medicine. This is because the tablets which we will make and sell will be made as aforesaid using water, and the claims of the patent relate only to tablets made by a process in which water is absent.

[59] The claim to non-infringement is spurious, assuming for the moment the validity of the 637 patent. I accept the evidence before me that Apotex paroxetine formulation is a formulation prepared on a commercial scale into tablets using a formulation process in which water is absent. Only after the tablets are prepared by a process in which water is absent, thus infringing the 637 patent, does Apotex' formulation process contemplate the addition of a film-coating using water. The addition of a film-coating is not part of the claimed tablet formulation process in the 637 patent and is superfluous to that process.

[60] In *Cabot Corp. v. 318602 Ontario Ltd.*,[30] Mr. Justice Rouleau wrote at page 164:

> An immaterial difference between the patent and the defendants' product is not a defence to infringement. As Mahoney J. stated in *Globe-Union Inc. v. Varta Batteries Ltd…* .

> The defendant's method works. Indeed, it is very likely a commercial improvement on that of the connector patent… .
>
> The principle to be applied was stated in *Lightning Fastener Co., Ltd. v. Colonial Fastener Co. Ltd. et al.* … as follows:
>
> "In each case the substance, or principle, of the invention and not the mere form is to be looked to. It has been stated in many cases that if an infringer takes the principle and alters the details, and yet it is obvious that he has taken the substance of the idea which is the subject matter of the invention, and has simply altered the details, the Court is justified in looking through the variation of details and see [*sic*] that the substance of the invention has been infringed and consequently can protect the inventor. And the question is not whether the substantial part of the machine or method has been taken from the specification, but the very different one, whether what is done by the alleged infringer takes from the patentee the substance of his invention."
>
> In my view, the defendant has appropriated the invention of the connection patent. [Citations omitted.]

Mr. Justice Mahoney, as quoted by Mr. Justice Rouleau, continues in his reasons with a further quote, this from *Wenham Gas Co., Ltd. v. Champion Gas Lamp Co.*:[31]

> … if the pith and marrow of the invention is taken it is no excuse to say that you have added something, or omitted something, even if the addition or omission be useful and valuable. The superadding of ingenuity to a robbery does not make the operation justifiable.

[61] I am satisfied that all of the foregoing can be said of the facts before me. In the terms of the last quotation, the pith and marrow of the alleged invention is here proposed to be taken. It is no excuse to add something, in this case a film-coating made using water as the solvent for the film-coating. The taking of the pith and marrow of the alleged invention would nonetheless remain a "robbery". The superadding of ingenuity in the form of a film-coating would not "make the operation justifiable."

[62] In the result, if the 637 patent were to be found valid, I am satisfied that Apotex' allegation of non-infringement could not be justified.

[63] Section 32 of the Act is instructive. It reads as follows:

> **32.** Any person who has invented any improvement on any patented invention may obtain a patent for the improvement, but he does not thereby obtain the right of making, vending or using the original invention, nor does the patent for the original invention confer the right of making, vending or using the patented improvement.

[64] Assuming for the moment that Apotex' film-coating made using water as the solvent for the film-coating is an improvement, it does not thereby confer on Apotex the right of making, vending or using the original invention, assuming such it is, of the 637 patent.

(d) Eligibility for Listing

[65] In Apotex' notice of allegation and supporting detailed statement, the following is alleged:

We further allege that patent 2178637 was not eligible for inclusion in the register in relation to your paroxetine hydrochloride tablets, on the following grounds:

> 1. Listing of the patent was precluded by section 4(4) of the Regulations, by reason of that [*sic*] fact that the date of your new drug submission for your paroxetine hydrochloride tablets was prior to December 14, 1994, the date of filing of the application for this patent.
>
> 2. The patent does not have any claim for the medicine itself or the use of the medicine for which it is listed, as your paroxetine tablets in relation to which the patent has been listed are made by a process in which water is present.

[66] The allegation of ineligibility for listing of the 637 patent was before this Court in *Apotex Inc. v. Canada (Minister of Health)*.[32] Madam Justice McGillis concluded [at paragraph 49], for reasons given,:

> … I have determined that the Minister did not err in including the 637 patent on the Register.

In the result, she dismissed Apotex' application for judicial review of the decision of the Minister of Health to add the 637 patent to the Patent Register in relation to SmithKline's paroxetine tablets. Madam Justice McGillis decision was affirmed by the Federal Court of Appeal.[33]

[67] While counsel for Apotex acknowledged that the first ground of allegation for impropriety of listing was *res judicata* or issue *estopped*, he urged that the second ground of the allegation remained a live issue as it was not dealt with by Madam Justice McGillis.

[68] I am satisfied that Madam Justice McGillis' decision, as affirmed by the Court of Appeal, is wholly dispositive of the issue of the propriety of listing of the 637 patent. If an issue in that regard was not raised before Madam Justice McGillis, it is too late in the day to raise it now. If it was raised before Madam Justice McGillis and her reasons do not address it, the appropriate forum in which to have dealt with that concern was in the Court of Appeal, not before me.

[69] Subsequent to the close of the hearing on this application, counsel for Apotex drew to my attention a decision of my colleague Mr. Justice Pinard in *Warner-Lambert Canada Inc. v. Canada (Minister of Health)*.[34] Mr. Justice Pinard's decision and reasons arose out of an application for judicial review of a decision of the Minister of Health not to add a patent list submitted with a supplemental new drug submission to the patent register and to remove certain patents from a patent list on the register. The application for judicial review was dismissed. I simply am not satisfied that Justice Pinard's decision is relevant to my decision herein.

CONCLUSION

[70] In summary, I conclude that SmithKline has failed to discharge the burden on it in this proceeding to demonstrate that Apotex' allegation that the 637 patent is invalid by reason of anticipation or lack of novelty is not justified. The fact that I have concluded that SmithKline has met the burden on it with regard to all other allegations of invalidity, and the allegation of non-infringement, and that Apotex cannot succeed on technical grounds on the allegation regarding listing of the 637 patent, cannot lead to success on this application in favour of SmithKline. In the result, this application by SmithKline for an order in accordance with subsection 6(1) of the Regulations prohibiting the Minister of Health from issuing a notice under section C.08.004 of the *Food and Drug Regulations* to the respondent Apotex Inc. in connection with paroxetine hydrochloride tablets until after the expiration of Canadian letters patent No. 2,178,637 will be dismissed.

COSTS

[71] Both counsel for SmithKline and counsel for Apotex were in agreement before me that, as between SmithKline and Apotex, costs should follow the event. An order will go for costs in favour of Apotex, as against SmithKline, assessed in accordance with Column III of the table to Tariff B to the *Federal Court Rules, 1998*.[35] There will be no order as to costs either in favour of or against the respondent, the Minister of Health.

[1] R.S.C., 1985, c. P-4, s. 55.2(4) [as enacted by S.C. 1993, c. 2, s. 4].

[2] SOR/93/133, s. 6 [as am. by SOR/98-166, s. 5].

[3] C.R.C., c. 870, s. C.08.004 [as am. by SOR/95-411, s. 6].

[4] SmithKline application record, Vol. 1, Tab 10, paras. 19-22.

[5] SmithKline application record, Vol. 1, Tab 5.

[6] SmithKline application record, Vol. 1, Tabs 5 and 6.

[7] [1956-60] Ex. C.R. 467.

[8] (1993), 51 C.P.R. (3d) 329 (F.C.A.).

[9] (1998), 84 C.P.R. (3d) 23 (F.C.T.D.).

[10] (1994), 55 C.P.R. (3d) 302 (F.C.A.).

[11] [1981] 1 S.C.R. 504.

[12] (1982), 61 C.P.R. 1 (F.C.A.).

[13] (1994), 56 C.P.R. (3d) 470 (F.C.A.).

[14] [2000] 2 S.C.R. 1024.

[15] [2000] 2 S.C.R. 1067.

[16] SmithKline record, Vol. 3, Tab 43, p. 000406. (While the transcript of the cross-examination of Dr. Roman is covered by a confidentiality order in this proceeding, I am satisfied that no claim of confidentiality attaches to this particular aspect of the cross-examination.)

[17] (1998), 78 C.P.R. (3d) 489 (F.C.T.D.).

[18] (2000), 7 C.P.R. (4th) 272 (F.C.A.).

[19] [1982] 2 S.C.R. 536.

[20] (1986), 8 C.P.R. (3d) 289 (F.C.A.).

[21] (1997), 77 C.P.R. (3d) 547 (F.C.T.D.).

[22] (1991), 35 C.P.R. (3d) 350 (F.C.A.).

[23] *Supra*, note 14.

[24] *Supra*, note 20.

[25] (1998), 79 C.P.R. (3d) 193 (F.C.T.D.); judgment varied on appeal to the Federal Court of Appeal in a manner not relevant to the quotation here relied upon: [2001] 1 F.C. 495 leave to appeal to the Supreme of Canada granted: [2000] S.C.C.A. No. 610 (QL).

[26] (1995), 60 C.P.R. (3d) 58 (Ont. Gen. Div.), appeal by *Apotex* dismissed, cross-appeal by *Bayer* allowed on an issue not relevant to the portion of the reasons quoted here, (1998), 82 C.P.R. (3d) 526 (Ont. C.A.); leave to appeal to the Supreme Court of Canada denied, [1998] S.C.C.A. No. 563 (QL).

[27] Application record, Vol. 1, Tab 22.

[28] Definition ”invention" in s. 2 of the Act.

[29] *Supra*, note 11.

[30] (1988), 20 C.P.R. (3d) 132 (F.C.T.D.).

[31] (1891), 9 R.P.C. 49, at p. 56.

[32] (1999), 87 C.P.R. (3d) 271 (F.C.T.D.).

[33] (2001), 11 C.P.R. (4th) 538 (F.C.A.).

[34] [2001] F.C.J. No. 801 (QL); 2001 FCT 514 (T.D.).

[35] SOR/98-106.