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IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

Presumption of Infringement Under *Notice of Compliance Regulations* is Rebutted in the Absence of Any Evidence

The Federal Court, Trial Division, in a decision dated September 13, 2002, in *Wyeth-Ayerst Canada Inc et al. v. Faulding (Canada) Inc et al*, concluded that the presumption of infringement of process dependent product claims under the *Patented Medicines (Notice of Compliance) Regulations (Regulations)* is displaced by a Notice of Allegation (NOA) and detailed statement which, if assumed to be factually true, supports non-infringement. The Court found that the NOA and detailed statements rebutted the presumption even though the generic filed no evidence whatsoever.

In the case, Faulding alleged non-infringement of a patent directed to a freeze-dried penicillin derivative (piperacillin sodium) when prepared by a specified process. Faulding provided a detailed statement setting out a process to make its allegedly non-infringing piperacillin sodium product. Wyeth-Ayerst commenced a proceeding relying on the presumption of infringement under Subsection 6 (6) of the *Regulations*, which provides:

> 6(6) For the purposes of an application referred to in subsection (1) [request for order of prohibition], where a second person has made an allegation...[of non-infringement]...in respect of a patent and where that patent was granted for the medicine itself when prepared or produced by the methods or processes of manufacture particularly described and claimed or by their obvious chemical equivalents, it shall be considered that the drug proposed to be produced by the second person is, *in the absence of proof to the contrary*, prepared or produced by those methods or processes. [emphasis added]

Faulding filed no evidence whatsoever in support of its allegation. While the trial judge interpreted Subsection 6(6) to require "proof to the contrary", she found that this requirement was met by Faulding's NOA and detailed statement. The trial judge came to this conclusion, notwithstanding that Subsection 6(6) was introduced by amendment to the *Regulations* in 1998, and despite the Regulatory Impact Analysis Statement accompanying the amendment which discussed placing the burden of proof on manufacturers seeking to produce a generic version of a drug covered by a product-by-process patent. The Court relied on pre-1998 jurisprudence which directs that facts asserted by a generic in an allegation and detailed statement should be assumed to be true (see *Merck Frosst Canada Inc v. Canada (Minister of National Health and Welfare)* (1994), 55 C.P.R. (3d) 302 (F.C.A.)). The Court distinguished *Bayer Inc v. Canada (Minister of National Health and Welfare)* (2002) 6 C.P.R. (4th) 285 (F.C.A) which held that the statutory presumption of patent validity had the effect of displacing the burden of proof, so as to require the generic to prove, by evidence, patent invalidity on a balance of probabilities. The Court noted that *Bayer* was limited to the presumption of validity and did not address the presumption of infringement. The judge stated:

> Applying the presumption of subsection 6(6), the drug proposed to be produced by the second person is, in the absence of proof to the contrary, prepared or produced by that method or process. Faulding has served and filed an NOA and detailed statement. The law is settled that the facts advanced by a second person in support of a notice of allegation are presumed to be true...

> Thus, I find that, for purposes of subsection 6(6), the NOA and detailed statement constitute proof to the contrary, in situations where, as here, it is clear from the NOA and detailed statement that the second person proposes to manufacture a medicine by a process not covered by the claims and therefore outside the scope of the patent...
>
> In my view, this construction best attains the purpose and intent of the Regulations specified to be: reducing unnecessary litigation and streamlining the process...
>
> I have determined that, in the present circumstances, Faulding's NOA and detailed statement constitute proof to the contrary for the purposes of the presumption in subsection 6(6) of the Regulations. The only evidence relating to the issue of infringement is Faulding's. That evidence must therefore be put into balance against the evidence of the applicants, which is no evidence at all.

This decision is of importance to pharmaceutical patentees, in respect of process dependent product claims, since it supports a generic being able to overcome the presumption of infringement by a factual assertion alone, in the absence of any evidence. Since a generic cannot be compelled to provide evidence, patentees will be forced to compel disclosure of the generic's regulatory information by way of a motion under Subsection 6(7) of the *Regulations*. In the absence of successfully compelling the disclosure, a patentee cannot succeed. The effect of this decision is that the presumption of infringement under the *Regulations* is redundant and has been effectively read out of the *Regulations*, providing no assistance whatsoever to pharmaceutical patentees.

Gunars A. Gaikis

Supreme Court of Canada Hearings

Smithkline Beecham Pharma Inc v. Apotex Inc (**paroxetine hydrochloride tablets** (**PAXIL**)), August 27, 2002

On August 27, 2002, Smithkline Beeham filed an application seeking leave to appeal the decision of the Federal Court of Appeal finding its formulation patent for paroxetine hydrochloride tablets invalid. The decision of the Court of Appeal was reported in the July 2002 issue of *Rx IP Update.*

Apotex Inc v. Merck Inc (**enalapril maleate** (**VASOTEC**)), August 27, 2002

On August 27, 2002, Apotex filed an application seeking leave to appeal the decision of the Federal Court of Appeal finding Apotex liable for patent infringement based on a prior finding of patent infringement (*res judicata* applied). The decision of the Court of Appeal was reported in the July 2002 issue of *Rx IP Update*.

Recent Court Decisions

Regulations

Bayer v. Apotex, August 22, 2002

Apotex received a Letter of Deficiencies from the Minister of Health, rejecting Apotex' submission for a Notice of Compliance (NOC). The patentee sought production of the Letter of Deficiencies in the corresponding prohibition proceeding. Production was denied: the *Regulations* impose no obligation on a generic to provide a patentee with a Letter of Deficiencies.

Full Judgment

Toba Pharma Inc v. Minister of Health (**sevoflurane** (**EVOTANE**)), September 3, 2002

Applicant unsuccessful in having Minister's decision refusing to add a patent to the patent register set aside. The Applicant missed the deadlines set forth under the *Regulations* for filing a patent list as against a new drug submission (NDS). A supplemental NDS (SNDS) was then filed, where only the manufacturer's name and brand name were changed, along with a patent list. The Court found that the timing requirements under the *Regulations* cannot be circumvented by filing an SNDS changing only the manufacturer's name and product name.

Full Judgment

AB Hassle v. Apotex (**omeprazole and omeprazole magnesium** (**LOSEC**)), September 4, 2002

The Minister was prohibited from issuing an NOC since the purported NOA did not constitute an NOA under the *Regulations*. A key factual issue in the case was the existence of a sub-coating in Apotex' tablets. The patentee could not respond to the allegation of non-infringement without samples. Apotex did not furnish samples and accordingly the Court found that the NOA was not sufficiently detailed or complete, failing to comply with the *Regulations*.

Full Judgment

Wyeth-Ayerst v. Faulding (**piperacillin sodium** (**PIPERACIL**)), September 13, 2002

Prohibition denied on the basis that the presumption of infringement was rebutted by facts set forth in the NOA and Detailed Statement. Under the *Regulations*, there is a presumption that process dependent product claims are infringed absent proof to the contrary. For more information, please see the article on page 1 of this issue.

Full Judgment

In the Matter of a Reference by the Minister of Health under Subsection 18.3(1) of the Federal Court Act regarding a Question as to the Application of Section 4 of the Patented Medicines (Notice of Compliance) Regulations (olanzapine (ZYPREXA)), September 25, 2002.

This judgment is the appeal of a decision striking the Minister of Health's application ("Reference") respecting a question of interpretation of the timing and relevance of listing a patent on a patent list under the *Regulations*. The Minister's appeal was dismissed and the Reference remains struck on the basis that the factual underpinning of the Reference was in dispute and so the Court was not in a position to decide the issues raised. Details of the lower level decision can be found in the June 2002 issue of *Rx IP Update.*

Full Judgment (Trial Division)

New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine: **paroxetine (GEN-PAROXETINE)**
Applicant: Genpharm Inc
Respondents: The Attorney General of Canada and Health Canada
Date Commenced: August 29, 2002
Comment: Genpharm seeks review of a decision by the Therapeutic Products Directorate that the "proposed drug substance used for Gen-Paroxetine is an isopropyl alcohol solvate that is not identical to Paroxetine hydrochloride hemihydrate" (the Canadian reference product). Genpharm seeks a declaration that its proposed drug substance is "pharmaceutically equivalent" and identical to the product used in the "Canadian Reference Product" as those terms are defined in C.08.001.1 of the *Food and Drug Regulations*.

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