Bristol-Myers Squibb Co. v. F.H. Faulding & Co. Ltd., FCA 316, 170 ALR 439 (2000)

(The Federal Court of Australia, Melbourne, 22 March 2000)

Prepared by UNCTAD's Intellectual Property Unit

Summary

In this case, the Australian Federal Court addressed the patentability of methods of treatment of the human body, how novelty can be destroyed and what amounts to secondary infringement.

The facts

Since its first extraction from the bark of the Pacific Yew, taxol had been known, for about three decades before this case, to have anti-carcinogenic properties. Its use was, however, complicated due to the fact that it is highly toxic, producing hypersensitivity reactions. Taxol was administered in a 24-hour infusion time with premedication in a clinical environment. Bristol-Myers Squibb (BMS) developed taxol with specific ranges of dosage, for administration within shorter periods of time with the reduction of its side effects. This case concerns its two petty patents – otherwise known as 'utility models' – for methods of administering taxol dated 30 September 1993 and 14 July 1994, and expiring on 29 January 1999 and 15 December 1999, respectively.

F.H. Faulding Co – a generic drug manufacturer – arranged two clinical trials in Australia in 1992 and two further clinical trials in 1994 in which taxol was administered under a clinical trial protocol that prescribed the dosage and methods of administration. Since 23 January 1995, F.H. Faulding sold and supplied taxol to doctors and hospitals in Australia, together with a product information guide providing details as to premedication, the dosage of taxol and the method of administration. BMS claimed F.H. Faulding infringed both petty patents. F.H. Faulding, by cross-claim, sought orders that the patents be revoked on the grounds, *inter alia*, that they disclosed no invention, that the alleged invention lacked novelty and that the claims were not fairly based on its specifications.

The primary judge (hereinafter the trial judge), in a decision issued in 1998, upheld the cross-claims, holding that each patent was invalid on each of the grounds presented by F.H. Faulding. The Australian Patent Act, 1990, does not specifically preclude methods of treatment from patentability. Section 18 (1) of the Act provides for the availability of patent protection for an invention that is a manner of manufacture within the meaning of the Statute of Monopolies (1623). The Statute of Monopolies prevents patents for those inventions that are contrary to the law, mischievous to the State, hurt of trade, or are generally inconvenient. According to the trial judge the petty patents were for a method of medical treatment of the human body and thus 'generally inconvenient' in accordance with earlier judicial decision. This decision was appealed to the Federal Court of Australia (hereinafter the Court).

The legal issues

The main legal issues concern the patentability of methods of treatment of a human body, novelty, scope of claims and acts of infringement. The Court considering the appeal ruled on each issue:

1. *Patentability of method of treatment:* The Court relied on its finding of a clear preponderance of opinion of judges at appellate level in favour of the patentability of methods of medical treatment of the human body and rejected the trial judge's conclusion for two reasons. First from a public policy viewpoint, the court rejected drawing a distinction which would justify allowing patentability for a *product* for treating the human body but denying patentability for a *method* of treatment. If an antivenom for spider bite is patentable, on what ground, the Court asked, can a new form of treatment for the same life-threatening bite be denied? Secondly, the Court considered a compelling factor that Parliament gave limited consideration to the issue during the enactment of the Patent Act, at a time when patents on methods of treatment were being granted.

2. *Novelty:* For a petty patent, the prior art includes information in a document publicly available anywhere in Australia. The trial judge held that seven documents on various clinical trials concerning taxol, all available in Australia before the priority date, deprived the claimed invention of novelty. According to the Court, the substantial question, however, is whether the mere disclosure in the course of the clinical trials deprived the claimed invention of novelty. In the view of the Court a prior publication, if it is to destroy novelty, must give a direction or make a recommendation or suggestion which will result, if the skilled reader follows it, in the claimed invention. Each of the patent claims involved a particular regimen for the infusion of taxol. Each of the clinical trials reported in the prior art was an investigation directed, particularly, to ascertaining safe dosage levels but none of the reports could be said to teach that which the petty patents claim. Instead, the Court turned to an abstract, which was also published in Australia, by a research of the Netherlands Cancer Institute, Amsterdam, with respect to a clinical trial testing the feasibility of the dosage and duration of infusion for taxol as it was claimed in the patent. Prudent practitioners might well take the view that they would prefer to await the final outcome of the trials before rushing to embrace the proposed method in the abstract. But, in the Court's view, there could be no serious doubt that the abstract taught the shorter infusion period, with premedication, as a treatment of cancer. The necessary consequence was that the claimed invention lacked novelty – not because of the clinical trials, but because of the published research abstract.

3. Claims construction: According to the Patent Act, the claims in a patent application must be fairly based on the matter described in the specification. The trial judge found several inconsistencies, including the fact that the claim was for a method of administration to patients suffering from any form of cancer; but the specification described a trial that involved patients suffering from one form of cancer only. The Court added to the list of discrepancies that the claims covered infusion of taxol through any vehicle and with or without premedication, whereas the specification described only one infusion vehicle, with premedication. The Court concluded that the claims travelled beyond the matter disclosed in the specification.

4. *Infringement*: The trial judge held that even if the claims had been valid they would not have been infringed, since there is no evidence that F.H. Faulding itself had administered

taxol to cancer patients in the dosages and over the periods referred to in the claims, or indeed at all. The trial judge interpreted the term 'authorise' among the rights of patent holders as giving authority or legal power. In this case, F.H. Faulding was supplying taxol to doctors and hospitals, with instructions on methods of administration. The accompanying instructions were no more than recommendations that the recipients were free to follow or not. The Court disagreed. It held that the term 'authorise' includes countenance and means to sanction or approve. It gave credit to a report of the Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia*, 1984, that dealt with contributory infringement, as follows:

> *We believe that it would be far more effective, realistic and just for the patentee to be able to take action against the supplier or middleman who facilitates the commission of the infringing act by the ultimate consumer. The most common example of indirect, secondary or contributory infringement is where goods, materials or parts are supplied to a consumer with the intention that they be used, consumed or assembled in a way which constitutes an infringement of a patent. The intention might be evident, for example, from the provision of brochures containing instructions on how to make a product or use a process which would infringe a patent, or by advertisements soliciting the commission of an act which would infringe."*[1]

The legislative history of the relevant provision of the Patent Act revealed that it was intended to give effect to the Committee's recommendations on contributory infringement. The Court concluded that, assuming validity of the petty patents, infringement is established, both in relation to taxol supplied with the product information guide and to taxol supplied for the purposes of the clinical trials.

Points of Significance

- The TRIPS Agreement in Article 27.3(a) provides that Members may exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals. The rationale behind this authorization is to immunize physicians in their every-day work from claims of patent infringement. Depending on national law, the petty patents at hand could also have been rejected for claiming a method of treatment of the human body.
- This is what happened in the United Kingdom, where BMS was also challenged on the validity of the same patents. The UK Court of Appeal found the patents invalid for lack of novelty, among others. Unlike the Australian court, the UK court also rejected the patent on the ground that the claims were basically claims for a medical treatment. The latter are excluded from patentability in the UK. (See Bristol-Myers Squibb Co. v. Baker Norton Pharmaceuticals Inc, Court Of Appeal, London, Case No: 98/1390/A3, 98/7637/A3, May 2000**).**

[1] Paragraph 93 of the decision.

- The claims in a patent must be supported in the patent specification and may not reach beyond what is described in the specification. This obligation results from the requirement in Article 29.1 TRIPS to disclose the patented invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art.
- Novelty can be destroyed if a prior publication gives a direction or makes a recommendation or suggestion which will result, if the skilled reader follows it, in the claimed invention, but not simply because a prior publication investigates in the same problem and solution that the patent claims cover.
- Indirect, secondary or contributory infringement takes place where goods, materials or parts are supplied to a consumer with the intention that they be used, consumed or assembled in a way which constitutes an infringement of a patent.

Key words: Patentability; methods of treatment; novelty; indirect infringement; contributory infringement; claims construction.

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