ASPECTS OF TESTING INVOLVING PATENTED HERBICIDES; MONSANTO v STAUFFER

P.C. DENGATE THRUSH

P.O. Box 852, Wellington

SUMMARY

In 1982 and 1983 Stauffer Chemical Company was conducting field trials and field experiments on a new herbicide, the active ingredient of which was allied to phosphonomethyl glycine. Monsanto, the makers of glyphosate, took exception to these trials claiming (a) that the Stauffer product fell within the claims of a Monsanto patent, and (b) that the trials were not experimental but commercial. Without determining the infringement question, the court upheld Monsanto's claim, finding Stauffer was deriving commercial advantage from the tests, and granted an injunction. In this and related English proceedings important distinctions are set out as to what is legitimate and illegitimate testing during the life of a patent. A comment is made on an amendment to the Pesticides Act.

HISTORY

In a dispute about phosphonomethyl glycine, the law relating to testing of herbicides was critically examined for what is believed to be the first time in New Zealand.

Phosphonomethyl glycine in the form of its isopropyl amine salt in water was the basis for Monsanto's phenomenally successful glyphosate (Roundup) herbicide.

Phosphonomethyl glycine was not a Monsanto discovery — curiously it was a Stauffer chemist by the name of Toy who first referred to it in the United States Patent 3,160,632, filed in the United States on January 30, 1961. The patent covers aminomethylenephosphonic acids and was looking at their uses as chelating agents, wetting agents and chemical intermediates. Tucked away as example 14 was an example which, almost inadvertently, produced phosphonomethyl glycine. However, its usefulness as a herbicide was not recognised. This was left to Monsanto, who eventually obtained a patent in New Zealand, 165252, dated 22 October 1971.

Monsanto's main claim in New Zealand was to a compound which included a salt forming cation. For reasons which have not yet been fully explained, the nature of this cation was required to be selected from a group, apparently carefully drafted, so as to include "cations of alkali metals, alkaline earth metals, copper, zinc, manganese, nickel, ammonium and organic ammonium." (The latter was subject to some provisos, irrelevant for present purposes).

Monsanto had further claims to examples of specific compounds incorporating these specific cations, and also claims to herbicidal compositions containing any of these compounds together with adjuvants and other herbicides.

Glyphosate was, and is enormously successful, and represented a huge commercial success for Monsanto. Other companies, naturally interested in such a successful product, investigated related compounds, and tested them for their efficacy. Stauffer Chemical Company, for whom the author acted, developed a compound which utilized as its cation a trimethylsulphonium salt. Stauffer plainly took the view, and argued it in open court, that a sulphur based compound was simply not one of the named groups of compounds which Monsanto had laid claim to.

Stauffer applied for a patent in New Zealand for its own product, and commenced trials, eventually obtaining an experimental use permit. At your conference, a paper was presented by Rahman *et al* (1983) comparing the activities of several New Zealand herbicides, Stauffer's product amongst them. Monsanto representatives were at that

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conference. Investigations by Monsanto revealed that other trials involving Stauffer's product were occurring, and Monsanto formed the view, eventually, that Stauffer was planning to obtain limited sales registration, and eventually launch its product.

LITIGATION

In January 1984 Monsanto applied to the High Court claiming infringement of its patent, and seeking an interim injunction to prevent Stauffer from conducting any further trials, or making any sales of its product.

Because an interim injunction was sought, the court never fully considered the question of whether Stauffer's product actually infringed. That is a matter requiring detailed chemical evidence, and cross examination of witnesses. For an interim injunction, the court had to be satisfied that rather than actual infringement, there was merely a serious question of infringement.

Stauffer argued first, that its product was clearly not covered by the claims, and second, that bona fide testing did not amount to an infringement.

For reasons which I will not go into now, the court accepted that there was a serious question of infringement, and moved on to the second point, namely whether Stauffer's activity in conducting field trials and other tests constituted an infringement.

It had been known since at least 1878, that an act, which would otherwise infringe a patent, would not do so if it was done for experimental purposes (see: *Frearson v Loe* [1878] 9 CHD 48). In that case, the judge said: "Patent rights were never granted to prevent persons of ingenuity exercising their talents in a fair way. But if there had been neither using nor vending of the invention for profit, the mere making for the purpose of experiment, and not for a fraudulent purpose, ought not to be considered within the meaning of the prohibition..."

It seemed clear, during pre-trial investigations, that the industry attitude toward testing in New Zealand was that testing of products did not infringe a patent. Stauffer also had its own patent application for its product, and claimed to be entitled to continue testing and experimenting with its product under its Pesticides Board licence.

Monsanto argued that Stauffer's testing was designed to permit it to launch its product commercially in New Zealand which, if it took place during the term of the Monsanto patent, would be an infringement. Monsanto also argued that if Stauffer conceded that theirs was an infringing product, at the expiry of the Monsanto patent (due to occur in October 1987) Stauffer would have obtained a market advantage by conducting its trials for commercial purposes during the term of the patent.

The court accepted that there was a doctrine of permitted experimental use of the "Frearson and Loe" type, but held that Stauffer's activities were not the taking of a patented item for the purpose of seeing whether it could be improved upon by way of testing, and trying to see whether something better could be invented. The judge held that Stauffer's field trials in New Zealand: "... all appear to me to point in the direction that the defendants have gone well past the demarcation line of permitted experimental use.... The time when the defendants may have been regarded as carrying out experiments of the permitted type must have long gone by."

He also approved earlier cases, in which it had been decided that possession of an infringing article for "trade purposes" or for "some deriving an advantage from the patent", had constituted infringement. In addition, he thought that Stauffer's activities in supplying potential customers, albeit primarily for the purposes of conducting tests, was analogous to similar cases which clearly amounted to infringement.

The question then is: Where does the demarcation line of permitted experimental use actually lie?

In a later passage in his judgment the judge set out a guide to the answer when he said: "I need not decide the status of trials carried out in the privacy of the defendant's own premises, which in any event could not be policed. Here, in the view that I have formed of the facts, the field trials are designed to obtain data necessary to achieve permission for commercial use in New Zealand. Even if initially that is only in the form of limited sales they are sales nevertheless, and the stepping stone towards a full commercial launch. Further, for the reasons already given, at the same time the defendants are able to tout SCO224 (Stauffer's product) to potential customers and to

make the community of ultimate users in this country aware of the existence and efficacy of their product, albeit as something not available until some future date. Such use, to my mind, clearly falls within the ambit of use for deriving of commercial advantage, and as such infringes the plaintiff's monopoly.'

New Zealand was not the only battleground between these protagonists. Because of the different regulations relating to testing in force, Stauffer had already launched its product in the United Kingdom when Monsanto applied for an injunction there. The Court of Appeal upheld the injunction, but returned the matter to the High Court to determine whether any of the trials proposed in the United Kingdom could be continued in the face of the injunction. The case was under new British legislation which included an explicit defence to infringement, where the act complained of was done "for experimental purposes relating to the subject matter of the invention". The trial judge declined to vary the original injunction (i.e. refused to permit any trials). Stauffer appealed again to the Court of Appeal.

The Court of Appeal declined to hold that the definition: "Relating to the subject matter of the invention" ought to be so narrowly construed as to exclude experiments directed to commercial exploitation.

The court (realistically in my view), realised that experiments will often have a commercial end in view, as do all the activities of companies in this field. Accordingly, the Court of Appeal modified the injunction so that it did not extend to acts done for experimental purposes relating to the subject matter of the invention in laboratories or glass houses in the United Kingdom, or on the defendant's own farms.

However, in relation to other types of testing, namely trials to be carried out by the defendant's personnel on land rented on other farms, and trials by third parties (which included a Forestry Commission), the judge found that these were not trials directed to finding out anything about the invention, but rather to demonstrate its efficacy to other parties for commercial advantage.

Although New Zealand had no specific definition in the law as was being considered in the English cases, the New Zealand decision, including the passage quoted above was approved in the English cases, and it seems likely that the United Kingdom Court of Appeal decision would be adopted in New Zealand. Testing other than in the conditions specifically approved above should be undertaken only with caution, and after taking the appropriate legal advice.

PESTICIDES AMENDMENT ACT 1987

In a further legal development relating to pesticides, the Pesticides Act has been amended by an amending Act which came into force earlier this year.

The principal amendment is in Section 4 which repealed the original Section 21.

Section 21 of the 1979 Act reads as follows:

"Pesticides are not to be sold unless registered:

(1) No proprietor of any pesticide shall sell, or apply for reward, the pesticide unless it is registered in accordance with this part of the Act or the sale or application of that pesticide by him is authorised by an experimental use permit issued by the Board under Section 25 of this Act.

(2) Every proprietor of a pesticide who sells or applies that pesticide in contravention of sub-section (1) of this Section commits an offence against this Act."

The amendment significantly dilutes requirements, and may now permit use of a pesticide within New Zealand without the need for the proprietor of the pesticide to go through the rigorous and long term approval procedures previously required under the Pesticides Act. Now the proprietor of a pesticide may be authorised by the Board to import a pesticide which has the same formulation as that of a registered product, providing it is obtained from a country which is authorised by the Minister, and satisfies certain labelling requirements. The authorisation of the proprietor is to import the pesticide for use by that proprietor on land owned or occupied by him.

How the Act is to be interpreted, is not yet clear. A serious problem may arise when the active pesticide or the particular formulation is the subject of patent protection. The Amendment Act permits the Board to authorise importation and use of the pesticide, but makes no mention of any rights conferred under patents covering the pesticide. If it

was the legislative intention to cover all pesticides, at the expense of the patentee's rights, then the new provisions might well permit individual companies or people to import a pesticide and use it on their own land even when that product is patented. However, the better view is that, as previously, Board approval is subject to any existing rights.

The consequences upon the pricing structure of patented herbicides may well be significant. It is well known that there are substantial initial research and development costs in finding any successful product, and, in this industry, long term and expensive testing and health clearances are required before sales can be made. The time taken to achieve a marketable product can be up to 5 to 10 years from an initial discovery. These costs are inevitably reflected in the sale price to provide some return to the discoverer of the product. It is no real surprise that a second company which does not invest in research can supply the same product at a much lower cost.

REFERENCES

- Rahman, A., James, T.K. and Mortimer, J., 1983. A comparison of post-emergence herbicides for control of grass weeds. *Proc. 36th N.Z. Weed and Pest Control Conf.*: 269-271.