***Elan Transdermal Ltd v Ciba Geigy (PTY) Ltd* 1994 BP 1**
(Court of the Commissioner of Patents, South Africa)

Prepared by UNCTAD's Intellectual Property Unit

Case summary

The Court of the Commissioner of Patents in this decision focused on two main issues: (1) the protection of new medical uses of known products under South African patent law and (2) the requirements for prior art to destroy novelty by anticipation.

The facts

The plaintiff, Elan, was granted a patent in 1987 on the use of nicotine patches to combat nicotine dependence. The defendant, Ciba Geigy (PTY), imported similar nicotine patches into South African territory during the term of the patent. Elan sued Ciba Geigy (PTY) for patent infringement. The defendant in defense argued lack of validity of the patent due to (1) use of a form of claims not authorized under South African patent law and (2) lack of novelty and inventive step of the claimed invention. It was undisputed among the parties that the claimed percutaneous administration of nicotine was not the first time nicotine was employed to fight dependence. There had been other methods before, including percutaneous applications.

The dispute for both alleged infringement and invalidity focused on Claims 52 and 54 of the patent specification, which read as follows:

> "52. Use of nicotine for the manufacture of a medicament for use in the once daily percutaneous administration of nicotine in a manner for the treatment of withdrawal symptoms associated with smoking cessation, and in which the nicotine is administered in an amount sufficient to maintain plasma levels of nicotine substantially equivalent to trough plasma levels resulting from intimate smoking."

Claim 54 was similar but addressed the use of nicotine to treat the psychological dependence caused by smoking. The defendant argued that the claims mainly contained directions for medical treatment and were therefore excluded from patentability under Section 25(11) of the South African Patents Act. Section 25(9) only allows the patentability of first medical uses of known substances, while the percutaneous administration of nicotine in this case was not the first medical use of nicotine. The plaintiff argued that the claims related mainly to a method of manufacturing and were therefore allowed under the "Swiss claims" form.

On novelty, the defendant invoked various prior art references in the transdermal use of nicotine to fight dependence. In the defendant's view these references anticipated the claimed invention, which thus lacked novelty. It was undisputed among the parties that none of these prior art references contained all of the elements cited in the plaintiff's patent. The defendant argued that the prior art nevertheless provided clarity on the concept of the claimed invention, which in its view was sufficient to destroy novelty through anticipation. The defendant also relied on the asserted minor difference between the claimed invention and the prior art to challenge the inventive character of the claimed invention. The defendant in this context argued that all separate prior art references if combined into a mosaic would clearly enable an expert skilled in the art to develop the claimed invention.

The legal issues

The court first explained the approach under South African patent law to new uses of known substances. Section 25(9) allows their patentability, but only to the extent that a first new use is claimed. Subsequent uses even if novel may not be patented under that Section, due to its broad reference to a new use in "any such method" of medical treatment. In order to enable the patenting of second, third and subsequent new uses, the Court referred to the concept of "Swiss claims" as practiced *inter alia* in the United Kingdom at that time. Accordingly, subsequent new uses of known products may be claimed if they are not drafted as method of *use* claims, but as methods of *manufacture*, along the lines of Claim 52, above. The court in this context rejected the defendant's view that parts of the disputed claims were more related to a method of medical treatment than a method of manufacture. The court stated that the medical directions in the claims did not alter the overall character of the claims as being related to the manufacture of a drug for the treatment of nicotine dependence.

On novelty, the court insisted that anticipation through prior art is only possible where the prior art contains all of the elements of the claimed invention. The court rejected the defendant's view that the concept of the invention was clear from the prior art, which would suffice for anticipation. The court countered that in that case the claimed invention would need to be so self-evident as to require no further explanation, and denied this possibility.

On obviousness, the court assessed the difference between the prior art and the claimed invention as sufficiently important to constitute a step of inventive character. According to the court, "it was the inventor's appreciation of the problem which at the very least was the maintenance of trough and plasma levels and the means giving effect to that appreciation, which provided that scintilla of invention justifying the grant of a patent." The court in this context expressed the view that a mosaic view of the prior art would not alter its assessment of inventive step in this case.

Overall, the court confirmed the validity of claims 52 and 54 of the patent and their infringement by the defendant.

Points of significance

- The court clearly distinguished between first and subsequent new uses of known products. First medical use patents are expressly allowed as process claims under Section 25(9) of the South African Patents Act. The language of that provision does not allow the patenting of subsequent uses. The court in this context has recourse to the "Swiss" claims format, which somewhat artificially shifts the focus of the claims from the method of use to a method of manufacture. This is an important case of creative interpretation of patent claims that almost entirely focuses on the desired policy outcome, i.e. to provide patent protection for new medical uses. In this context, the court's observation that the medical directions in the disputed claims do not change the overall character of the invention as a method of manufacture is coherent with the court's acceptance of the Swiss claims format. It appears nevertheless artificial, as the true focus of the disputed claims *in casu* and of Swiss claims in general is not a method of manufacture, but a method of treatment. The European Patent Convention has recently been amended by expressly providing for the patentability of subsequent new uses of known products,[1] making the recourse to the unconvincing Swiss claims format superfluous.

[1] Article 54(5), EPC.

- The TRIPS Agreement contains no express obligation to make patents available for new uses of known products.
- From an access to medicines perspective, Swiss claims for new medical uses may be problematic. In order to come to a finding of patent infringement, an accused activity would need to meet both integers of the Swiss claim, i.e. (1) use in the manufacture of a product (2) for the claimed indication. Integer (2) has been interpreted in South Africa as not requiring any knowledge on the part of the accused infringer.[2] Thus a generic producer that makes a generic copy of a drug for an indication that has gone off-patent may be liable for infringing a patent on a subsequent indication if the generic copy may also be used to treat the subsequent indication, even where the generic producer has no knowledge in that respect. This approach may considerably facilitate a finding of patent infringement and thus provide injunctive relief to patent holders in situations where foreign courts would deny infringement. By way of comparison, the England and Wales Court of Appeal has held that for an infringement of a Swiss claim, it is required that the alleged infringer has the knowledge/can foresee that others will intentionally use the drug for the patented indication.[3] Courts in South Africa are not required to waive the knowledge requirement to affirm infringement by a non-authorized party. Courts would be free to treat infringement of medical uses similarly to the England and Wales Court of Appeal to provide generic producers with more legal certainty on their activities.
- The court applied a strict approach to anticipation, requiring that all elements of the disputed patent must be present in the prior art.
- The decision remains very brief on inventive step. Considering the multiple prior art, the question if the maintenance of trough and plasma levels through the application of nicotine patches is non-obvious may have merited a more substantial analysis. A mosaic view of the prior art would have been useful. By way of comparison, the US Supreme Court decision in *KSR International v Teleflex* from 2007[4] stressed the importance of combining separate prior art references to a mosaic to avoid the granting of patents for trivial inventions. The policy rationale behind this decision was the need to maintain patent quality for the promotion of genuine innovation.

Key words

New use patents, Swiss claims, method of treatment, method of manufacture, novelty, anticipation, prior art, inventive step, obviousness.

Link: Link to digital version of the original decision not available. The case is cited in Bromine Compounds Limited v Buckman Laboratories (Pty) Ltd (92/4018) [2006] ZACCP 1 (12 September 2006), available at http://www.saflii.org/za/cases/ZACCP/2006/1.html.

[2] See South African Group response to Question Q238 of the International Association for the Protection of Intellectual Property (AIPPI) on South African law and practice, 1 April 2014, Response 5 c). Available at http://aippi.org/wp-content/uploads/committees/238/GR238south_africa.pdf

[3] *Warner-Lambert Company, LLC v (1) Actavis Group PTC EHF (2) Actavis UK Limited (3) Caduceus Pharma Limited*, 28 May 2015 (England and Wales Court of Appeal). Available in this database.

[4] *KSR International Co. v. Teleflex Inc. et al.,* 550 U.S. (2007), Supreme Court of the United States. Available in this database.