***Pharma Dynamics (Pty) Ltd v. Bayer Pharma AG*, 2014**

(The Supreme Court of Appeals of South Africa)

Prepared by UNCTAD's Intellectual Property Unit

Case summary

In this case, the Supreme Court of Appeals interpreted the claims of a pharmaceutical divisional patent and examined its novelty and inventive step. The Court also provided guidance on the admissibility of divisional patents under South African law.

The facts

In 2002, Bayer AG filed an application in South Africa for a pharmaceutical combination comprising ethinylestradiol (EE) and drospirenone (DSP) for use as a contraceptive by way of rapid dissolution, i.e. a pharmaceutical product unprotected by an enteric coating ("the 2002 patent"). The priority date of the 2002 patent was ante-dated to 31 August 1999. In 2004 Bayer AG filed an application for a divisional patent, based on the 2002 patent application ("the 2004 patent"), under the name of "Yasmin". This happened prior to the granting of the 2002 patent. As its parent patent, the priority date of the 2004 patent was ante-dated to 31 August 1999. Both patents relied on the unexpected effect of high dissolution DSP on the human body. *In vitro* tests had indicated the need to cover the contraceptive with an enteric coating to protect it from acids in the stomach. By contrast, *in vivo* tests surprisingly showed that without coating the contraceptive would show a good degree of bioavailability while at the same time avoiding certain therapeutic disadvantages caused by an enteric coating. The 2002 patent was specific on how to achieve high dissolution DSP by claiming DSP in micronized form or alternatively sprayed from a solution to achieve rapid dissolution in the human body. The 2004 patent in its specification[1] disclosed that the composition could be formulated in any manner known in the pharmaceutical art and referred "in particular" to the two methods claimed in the 2002 patent.[2] The 2004 patent also contained, in its claims section, a detailed definition of what constitutes a high resolution rate of DSP.

In 2011, Pharma Dynamics received regulatory approval to market in South Africa a generic copy of Bayer's Yasmin named "Ruby". Ruby contains highly soluble EE and DSP as claimed under the 2002 and 2004 patents. By contrast, Ruby does not achieve the high dissolution rate through the particular means expressly mentioned in the 2004 patent disclosure, but through an alternative process. Bayer sued Pharma Dynamics for infringement of the 2004 divisional patent.

[1] The specification is the part of the patent document that describes or discloses the invention. It precedes the claims and serves the purpose of further explaining them. The specification therefore provides an important source of interpretation for the judge when construing the scope of a patent claim.

[2] See Paragraph 29 of the decision.

Bayer contended that its 2004 patent claimed all possible means of achieving a high dissolution rate, including the means employed by Pharma Dynamics. According to the claimant, the inventive core of the 2004 patent was that against all expectations from *in vitro* tests, using DSP in rapidly dissolving form (normally meaning an increased risk of destruction by the stomach acids) would nevertheless result in good bioavailability in the patient's intestine in *in vivo* tests, no matter how rapid dissolution was achieved. By contrast, the defendant argued that the claimed inventive core related to the fact that rapid dissolution could be achieved *in vitro* through one of the methods specifically referred to in the 2004 patent disclosure, i.e. DSP in micronized form or alternatively sprayed from a solution. Accordingly, its generic copy would fall outside the scope of the 2004 patent. In addition, the defendant claimed obviousness of the 2004 patent, based on the view that despite the results of the *in vitro* tests, an expert skilled in the art would have performed *in vivo* tests comparing the results of coated and uncoated DSP as a matter of routine and would thus have discovered at early stage the good bioavailability results of uncoated DSP. According to the defendant, it was obvious to try in vivo testing. Finally, the defendant argued that the 2004 patent was not a true divisional patent, as it did not meet the requirements under Section 37(1) of the South African Patents Act. The latter provides that:

> "(1) Where at any time after an application has been lodged at the patent office and before it is accepted, a fresh application is made in the prescribed manner by the same applicant in respect of part of the matter disclosed in the first-mentioned application, the registrar may, on application made to him in the prescribed manner before that application is accepted, direct that fresh application to be ante-dated to a date not earlier than the date on which the first-mentioned application was so lodged.
>
> (2) A patent granted on such fresh application shall not be revoked or invalidated on the ground only that the invention claimed in such fresh application is not new having regard to the matter disclosed in the first-mentioned application."

Based on its interpretation of the patent claims, the defendant argued that the claims under the 2002 and 2004 patents were the same, both referring to the same two methods of *in vitro* rapid dissolution of DSP. Alternatively, the defendant expressed the view that in case the Court considered the 2004 claims as broader than the 2002 claims, this would not meet the requirements under Section 37(1) of the South African Patents Act as quoted above. Accordingly, this provision would require divisional patents to have narrower claims than the parent patent ("… a fresh application is made … in respect of part of the matter disclosed…").

The legal issues

The Court first addressed the issue of infringement, i.e. the question of whether the defendant's product fell within the claims of the plaintiff's product patent. For that purpose, the Court construed the claims of the 2004 patent. It rejected the defendant's view by noting that what the defendant considered the inventive core was well known to an expert skilled in the art at the time

of filing the patent application.[3] The Court agreed with the plaintiff that the claims had to be construed as covering the pharmaceutical combination in high dissolution which, against all expectations from *in vitro* trials, nevertheless resulted in good bioavailability *in vivo*. In the Court's view, the claims covered any method of achieving high dissolution, thus including the method employed by the defendant. Consequently, the Court confirmed infringement of the 2004 patent by the defendant.[4]

On inventive step, the Court rejected the defendant's view that conducting *in vivo* trials was a matter of routine. First, the Court accepted the defendant's argument that there was prior art research on a similar case, where *in vivo* tests were conducted as a matter of routine. But the Court observed that in that particular case, the *in vivo* tests had confirmed the *in vitro* tests, and thus actually taught away from the use of *in vivo* testing in comparable cases.[5] Importantly, the Court observed that it would not make sense for a person skilled in the art to carry out *in vitro* tests and then ignore their results to embark on time consuming and costly *in vivo* testing.[6] The Court also noted that for the *in vivo* testing to be obvious to try, an expert skilled in the art would need to consider *in vivo* testing as reasonably leading to some useful results - which in light of the *in vitro* results was not the case in the Court's view.[7]

Finally, on novelty, the Court rejected the defendant's view that the 2002 patent already disclosed the substance of the 2004 patent, thereby depriving the latter of its novelty. Based on its construction of the claims for the 2004 patent, the Court stated that the claims under that patent were broader than those under the 2002 patent in that they referred to all possible methods of rapidly dissolving DSP. The Court then noted that under Section 37 of the Patents Act, the claims of a divisional patent may be broader than the parent claims, as long as the claims in the divisional patent are fully disclosed in the parent patent. As opposed to the view expressed by the defendant, what mattered under Section 37 was not a comparison of the claims, but between the specification of the invention in the parent patent and the claims in the divisional patent. The 2002 specification disclosed a pharmaceutical composition with two active ingredients, which is used in quick dissolution format. The 2004 claims did not go beyond this disclosure (but merely provided a detailed definition of what constitutes a quick dissolution rate). For this reason, the Court considered the 2004 patent a divisional of the 2002 patent and thus its novelty preserved under Section 37(2) of the Patents Act.

Points of significance

- The authorization to file divisional patents enables a patent applicant to submit new claims in respect of the disclosed invention before the parent application is accepted.

[3] Para 31 of the decision.
[4] Paras 32, 33.
[5] Para 36.
[6] Para 40.
[7] Para. 39.

- Citing previous case law,[8] the Court noted that a divisional patent is independent of the parent patent. As its date of filing is deemed to be identical to the parent patent to preserve novelty, the divisional patent cannot be used to extend the term of protection under the parent patent.
- An invention is "obvious to try" and thus lacks inventive step only if the expert skilled in the art may reasonably expect a useful outcome.

Key words

Divisional patent, claims construction, novelty, inventive step, obvious to try.

Available at

http://www.saflii.org/za/cases/ZASCA/2014/123.html

[8] Para 46.