Hospira (UK) Limited v. Genentech, Inc. (English and Wales Court of Appeal, 6 February 2015)

Prepared by UNCTAD's Intellectual Property Unit

Case summary

The Court of Appeal (hereinafter "the Court") confirmed the invalidity of a patent on a pharmaceutical dosing regimen based on obviousness.

The facts

The appellant, Genentech, holds a patent on a dosing regimen for the biological anti-cancer drug trastuzamab (brand name Herceptin). As trastuzamab was already approved for use in humans at the time of filing the patent, the patent specifically claims a novel dosing regimen, which differs from the prior art, i.e. the dosage approved by the United States Food and Drug Administration (FDA). Before the first instance court, the respondent, Hospira, sought to establish through evidence that the claimed dosing regimen was obvious from the prior art. It convinced the judge that it was possible for an average person skilled in the art to determine through calculation a dosage that was only slightly above the claimed dosage. As the respondent had shown through expert opinion that in oncology, small changes of dose have no bearing on efficacy and toxicity, this was the basis for the first instance court in April 2014 to invalidate the patent *inter alia* for lack of inventive step. Upon appeal from Genentech, the Court upheld the first instance decision on the same basis.

The legal issues

The decisive question was whether the respondent had furnished sufficient evidence to justify a finding of non-obviousness. The appellant stressed the fact that the calculation advanced by the respondent only concerned a dosage that was (slightly) higher than the claimed one. Such calculation, the appellant argued, only proved the obviousness of the calculated (higher) dosage but did not permit to make any conclusions about the inventive character of the actually claimed (i.e. lower) dosage. The Court did not follow this argument. It clarified that for the inventive step test, the appropriate question to ask was not whether on the basis of prior art the team of skilled experts would positively know that the claimed dosing regimen would work. Rather, what mattered was whether the prior art would motivate the skilled team to "consider the prospects" of the claimed regimen "to be sufficiently good to warrant a small clinical trial."[1] As the respondent had shown that in oncology, small changes of dose have no bearing on efficacy and toxicity, the Court concluded that the skilled pharmacokineticist "does not consider himself as tightly bound to the arithmetic results of the modelling calculations which he carries out",[2] but would be motivated by the prior art to try the claimed dosage. Thus, the Court considered that "Hospira

[1] Paragraph 42 of the judgment.
[2] Ibid, at paragraph 50.

had shown that there was a range of dosages about which the skilled team would have the necessary degree of confidence"[3] that some clinical trials could be successful.

Points of significance

- Even if a claimed dosing regimen cannot be exactly calculated from the prior art, it lacks inventive step if it lies within a range of doses for which an expert skilled in the art would, in the course of his/her routine research into improving dosage efficacy consider the prospect of success good enough to warrant a small clinical trial.
- For the above reason, claimed dosing regimens will in many cases fail the test of inventive step.
- One exception is where the patent holder can show that the claimed dosage has an unexpected advantage over the prior art.

Key words: non-obviousness/inventive step; prior art; dosing regimen; unexpected advantage.

Available at http://www.bailii.org/ew/cases/EWCA/Civ/2015/57.html

[3] Ibid, at paragraph 53.