Smithkline Beecham Corporation v. Apotex, 403 F.3d 1331 (Fed. Circ. 2005)
(United States Court of Appeals for the Federal Circuit)

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Summary

In this decision the United States Court of Appeals for the Federal Circuit (hereinafter: the Federal Circuit) ruled that the generic paroxetine hydrochloride anhydrate product which Apotex Corp., Apotex Inc., and TorPharm, Inc. (hereinafter collectively: Apotex) intended to produce would infringe upon claim 1 of U.S. Patent No. 4,721,723 (hereinafter: '723 patent) held by SmithKline Beecham Corporation (hereinafter: SmithKline). However, it found claim 1 to be invalid as anticipated under 35 U.S.C. §102(b) (exceptions to novelty).

The facts

The compound paroxetine anhydrate, its salts and their antidepressant properties were invented by the British company Ferrosan in the late 1970s and patented under U.S. Patent No. 4,007,196 (hereinafter: ' 196 patent). Ferrosan later developed a method to produce the crystalline hydrochloride salt of paroxetine, or paroxetine hydrochloride (hereinafter: PHC). In 1980, Ferrosan licensed its PHC-related technology including the '196 patent to SmithKline, which began manufacturing PHC in England.

In 1985, a SmithKline chemist discovered a new form of PHC, the PHC hemihydrate.[1] In comparison with the previous form, PHC anhydrate, it proved to be more stable, and therefore easier to package and preserve. In 1986, SmithKline filed a U.S. patent application for PHC hemihydrate. The patent was issued as the '723 patent in 1988. Claim 1 refers neither to PHC anhydrate nor mixtures of the two PHC forms, but is limited to PHC hemihydrate ("Crystalline paroxetine hydrochloride hemihydrate").

In 1993, SmithKline started selling its antidepressant drug with PHC hemihydrate as active ingredient under the name of Paxil®. In 1998, TorPharm, Inc., an Apotex affiliate and manufacturer of Apotex's generic antidepressant, filed an Abbreviated New Drug Application (ANDA) with the FDA under 21 U.S.C. §355(j). It sought approval to place on the market its own PHC antidepressant drug prior to the expiration date of SmithKline's '723 patent, holding that its product would not infringe the latter. The active ingredient of Apotex's generic antidepressant was PHC anhydrate, i.e the substance originally protected under the expired '196 patent.

SmithKline initiated infringement action against Apotex under 35 U.S.C. §271(e)(2) in 1998. It based its claims on Apotex's ANDA filing and alleged that Apotex's proposed drug infringed claim 1 of their '723 patent. While it acknowledged that PHC anhydrate is prior art to the '723 patent and did not claim that PHC anhydrate is covered by its '723 patent, SmithKline asserted, however, that the PHC anhydrate

[1] PHC hemihydrate comprises PHC crystals with one bound water molecule for every two PHC molecules, whereas PHC anhydrate comprised crystals of PHC without any such bound water molecules.

tablets that Apotex intended to manufacture would necessarily contain at least small amounts of PHC hemihydrate.[2]

In the bench trial, the District Court determined the proper interpretation of claim 1 and discussed the remaining infringement and validity issues. The District Court construed and limited claim 1 to PHC hemihydrate *in commercially significant amounts* and found that Apotex's PHC anhydrate tablets will not contain any commercially significant amount of PHC hemihydrate. It rejected SmithKline's evidence to the contrary. The trial court found claim 1 to be valid, but not infringed.[3]

The case was appealed to the Federal Circuit, which built its decision on the District Court's factual findings.

The legal issues

Claim Construction & Indefiniteness

The Federal Circuit found that the language employed in claim 1, "Crystalline paroxetine hydrochloride hemihydrate" was unambiguous and to be understood to embrace PHC hemihydrate without any further limitation, as opposed to the District Court's view. The Federal Circuit established that nothing in the patent limits the compound to its commercial embodiments and held that the District Court had therefore given the clear language of the claim an unexpected, limiting meaning. The District Court had feared that the claim would be indefinite if it was to cover all undetectable trace amounts of PHC hemihydrate; it had warned that such an interpretation would make it impossible for potential infringers to actually determine infringement. Therefore, it had limited the claim to commercially significant amounts. Concerning this reasoning, the Federal Circuit held that the court had missed the purpose of the definiteness requirement. It set out that section 35 U.S.C. §112 (i.e. description of the invention, enablement) "requires the specification of a patent to 'conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention'."[4] This requirement is to be considered satisfied if the claim, read in light of the specification, will teach those skilled in the art of the scope or the bounds of the claim.[5] It is without relevance to the question of indefiniteness whether the potential infringer is unable to ascertain the nature or characteristics of its own product.[6] In other words, claims have to be drafted in a way that defines their boundaries, but they do not have the function of explaining the nature of the potentially infringing competitor's product. The court found that in the present case, the scope of the claim was clear, whereas infringement by the Apotex product was not. Before this background, claim 1 of the '723 patent could not be invalid for indefiniteness under §112.[7] It covers PHC hemihydrate without further limitations.

Infringement and anticipation (lack of novelty)

[2] See decision para.6.
[3] See decision para. 8-13 for the discussion on the interpretation of claim 1.
[4] Ibid, § 31.
[5] See decision § 31, referring to *Morton.*
[6] See decision § 31-33.
[7] See decision § 30.

Based on the claim construction as explained above and the factual findings of the District Court that Apotex's product contains traces of PHC hemihydrate, the Federal Circuit as opposed to the District Court stated that Apotex's product would infringe the patent. This, however, would only apply if the claim to PHC hemihydrate were valid. In this context, the Federal Circuit raised the issue of anticipation of the claimed invention through prior art (i.e. lack of novelty): Apotex sought to practice prior art (i.e. the '196 patent) and, as had just been established, this practice constituted an infringement. This raised questions concerning anticipation:

> "if the prior art infringes now, logically the prior art should have anticipated the claim before the filing of the '723 patent", in line with a previous holding that "that which would literally infringe if later in time anticipates if earlier".[8]

The Federal Circuit recalled its own jurisprudence that a patent is anticipated

> "if a single prior art reference discloses each and every limitation of the claimed invention. […] Moreover, a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference."[9]

Building on the above, the Federal Circuit stressed the fact that the production of PHC anhydrate under the '196 patent naturally results in the production of traces of PHC hemihydrate as claimed under the '723 patent.[10] It was not necessary for Apotex to prove that PHC hemihydrate existed before the priority date of the '723 patent, because

> "inherent anticipation does not require a person of ordinary skill in the art to recognize the inherent disclosure in the prior art at the time the prior art is created."[11]

It is sufficient for the prior art to disclose

> "that the natural result flowing from the operation as taught [in the prior art] would result in the claimed product."[12]

The Federal Circuit considered the natural generation of PHC hemihydrate traces in the production of PHC anhydrate as meeting this requirement.[13] In this context, the Federal Circuit made an important policy observation:

> "[] this court noted that one of the principles underlying the doctrine of inherent anticipation is to ensure that '[t]he public remains free to make, use or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup or the underlying scientific principles which allow them to operate.' […] Invalidating claim 1 of the '723 patent for

[8] The Federal Circuit refers to *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.2001.*
[9] See decision, § 43.
[10] Ibid, § 49.
[11] Ibid, § 44.
[12] Ibid, § 45.
[13] Ibid, § 46.

inherent anticipation by the '196 patent furthers this policy of allowing the public to practice expired patents."[14]

Points of significance:

- This is a case of attempted "ever greening" of an original patent: by asserting that the practice of the expired '196 patent would automatically result in the infringement of the '723 patent, the patent holder attempted to extend its exclusive rights over PHC anhydrate beyond the term of the '196 patent.
- Both the Federal Circuit and the District Court found appropriate means to use patent law to prevent such ever greening: either by invalidating the more recent patent (lack of novelty) or by limiting its claims to avoid findings of infringement. The latter approach, however, has been expressly rejected by the Federal Circuit, not only in the case at hand, but in its earlier decision in *Scripps Clinic Research Foundation v. Genentech Inc Scripps Clinic & Research Foundation* (1991) (see summary of that case in this database).
- Patent claims need to be definite in scope to allow third parties to understand the bounds of the protected territory to avoid infringement. Indefinite claims are invalid.
- Definiteness of scope does not require the claims to be plain on their face. But claims need to be sufficiently definite to allow claims construction, even if the latter proves very difficult.
- To meet the definiteness requirement, a claim needs to be sufficiently precise to permit a potential competitor to determine whether or not it is infringing; the claim must teach the person skilled in the art about the bounds of the claim. By contrast, claims cannot be expected to enable a potential infringer to determine the nature of its own product.
- "That which would literally infringe if later in time anticipates if earlier", thus destroying novelty.
- A single prior art reference may anticipate an invention even if not all features of the invention are disclosed, provided the missing feature is necessarily inherent in the single prior art reference.
- Inherent anticipation does not require the person skilled in the art to understand how to actually make the anticipated invention. In the words of the Court, it is sufficient for the prior art to disclose "that the natural result flowing from the operation as taught [in the prior art] would result in the claimed product."

Key words: Definiteness requirement, claims construction, novelty, inherent anticipation.

Available at: https://casetext.com/case/smithkline-beecham-corp-v-apotex-corp-5

and

https://law.justia.com/cases/federal/appellate-courts/cafc/03-1285/03-1285-2011-03-27.html

[14] Ibid, § 50.