Scripps Clinic Research Foundation v. Genentech Inc Scripps Clinic & Research Foundation (1991)
(U.S. Court of Appeals for the Federal Circuit - 927 F.2d 1565 (Fed. Cir. 1991))

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Case summary

The Federal Circuit remanded for trial (further clarification of facts) to the district court a number of motions for summary judgment regarding the validity and the infringement of certain product claims and product-by-process claims. The Federal Circuit *inter alia* decided that in litigation (concerning patent infringement and validity), patent claims must be construed in a similar manner as under patent prosecution (concerning the grant of a patent). The Court also clarified further the extent to which open ended claims are admissible under the enablement (disclosure) requirement, the role of prior art extrinsic evidence in anticipation (novelty test), the limits of claims construction, and the purpose of the so-called "reverse doctrine of equivalents".

The facts

Scripps Clinic Research Foundation (hereafter Scripps) holds a patent on highly purified and concentrated human or porcine Factor VIII:C, i.e. a protein occurring naturally in blood and essential to its clotting. The patent originally comprised process and product-by-process claims. Scripps subsequently added product claims and the patent was reissued. Factor VIII:C can be produced in several ways, such as through the separation from blood plasma or through recombinant technology as practiced by Genentech.

The legal issues

Inequitable conduct and enablement

In the view of the district court, Scripps' additional product claims were too open-ended with respect to the degree of purity of the claimed substance to satisfy the enablement requirement. As Scripps had nevertheless asserted an enabling character of its patent specification before the patent examiner, the district court qualified such assertion as inequitable conduct and accordingly granted Genentech's motion for summary judgment of unenforceability of the product claims. The Federal Circuit rejected this view, stating that the enablement requirement may be met even through open-ended claims, provided the latter contain an inherent upper limit of a given property (e.g. the degree of purity of a substance) and the specification enables a person skilled in the art to approach that limit.[1] As the district court had failed to establish all relevant facts in that regard as well as for a finding of inequitable conduct (i.e. intent to deceive) the Federal Circuit reversed the partial summary judgment on unenforceability and remanded the issue for trial.[2]

Anticipation through prior art (novelty)

[1] See decision, para. 39.
[2] Ibid, paras 52-54 ; 71.

The district court considered the product claims anticipated by a prior art dissertation. The Federal Circuit underlined the requirement for anticipation to be derived only from a single prior art reference. Extrinsic evidence may not be used to fill any gaps in the prior art reference, but only to help understand the exact meaning of the reference. A combination of prior art references may properly be taken into account under the obviousness examination.[3] As the exact content of the dissertation, and how this would relate to the claimed substance, was controversial among the parties, the Federal Circuit reversed the partial summary judgment of invalidity for anticipation and remanded the issue for trial.[4]

Infringement of the product claims

The district court found the product claims infringed by Genentech's recombinantly-produced human Factor VIII:C, as product claims cover all ways of making a protected substance. The issue before the Federal Circuit was whether the product claims should be limited to those production methods not practiced by Genentech to avoid a finding of patent infringement. The Federal Circuit clarified that claims are construed independent of the accused product. Claims are construed to understand their scope but not to modify it. The court saw no reason for limiting the product claims to a certain method of production.[5] By contrast, it did not exclude the possibility for Genentech to avoid infringement under the "reverse doctrine of equivalents". Under that doctrine, an accused product is to be considered as not infringing if, despite its being within the literal claims of a protected product, it has been modified to such an extent that it performs the same function in a substantially different way. As the exact differences between Genentech's product and the patented invention were not clarified by the district court, the Federal Circuit reversed the grant of summary judgment of infringement of the product claims and remanded the issue for trial.

Infringement of the product-by-process claims

The district court had expressed the view that product-by-process claims are not infringed unless the same process is used. The Federal Circuit noted in this context a tendency by some lower courts to limit product-by-process claims in infringement litigation to the process, while requiring the patent office to determine patentability based on the product as such.[6] It recognized that its own precedent (*In re Thorpe*) was limited to cases of patent prosecution (i.e. the procedure before the patent office regarding patent grant and review of its decision by the courts), not patent litigation (i.e. the procedure before the courts regarding infringement of a patent and its validity). But it expressed the view that claims should be construed similarly under patent prosecution and patent litigation. Referring to its characterization of product-by-process claims as product claims in *In re Thorpe*, the Federal Circuit accordingly stated that infringement of product-by-process claims is not limited to the use of the process expressly mentioned in the claim.[7] It remanded the issue for trial, as the examination of product claims infringement (see above).

[3] Ibid, para 75.
[4] Ibid, para. 88.
[5] Ibid, para 109.
[6] Ibid, para 134.
[7] Ibid.

Points of significance

- The Federal Circuit maintains its treatment of product-by-process claims as ordinary product claims. While the Court previously used this approach in the context of **patent prosecution** cases (*In re Thorpe*, see case summary in this database), the Court in the case at hand applies this interpretation to the issue of **infringement litigation** (i.e. scope of claims and validity of a patent). Only one year later, the same Court issued a contradictory opinion on this very topic, see case summary of *Atlantic Thermoplastics Co. v. Faytex Corp*. (1992). The treatment in infringement cases of product-by-process claims as product claims is arguably contradictory to what the Federal Circuit itself said about product-by-process claims in *In re Thorpe*: "[…] product-by-process claims are limited by and defined by the process […]"[8] If the patent is nevertheless infringed by using a process not mentioned in the patent, this begs the question of how the mentioned process actually limits these claims.
- The Federal Circuit rejected the idea of construing claims in a way to avoid their infringement by an accused product. Accordingly, claims are construed to understand their scope but not to modify it. The Federal Circuit subsequently confirmed this approach in *Smithkline Beecham Corporation v. Apotex* (2005).[9]
- While the Court rejects the idea of using multiple prior art references to support a finding of anticipation in the novelty context, it expressly refers to the non-obviousness test as the appropriate place to examine multiple prior art references. This approach was subsequently much further developed by the US Supreme Court in its decision in *KSR International Co. v. Teleflex Inc. et al.* (2007) (see related case summary in this database).
- The Federal Circuit recalled the objective of the "reverse doctrine of equivalents" as compared to the doctrine of equivalents. While the latter is intended to protect the patent holder from certain free riders, the former serves the opposite purpose, i.e. to avoid the inappropriate extension of the scope of a patent. In brief:
    - Doctrine of equivalents: where an accused product, despite its falling outside the literal claims, performs a similar function as the protected product in a substantially similar way. This results in a finding of patent infringement.
    - Reverse doctrine of equivalents: where an accused product, despite its being within the literal claims, has been modified to such an extent that it performs a similar function as the protected product in a substantially different way. This results in a finding of no patent infringement.

Key words

Product-by-process claims, product claims, open-ended claims, patent prosecution, patent infringement, patent litigation, patent validity, enablement, anticipation, extrinsic evidence, doctrine of equivalents, reverse doctrine of equivalents.

Link: https://law.justia.com/cases/federal/appellate-courts/F2/927/1565/110240/

[8] *In re Thorpe*, pp. 2/3 (see case summary).
[9] See the summary in this database.