Ex. 2002

Pozen Inc. v. Par Pharm., Inc.,
696 F.3d 1151 (Fed. Cir. 2012)

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position of the sensor control unit." Instead, the dispute between the parties lies in whether "some movement" includes the degree of movement in the Shichiri I system such that the sensor need only be "somewhat restrained." We conclude that it does not.

The external wires of the Shichiri I sensor are only "somewhat restrained" because they are tethered to a watch-shaped assembly and therefore only restrained by human arm or wrist movement. This degree of arm and wrist movement is not only significantly greater than the movement allowable under the Board's original construction of "substantially fixed," it is also greater than the movement described in the specification. Indeed, the embodiments disclosed in the '509 patent all show the above-skin portion of the electrochemical sensor maintained in a fixed position. Specifically, the specification teaches a "support structure 82" that "hold[s], support[s], and/or guide[s] the sensor 42 into the correct position." '509 patent col.34 ll.54–55. While the Board's original construction is reasonable in view of the specification, the Board's modified construction requiring only a "somewhat restrained" sensor is not. On remand, the Board should apply its original construction of "substantially fixed."

C. Official Notice

During reexamination of the '752 patent, the examiner invoked the doctrine of official notice in combination with other primary references to reject 157 newly added independent and dependent claims. The Board affirmed, and now nineteen of these official notice-rejection claims are before this court on appeal.[3] The PTO, however, now agrees with Abbott that the examiner's official notice rejection of these nineteen claims should be remanded and withdrawn. Therefore, we vacate the Board's rejection of these nineteen claims and remand to the Board for appropriate further proceedings.

III. Conclusion

The Board's construction of "electrochemical sensor" and its modified construction of "substantially fixed" are unreasonable and inconsistent with the specification. We therefore vacate the Board's decisions as to the patentability of Abbott's independent claims at issue and remand for the Board to apply the correct claim constructions. We also vacate the Board's official notice rejection of the nineteen claims before us and remand to the Board for appropriate further proceedings.

VACATED–IN–PART AND REMANDED.

POZEN INC., Plaintiff–Appellee,

v.

PAR PHARMACEUTICAL, INC., Defendant–Appellant,

and

Dr. Reddy's Laboratories, Inc., Defendant–Appellant,

and

Alphapharm Pty Ltd., Defendant–Appellant.

Nos. 2011–1584, 2011–1585, 2011–1586.

United States Court of Appeals, Federal Circuit.

Sept. 28, 2012.

Background: Patentee brought infringement action against competitors for in-

3. These include claims 96, 98, 107, 125, 127, 139, 157, 159, 168, 186, 188, 196, 214, 216, 225, 244, 247–248, and 251 of the '752 patent.

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fringement of patents relating to a method for treating migraines by combining two drugs in a single tablet, seeking a permanent injunction against competitors from making, using, selling, offering to sell, or importing into the United States accused Abbreviated New Drug Application (ANDA) products. Following claim construction, 719 F.Supp.2d 718, the United States District Court for the Eastern District of Texas, Leonard Davis, J., 800 F.Supp.2d 789, entered judgment in favor of patentee, and enjoined competitors. Competitors appealed.

Holdings: The Court of Appeals, Wallach, Circuit Judge, held that:

(1) prior art references did not render patents invalid for obviousness;

(2) district court did not clearly err in determining one of the patents satisfied the written description requirement; and

(3) district court did not clearly err in concluding that accused products infringed one of the patents under doctrine of equivalents.

Affirmed.

Clevenger, Circuit Judge, filed an opinion dissenting in part.

1. Federal Courts ⚿13
Patents ⚿249.1

Patent law provision providing that it is an act of infringement to submit an application for approval from the Food and Drug Administration (FDA) to manufacture a drug claimed in a patent creates case-or-controversy jurisdiction to enable the resolution of an infringement dispute before the Abbreviated New Drug Application (ANDA) applicant has actually made or marketed the proposed product; the determination under the provision is the same as any other infringement suit to inquire whether a product would infringe a patent if the ANDA product was on the market. U.S.C.A. Const. Art. 3, § 2, cl. 1; 35 U.S.C.A. § 271(e)(2)(A).

2. Federal Courts ⚿758, 850.1

Court of appeals reviews judgments of the district court after a bench trial for errors of law and clearly erroneous findings of fact.

3. Patents ⚿16(2, 3), 36.1(4), 36.2(1)

To determine if a patent is obvious a district court looks to: (1) the scope and content of the prior art; (2) differences between the prior art and the claims; (3) the level of ordinary skill in the art; and (4) secondary considerations such as commercial success and failure of others. 35 U.S.C.A. § 103(a).

4. Patents ⚿324.5, 324.55(4)

Obviousness under patent law is a question of law, reviewed de novo, based upon underlying factual questions which are reviewed for clear error following a bench trial. 35 U.S.C.A. § 103(a).

5. Patents ⚿101(11)

Term "unit dose," in patents relating to a method for treating migraines by combining two drugs in a single tablet, construed as a single drug administration entity, necessarily limited the term "concomitant administration" to mean simultaneous administration, because a single drug administration entity could not have been administered in any other fashion.

6. Patents ⚿36(3)

There was not clear and convincing evidence that patents relating to a method for treating migraines by combining two drugs in a single tablet were obvious over prior art epidemiological survey assessing various migraine treatments, so as to render the patents invalid; the prior art reference revealed the types of treatments used and documented the number of unsatisfac-

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tory results of monotherapy treatment, but it did not indicate the relative successes of various combination treatments. 35 U.S.C.A. § 103(a).

7. Courts ⚿96(7)

Federal Circuit Court of Appeals reviews evidentiary determinations under the law of the regional circuit.

8. Federal Courts ⚿823

Fifth Circuit reviews decisions to admit or exclude evidence for abuse of discretion.

9. Evidence ⚿314(1)

Under Fifth Circuit law, the residual hearsay exception is to be used only rarely, in truly exceptional cases. Fed.Rules Evid.Rule 807, 28 U.S.C.A.

10. Evidence ⚿314(1)

Under Fifth Circuit law, to admit evidence under the residual hearsay rule, there must be at least circumstantial guarantees of trustworthiness. Fed.Rules Evid.Rule 807, 28 U.S.C.A.

11. Patents ⚿16.25

Prior art migraine therapy report disclosing the simultaneous delivery of several components, including ergotamine, metoclopramide, and naproxen, did not make it obvious to substitute sumatriptan for ergotamine and remove metoclopramide and caffeine as unnecessary, so as to render invalid patents relating to a method for treating migraines by combining two drugs in a single tablet; the prior art reference disclosed each drug as having a specific purpose, and even though another article taught that antiemetics were unnecessary with sumatriptan, that article did not provide the motivation to a skilled artisan to substitute one agent in place of three, and the prior art reference did not teach the remaining efficacy limitations, since it gave no reason to assume that an entirely different combination of agents would have the same success as the combination disclosed, nor did it disclose the combination therapy had any added benefits over any of the components given individually. 35 U.S.C.A. § 103(a).

12. Patents ⚿16.25

Prior art patient records showing doctors prescribed a daily dose of naproxen as a prophylactic treatment and sumatriptan for treating acute migraines did not render patents relating to a method for treating migraines by combining two drugs in a single tablet invalid for obviousness; treating doctor testified that he did not recall ever prescribing or giving a patient sumatriptan and naproxen simultaneously, and the records did not suggest that it produced longer lasting efficacy or reduced migraine relapse, as at least one of the patients' prescriptions was soon altered to sumatriptan and an antidepressant, suggesting the combination of sumatriptan and naproxen did not work to relieve migraine symptoms. 35 U.S.C.A. § 103(a).

13. Patents ⚿16.25

Prior art case report describing a single patient who developed ergotamine-induced headaches and subsequently replaced ergotamine with daily administration of sumatriptan did not teach a combination of sumatriptan and naproxen provided migraine relief, so as to render patents relating to a method for treating migraines by combining two drugs in a single tablet invalid for obviousness; the prior art reference concluded that the only effective treatment for the patient was sumatriptan and acupuncture, and the district court determined that the prior art reference discouraged combining sumatriptan and naproxen to achieve the claimed efficacy benefits, teaching away from the invention. 35 U.S.C.A. § 103(a).

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14. Patents ⚿99

Purpose of patent law's written description requirement is to ensure adequate disclosure of the invention. 35 U.S.C.A. § 112.

15. Patents ⚿99

A specification adequately describes an invention, in satisfaction of patent law's written description requirement, when it reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date. 35 U.S.C.A. § 112.

16. Patents ⚿324.55(3.1)

Following a bench trial, the court of appeals reviews compliance with patent law's written description requirement, a question of fact, for clear error. 35 U.S.C.A. § 112.

17. Patents ⚿99

District court did not clearly err in determining specification for patent relating to a method for treating migraines by combining two drugs in a single tablet met patent law's written description requirement, despite argument that the limitations "therapeutic package," "finished pharmaceutical container," and "said container further containing or comprising labeling directing the use of said package in the treatment of migraine" lacked adequate written description; district court reasoned that dispensing pharmaceutical products in containers or packages was not a new or unpredictable concept, and that a person of ordinary skill in the art would know that medications were not simply handed out to patients, but, rather, pharmaceutical products, like the claimed tablets, were routinely administered in containers or packages. 35 U.S.C.A. § 112.

18. Patents ⚿99

In order to satisfy patent law's written description requirement, the disclosure as originally filed does not have to provide in haec verba support for the claimed subject matter at issue; nonetheless, the disclosure must convey with reasonable clarity to those skilled in the art that the inventor was in possession of the invention. 35 U.S.C.A. § 112.

19. Patents ⚿237

Infringement under the doctrine of equivalents allows the patentee to claim those insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes.

20. Patents ⚿237

The "all limitations rule" restricts patent infringement under the doctrine of equivalents by preventing its application when doing so would vitiate a claim limitation.

See publication Words and Phrases for other judicial constructions and definitions.

21. Patents ⚿237

Equivalence, in the context of patent infringement under the doctrine of equivalents, is not an absolute to be considered in a vacuum.

22. Patents ⚿230, 237

The essential inquiry in determining patent infringement under the doctrine of equivalents is whether the accused product or process contains elements identical or equivalent to each claimed element of the patented invention.

23. Patents ⚿237

One way of proving infringement under the doctrine of equivalents is by showing on a limitation by limitation basis that the accused product performs substantially the same function in substantially the same way with substantially the same re-

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