456 F.Supp.2d 644
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United States District Court,
D. New Jersey.
JANSSEN PHARMACEUTICA N.V., and Janssen Pharmaceutica Products, L.P., Plaintiffs,
v.
MYLAN PHARMACEUTICALS., INC., Defendants.
Janssen Pharmaceutica N.V., and Janssen Pharmaceutica Products, L.P., Plaintiffs,
v.
Dr. Reddy's Laboratories, Ltd., and Dr. Reddy's Laboratories, Inc., Defendants.

Civil Action Nos. 03–6220 (JCL), 03–6185(JCL).
Oct. 13, 2006.

Background: Inventors and producers of name brand drug for the treatment of schizophrenia brought infringement action against drug manufacturers which sought to market a generic version of the patented drug. Generic manufacturers admitted infringement but claimed that patent was invalid due to obviousness, and alternatively, was unenforceable due to alleged inequitable conduct.

Holdings: The District Court, Lifland, J., held that:
(1) claims of patented schizophrenia drug were not invalid for obviousness, and
(2) patent applicant's nondisclosure of prior art regarding the dopamine antagonism of lead chemical compound in patented schizophrenia drug did not constitute inequitable conduct.

Judgment for plaintiffs.

West Headnotes

[1] Patents 291 ⚿112.5

291 Patents
291IV Applications and Proceedings Thereon
291k112 Conclusiveness and Effect of Decisions of Patent Office
291k112.5 k. Sufficiency of evidence to offset effect of decision in general. Most Cited Cases

Party challenging patent bears the burden of proving by clear and convincing evidence the invalidity or unenforceability of the claims of a patent; satisfaction of "clear and convincing" standard of proof requires evidence which produces in the mind of the trier of fact an abiding conviction that the truth of the factual contentions is highly probable. 35 U.S.C.A. § 282.

[2] Patents 291 ⚿16(3)

291 Patents
291II Patentability
291II(A) Invention; Obviousness
291k16 Invention and Obviousness in General
291k16(3) k. View of person skilled in art. Most Cited Cases

Claimed invention is unpatentable if the differences between it and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. 35 U.S.C.A. § 103(a).

[3] Patents 291 ⚿16(2)

291 Patents
291II Patentability
291II(A) Invention; Obviousness
291k16 Invention and Obviousness in General
291k16(2) k. Prior art in general. Most Cited Cases

Patents 291 ⚿16(3)

291 Patents
291II Patentability
291II(A) Invention; Obviousness
291k16 Invention and Obviousness in General

291k16(3) k. View of person skilled in art. Most Cited Cases

Patents 291 ⚷16.13

291 Patents
291II Patentability
291II(A) Invention; Obviousness
291k16.13 k. Fact questions. Most Cited Cases

Patents 291 ⚷36.1(1)

291 Patents
291II Patentability
291II(A) Invention; Obviousness
291k36 Weight and Sufficiency
291k36.1 Secondary Factors Affecting Invention or Obviousness
291k36.1(1) k. In general. Most Cited Cases

Obviousness determination in patent case depends on four underlying factual inquiries: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. 35 U.S.C.A. § 103(a).

[4] Patents 291 ⚷16(2)

291 Patents
291II Patentability
291II(A) Invention; Obviousness
291k16 Invention and Obviousness in General
291k16(2) k. Prior art in general. Most Cited Cases

For purposes of obviousness determination in patent case, scope and content of the prior art is limited to art that is analogous to the claimed invention; analogous art is that which is from the same field of endeavor or, if not within the field of endeavor, is still reasonably pertinent to the particular problem with which the inventor is involved. 35 U.S.C.A. § 103(a).

[5] Patents 291 ⚷16(3)

291 Patents
291II Patentability
291II(A) Invention; Obviousness
291k16 Invention and Obviousness in General
291k16(3) k. View of person skilled in art. Most Cited Cases

In patent case, obviousness analysis is conducted from the perspective of a hypothetical person who is presumed to be aware of all the relevant prior art; however, that hypothetical person of ordinary skill in the art is presumed to be one who thinks along the line of conventional wisdom in the art and is not one who undertakes to innovate, whether by patient, and often expensive, systematic research or by extraordinary insights. 35 U.S.C.A. § 103(a).

[6] Patents 291 ⚷16(3)

291 Patents
291II Patentability
291II(A) Invention; Obviousness
291k16 Invention and Obviousness in General
291k16(3) k. View of person skilled in art. Most Cited Cases

Factors considered in defining the level of ordinary skill in the art for purposes of obviousness analysis in patent case include: (1) the educational level of the inventor; (2) types of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field. 35 U.S.C.A. § 103(a).

[7] Patents 291 ⚷16.25

291 Patents
291II Patentability
291II(A) Invention; Obviousness

291k16.25 k. Chemical compounds. Most Cited Cases

For a chemical compound, a prima facie case of obviousness requires structural similarity between claimed and prior art subject matter where the prior art gives reason or motivation to make the claimed compositions. 35 U.S.C.A. § 103(a).

[8] Patents 291 ⚿16.5(1)

291 Patents
291II Patentability
291II(A) Invention; Obviousness
291k16.5 State of Prior Art and Advancement Therein
291k16.5(1) k. In general. Most Cited Cases

It is not enough for a party seeking to defeat a patent on obviousness grounds to merely identify each element of the invention in the prior art; instead, a prima facie case of obviousness requires the party to explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious. 35 U.S.C.A. § 103(a).

[9] Patents 291 ⚿16.25

291 Patents
291II Patentability
291II(A) Invention; Obviousness
291k16.25 k. Chemical compounds. Most Cited Cases

Claims of patented schizophrenia drug were not invalid for obviousness; it would not have been obvious to the person of ordinary skill in the art that lead chemical compound was short-lasting and that that was a problem requiring a modification of its molecular structure, none of the cited references would convince the person of ordinary skill in the art that metabolism at the ketone was causing lead compound to be short acting, the solution to the lead compound's duration problem would not have been obvious to the person of ordinary skill in the art, and secondary considerations overwhelmingly demonstrated the nonobviousness of the patent. 35 U.S.C.A. § 103(a).

[10] Patents 291 ⚿16.5(1)

291 Patents
291II Patentability
291II(A) Invention; Obviousness
291k16.5 State of Prior Art and Advancement Therein
291k16.5(1) k. In general. Most Cited Cases

When applying the "motivation-suggestion-teaching" test in conducting obviousness analysis in patent case, court must ask whether the person of ordinary skill in the art at the relevant time, motivated by the general problem facing the inventor, would have been led to make the combination recited in the claims. 35 U.S.C.A. § 103(a).

[11] Patents 291 ⚿36.1(1)

291 Patents
291II Patentability
291II(A) Invention; Obviousness
291k36 Weight and Sufficiency
291k36.1 Secondary Factors Affecting Invention or Obviousness
291k36.1(1) k. In general. Most Cited Cases

Patents 291 ⚿36.2(1)

291 Patents
291II Patentability
291II(A) Invention; Obviousness
291k36 Weight and Sufficiency
291k36.2 Commercial Success
291k36.2(1) k. In general. Most Cited Cases

Objective evidence of nonobviousness in patent case includes commercial success, long felt, but unsolved need, failure of others, copying, acclaim,

and unexpected superior results. 35 U.S.C.A. § 103(a).

[12] Patents 291 ⚷97.14

291 Patents
291IV Applications and Proceedings Thereon
291k97.7 Unenforceability of Patent; Inequitable Conduct or Fraud on Office
291k97.14 k. Determination; summary judgment. Most Cited Cases
(Formerly 291k97)

In order to find inequitable conduct in patent case, there must have been a misrepresentation or omission of a material fact, the misrepresentation or omission must have been made with an intent to deceive the Patent and Trademark Office (PTO), and the equities must warrant a conclusion that the patentee has engaged in inequitable conduct. 37 C.F.R. § 1.56(a).

[13] Patents 291 ⚷97.9

291 Patents
291IV Applications and Proceedings Thereon
291k97.7 Unenforceability of Patent; Inequitable Conduct or Fraud on Office
291k97.9 k. What information is material. Most Cited Cases
(Formerly 291k97)

For purposes of inequitable conduct analysis in patent case, materiality does not require that any withheld information, if it had been provided, would have resulted in a rejection of the patent claims by the patent examiner; information can be "material" even if a patent examiner would find the claimed invention to be patentable after considering such information. 37 C.F.R. § 1.56(a).

[14] Patents 291 ⚷97.9

291 Patents
291IV Applications and Proceedings Thereon
291k97.7 Unenforceability of Patent; Inequitable Conduct or Fraud on Office
291k97.9 k. What information is material. Most Cited Cases
(Formerly 291k97)

Patents 291 ⚷97.12

291 Patents
291IV Applications and Proceedings Thereon
291k97.7 Unenforceability of Patent; Inequitable Conduct or Fraud on Office
291k97.12 k. Failure to disclose material information. Most Cited Cases
(Formerly 291k97)

Patents 291 ⚷97.13

291 Patents
291IV Applications and Proceedings Thereon
291k97.7 Unenforceability of Patent; Inequitable Conduct or Fraud on Office
291k97.13 k. Evidence. Most Cited Cases
(Formerly 291k97)

Patent applicant's nondisclosure of prior art regarding the dopamine antagonism of lead chemical compound in patented schizophrenia drug did not constitute inequitable conduct rendering the patent unenforceable; information that applicant failed to disclose to the Patent and Trademark Office (PTO) during the patent prosecution was not material since such information taught away from the invention, not towards it, and there was no clear and convincing evidence that anyone acted with an intent to deceive the PTO. 37 C.F.R. § 1.56(a).

[15] Patents 291 ⚷97.8

291 Patents
291IV Applications and Proceedings Thereon
291k97.7 Unenforceability of Patent; Inequitable Conduct or Fraud on Office
291k97.8 k. In general. Most Cited Cases
(Formerly 291k97)

Because non-inventor was not substantively involved in the prosecution of patent for chemical compound, he had no disclosure obligations im-

posed on him by the Patent and Trademark Office and could not have committed inequitable conduct. 37 C.F.R. § 1.56(a).

Patents 291 ⚿328(2)

291 Patents
291XIII Decisions on the Validity, Construction, and Infringement of Particular Patents
291k328 Patents Enumerated
291k328(2) k. Original utility. Most Cited Cases

4,335,127, 4,342,870, 4,352,811. Cited as Prior Art.

Patents 291 ⚿328(2)

291 Patents
291XIII Decisions on the Validity, Construction, and Infringement of Particular Patents
291k328 Patents Enumerated
291k328(2) k. Original utility. Most Cited Cases

4,804,663. Valid and Infringed.

***647** Douglas Scott Eakeley, John R. Middleton, Kaylynn Sun–Lee Yoon, Matthew Jonathan Atlas, Rita Marie Jennings, Lowenstein Sandler PC, Roseland, NJ, Gregory L. Diskant, Scott B. Howard, Stuart E. Pollack, Melissa Mandgroc, Irena Royzman, Patterson, Belknap, Webb, & Taylor, New York, NY, for Plaintiffs.

Arnold B. Calmann, Jeffrey Soos, Saiber, Schlesinger, Satz & Goldstein, LLC, Newark, NJ, Robert F. Gree, John E. Rosenquist, Christopher T. Griffith, Peter H. Domer, Leydig, Voit & Mayer, Chicago, IL, for Mylan Pharmaceuticals., Inc.

Alan Henry Pollack, Budd Larner, Short Hills, NJ, for Dr. Reddy's Laboratories, Ltd., and Dr. Reddy's Laboratories, Inc.

OPINION

LIFLAND, District Judge.

I. *Introduction*

Plaintiffs, Janssen Pharmaceutica, N.V., a Belgian corporation, and its New Jersey-based subsidiary, Janssen Pharmaceutica, L.P. (collectively "Janssen"), are the inventors and producers of risperidone, the active ingredient in Janssen's successful drug for the treatment of schizophrenia, Risperdal. It is perhaps an understatement to describe Risperdal as merely "successful." The drug has been described by the American Chemical Society as "a standard in the treatment of psychosis, revolutionizing anti-psychotic treatments." Pl.'s Ex. ("PX") 309. In 2005 alone, Risperdal accounted for over $3 billion in worldwide sales for Janssen's parent company, Johnson & Johnson. Vergis Tr. 78:9–16.

Defendants, Mylan Pharmaceuticals, Inc. ("Mylan"), a West Virginia corporation, Dr. Reddy's Laboratories, Ltd., an Indian corporation, and its New Jersey-based subsidiary, Dr. Reddy's Laboratories, Inc. (collectively, "DRL"), are drug manufacturers seeking to market a generic version of risperidone. Janssen filed this suit claiming infringement of its U.S. Patent No. 4,804,663 ("the '663 patent"), which claims risperidone, among other chemical compounds. Mylan and DRL concede they have infringed the '663 patent; they counter, however, that the '663 patent is invalid due to obviousness, and alternatively, Mylan argues that the '663 patent is unenforceable due to Janssen's alleged inequitable conduct.

The parties tried the case before the Court from June 28, 2006 through June 30, 2006 and on July 5, 2006. Thereafter, they submitted proposed findings of fact and conclusions of law. The parties' submissions and the record evidence have been carefully considered. For the reasons set forth below,[FN1] the Court finds that Mylan and DRL have failed to prove by clear and convincing evidence that the '663 patent is obvious under 35 U.S.C. § 103(a), and that Mylan has failed to prove by clear and convincing evidence that Janssen engaged in inequitable conduct. Thus, the '663 patent***648** is

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