

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES, LTD. AND DR. REDDY'S
LABORATORIES, INC.,

Petitioner,

v.

MONOSOL RX, LLC,

Patent Owner.

Case IPR2016-01112

Patent 8,017,150 B2

Before ERICA A. FRANKLIN, TINA E. HULSE, and
CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

FRANKLIN, *Administrative Patent Judge*.

DECISION

Denying Institution of *Inter Partes* Review

37 C.F.R. § 42.108

I. INTRODUCTION

Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "Petitioner") filed a Petition to institute an *inter partes* review of claims 1, 3–10, and 12–18 of U.S. Patent No. 8,017,150 B2¹ (Ex. 1001, "the '150 patent"). Paper 1 ("Pet."). MonoSol RX, LLC ("Patent Owner") filed a Preliminary Response to the Petition. Paper 10 ("Prelim. Resp.").

We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a).

Upon considering the Petition and Preliminary Response, we determine that the Petitioner has not demonstrated a reasonable likelihood that it would prevail in showing the unpatentability of at least one of the challenged claims. Accordingly, we decline to institute an *inter partes* review of any challenged claim.

A. *Related Proceedings*

Petitioner and Patent Owner identify a number of district court proceedings and that "may affect or be affected by a decision in this proceeding." Pet. 12–13; Paper 4, 2–3. In particular, both parties identify *Reckitt Benckiser Pharmaceuticals Inc. v. Watson Laboratories, Inc. et al.*, C.A. No.1:13-CV-01674-RGA (D. Del.) and *Reckitt Benckiser Pharmaceuticals Inc. v. Par Pharmaceutical, Inc. et al.*, C.A. No.1:14-CV-00422-RGA (D. Del.), wherein each case included MonoSol Rx among the

¹ Issued to Robert K. Yang et al., Sept. 13, 2011.

plaintiffs and for which a consolidated trial opinion addressing the '150 patent was issued on June 3, 2016. Ex. 2009.

B. The '150 Patent (Ex. 1001)

The '150 patent relates to polyethylene oxide-based film products that demonstrate non-self-aggregating uniform heterogeneity. Ex. 1001, Title and Abstract. The polyethylene oxide may be blended with cellulosic polymers. *Id.* at 1:34–36. The film may also comprise an active ingredient that is evenly distributed throughout the film. *Id.* at 1:36–38. The Specification explains that “[t]he even or uniform distribution is achieved by controlling one or more parameters, and particularly the elimination of air pockets prior to and during film formation and the use of a drying process that reduces aggregation or conglomeration of the components in the film as it forms into a solid structure.” *Id.* at 1:38–43.

C. Illustrative Claim

Independent claim 1 of the '150 patent is illustrative and reproduced below:

1. A mucosally-adhesive water-soluble film product comprising:
an analgesic opiate pharmaceutical active; and
at least one water-soluble polymer component consisting of
polyethylene oxide in combination with a hydrophilic
cellulosic polymer;
wherein:
the water-soluble polymer component comprises greater
than 75% polyethylene oxide and up to 25% hydrophilic
cellulosic polymer;
*the polyethylene oxide comprises one or more low molecular
weight polyethylene oxides and one or more higher
molecular weight polyethylene oxides, the molecular weight
of the low molecular weight polyethylene oxide
being in the range 100,000 to 300,000 and the molecular*

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weight of the higher molecular weight polyethylene oxide being in the range 600,000 to 900,000; and the polyethylene oxide of low molecular weight comprises about 60% or more in the polymer component.

Ex. 1001, 57:37–54; (emphasis added to identify dispositive limitations).

D. The Cited References and Declaration

Petitioner relies upon the following references:

Chen	Patent Application Publication No. WO 00/42992, published Jul. 27, 2000	Ex. 1021
Schiraldi	US Patent No. 4,713,243 issued to Michael T. Schiraldi et al., Dec. 15, 1987	Ex. 1004
Chen II	Patent Application Publication No. US 2002/0147201 A1, issued Oct. 10, 2002	Ex. 1049
Verma	US Patent No. 6,322,811 issued to Surendra Kumar Verma et al., Nov. 27, 2001	Ex. 1005
Khan	US Patent No. 5,656,296 issued to Sadath U. Khan et al, Aug. 12, 1997	Ex. 1046
Yang	Patent Application Publication No. US 2005/0037055 A1, published Feb. 17, 2005	Ex. 1006

Petitioner relies also upon the Declaration of Russell J. Mumper, Ph.D. (Ex. 1003).

E. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1, 3–10, and 12–18 of the '150 patent on the following grounds (Pet. 16):

Claim(s) Challenged	Basis	Reference(s)
1, 3–10, 12–18	§ 103	Chen, Schiraldi, and Chen II
1, 4–5, 8, 10, 12–14, and 17	§ 103	Schiraldi and Verma
6–7, 9, 15–16, 18	§ 103	Schiraldi, Verma, and Khan
1, 4–10, and 13–18	§ 103	Yang

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016) (affirming applicability of broadest reasonable construction standard to *inter partes* review proceedings). Under that standard, and absent any special definitions, we give claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Only terms which are in controversy need to be construed, and only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

Petitioner proposes a construction for the claim phrase: “at least one water-soluble polymer component consisting of polyethylene oxide in combination with a hydrophilic cellulosic polymer; wherein: the water-

soluble polymer component comprises greater than 75% polyethylene oxide and up to 25% hydrophilic cellulosic polymer,” recited by independent claim 1 and the similar claim phrase: “at least one water-soluble polymer component consisting of polyethylene oxide in combination with a hydrophilic cellulosic polymer; wherein: the water-soluble polymer component comprises the hydrophilic cellulosic polymer in a ratio of up to about 4:1 with the polyethylene oxide,” recited in independent claim 10. Pet. 17–19. According to Petitioner, the term “up to” in each of those claim phrases should be construed broadly as “and optionally,” such that the water-soluble polymer component may optionally include a hydrophilic cellulosic polymer. *Id.* at 19. Petitioner asserts that proposed construction is what Patent Owner proffered in a related district court proceeding. *Id.*

Patent Owner correctly notes that Petitioner does not rely on its proposed claim construction in the Petition. Prelim. Resp. 7. Nor does Petitioner provide any discussion supporting its position that the construction that it proposes represents the broadest reasonable construction in light of the specification of the patent, other than asserting that it is the same construction that was proffered in a district court proceeding. For purposes of this decision, we agree with Patent Owner that the plain and ordinary meaning of the phrases apply. *Id.* at 7. In any event, this Decision does not turn on the claim phrases for which Petitioner has proposed a construction.

B. Obviousness over Chen, Schiraldi, and Chen II

Petitioner contends that claims 1, 3–10, 12–18 would have been obvious over the combination of Chen, Schiraldi, and Chen II. Pet. 30–39. Patent Owner disagrees. Prelim. Resp. 10–15.

1. *Chen*

Chen discloses a dosage unit comprising a water-soluble hydrocolloid and a mucosal surface-coat-forming film that includes an effective dose of an active agent. Ex. 1021, 3:30–32. The active ingredient may be hydromorphone. *Id.* at 4:9. Chen describes that “the film may be formed using a mixture of two or more types of the same hydrocolloid that differ only in molecular weights and/or different degrees of substitution.” *Id.* at 13:28–31. Included among the list of synthetic hydrocolloids that may be used to form the film are hydroxypropyl cellulose, hydroxypropyl methyl cellulose (“HPMC”) (hydrophilic cellulosic polymers) and polyethylene oxides. *Id.* at 14:22–29. Chen’s Example 11 describes the preparation of film using dry extrusion techniques. *Id.* at 27:1. In the example, 77.8 g polyethylene oxide (Polyox®WSR N-10) was mixed with additional ingredients (estradiol, peppermint, propylene glycol, aspartame, citric acid Cremphor EL, and benzoic acid) totaling 22.25 g to form about a 100 g blend. *Id.* at 27:2–5.

2. *Schiraldi*

Schiraldi discloses a bioadhesive extruded film useful for intra-oral controlled-releasing drug delivery. Ex. 1004, 1:7–12. The bioadhesive layer contains 40–95% of a thermoplastic cellulose ether and 5–60% of a homopolymer of ethylene oxide. *Id.* at 1:13–14. The film forming polymers useful for the invention include water-soluble polymers, i.e., hydroxypropyl cellulose and polyethylene oxide homopolymers. *Id.* at 3:14–16. Schiraldi also explains that non-soluble polymers may be incorporated for modification of the film’s permeability properties. *Id.* at 3:21–23. Chen states, “[b]y varying the ratios of the above polymers both the solubility and

the adhesive properties of each layer of film may be controlled.” *Id.* at 3:25–27. Chen teaches that “it is possible to custom design the film by selecting and blending various polymers.” *Id.* at 3:30–32. Chen explains that the homopolymer of ethylene oxide useful for the invention has a relatively high molecular weight, i.e., above 100,000, and preferably above 3,000,000. *Id.* at 4:24–27. Chen teaches that the commercially available ethylene oxide, Polyox WSR-301, “has a molecular weight of approximately 4,000,000–5,000,000 and is most preferred for the purposes of the present invention.” *Id.* at 4:27–31.

3. *Chen II*

Chen II is directed to compositions containing active agents complexed with glycyrrhizin so as to increase the solubility and bioavailability of the active agents. Ex. 1049 ¶¶ 2, 19.

4. *Analysis*

A conclusion that the claimed subject matter is obvious must be supported by evidence, as shown by some objective teaching in the prior art or by knowledge generally available to one of ordinary skill in the art that would have led that individual to combine the relevant teachings of the references to arrive at the claimed invention. *See In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988). Obviousness grounds must be supported with “articulated reasoning with some underpinning” and not by “mere conclusory statements.” *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S 398, 418 (2007).

According to Petitioner, Chen teaches or suggests certain limitations shared by independent claims 1 and 10, i.e., a mucosally-adhesive water-soluble film product comprising an analgesic opiate pharmaceutical active,

at least one water-soluble polymer component consisting of polyethylene oxide in combination with a hydrophilic cellulosic polymer, wherein the water-soluble polymer component comprises greater than 75% polyethylene oxide and up to 25% hydrophilic cellulosic polymer (claim 1), wherein the water-soluble polymer component comprises the hydrophilic cellulosic polymer in a ratio of up to about 4:1 with the polyethylene oxide (claim 10), and the polyethylene oxide of low molecular weight comprises about 60% or more in the polymer component. Pet. 34–36.

With regard to the requirement in each of independent claims 1 and 10 that “the polyethylene oxide comprises one or more low molecular weight polyethylene oxides and one or more higher molecular weight polyethylene oxides, the molecular weight of the low molecular weight polyethylene oxide being in the range 100,000 to 300,000 and the molecular weight of the higher molecular weight polyethylene oxide being in the range 600,000 to 900,000,” i.e., “the polyethylene oxides molecular weights limitation,” Petitioner asserts that “[b]oth Chen and Schiraldi teach varying the ratios of film polymers to control film properties.” *Id.* at 35. In particular, Petitioner refers to Chen’s teaching that its film “may be formed using a mixture of two or more types of the same hydrocolloid that differ only in molecular weights and/or different degrees of substitution.” *Id.* (quoting Ex. 1021, 3:28–32). Petitioner refers also to Schiraldi’s teaching that “[b]y varying the ratios of the above polymers both the solubility and the adhesive properties of each layer of film may be controlled.” *Id.* (quoting Ex. 1004, 3:25–27). Petitioner additionally refers to Schiraldi’s teaching that its films may be custom-designed by selecting and blending various polymers depending on the desired delivery rate, disorder being treated, and area affected by

administration of the drug. *Id.* at 32 (citing Ex. 1004, 3:28–32). According to Petitioner, those combined teachings would have “motivated a person of ordinary skill to test different ratios of polyethylene oxides, and thereby arrive at the claimed combination of low and higher molecular weight polyethylene oxides.” *Id.* at 32–33.

Petitioner relies on Chen II only for additional limitations recited in dependent claims 6 and 15, which are unrelated to the polyethylene oxides molecular weights limitation of independent claim 1. Pet. 39.

We find Petitioner’s arguments to be conclusory and unpersuasive. In particular, Petitioner has not explained adequately why a person of skill in the art at the time of the invention would have had a reason to combine the teachings of Chen and Shiraldi. As discussed, *supra*, Chen describes using a mixture of two or more types of the same hydrocolloid that differ only in molecular weights and Shiraldi describes selecting and blending various polymers. Petitioner has not shown that a person of skill in the art would have understood that Shiraldi teaches or suggests selecting various polymers based upon high and low molecular weights. Nor has Petitioner established that Chen’s teaching to combine two or more types of the same hydrocolloid having differing molecular weights involved selecting a mixture of high and low molecular weights in the manner claimed. Indeed, neither reference provides a teaching or an example of such a practice. The example in Chen relied upon by Petitioner includes only a low molecular weight polyethylene oxide. Pet. 32 (referring to Chen Example 11 using a polyethylene oxide having an average molecular weight of 100,000 Da). In contrast to Chen, Shiraldi preferred and exemplified only high molecular weight polyethylene, in a range well beyond that recited in the claims for that

component. That is, Schiraldi describes the ethylene oxide useful for its invention as having “a relatively high molecular weight” and preferring molecular weights above 3,000,000, whereas the claims recite a molecular weight range of 600,000 to 900,000. *See* Ex. 1004, 4:25–31. Moreover, Petitioner has not shown that the cited prior art, alone or in combination, taught or suggested a film comprising both low and high molecular weight polyethylene oxide in the respective ranges recited by the claims, or with the specific percentage of the low molecular weight component required.

The portions of Dr. Mumper’s declaration cited by Petitioner do not provide any further support for Petitioner’s position. We note that Dr. Mumper does not explain why the polyethylene oxides molecular weights limitation would have been obvious to a person of ordinary skill over the combined teachings of the prior art. Instead, Dr. Mumper opines only that the skilled artisan “would be highly motivated to vary the amounts of the low and high molecular weight polyethylene oxide to achieve the desired effects including, but not limited to drug solubility, mucoadhesion and drug release rate.” Ex. 1003 ¶ 30. That opinion does not address a skilled artisan’s motivation, ability, or reasonable expectation of successfully achieving a film comprising the specific ranges and proportion of low and high molecular weight polyethylene oxides required by the claims. *See In re Fine*, 837 F.2d at 1074 (a showing of obviousness must be supported by evidence, as shown by some objective teaching in the prior art or by knowledge generally available to one of ordinary skill in the art that would have led that individual to combine the relevant teachings of the references to arrive at the claimed invention).

Based on at least those deficiencies, we determine that Petitioner has not demonstrated a reasonable likelihood of establishing that it would prevail in showing the unpatentability of independent claims 1 and 10, or their respective dependent claims, 3–9 and 12–18, over Chen, Schiraldi, and Chen II.

C. Obviousness over Schiraldi and Verma

Petitioner contends that claims 1, 4–5, 8, 10, 12–14, and 17 would have been obvious over the combination of Schiraldi and Verma. Pet. 39–48. Patent Owner disagrees. Prelim. Resp. 15–19.

1. Verma

Verma is directed to alkylene oxide polymer compositions having particular molecular weight distributions making the compositions suitable for the manufacture of water-soluble films, e.g., for use in soft gel capsules. Ex. 1005, 1:9–13. In particular, the compositions of the invention “can replace gelatin in the manufacture of soft shell capsules.” *Id.* at 5:24–26. The compositions may also be used in the manufacture of hard shell capsules, which are generally rigid. *Id.* at 5:31–33. The capsules may be used for the oral delivery of pharmaceutically active agents. *Id.* at 6:16–18. Preferably, the alkylene oxide polymers of the invention comprise ethylene oxide polymers. *Id.* at 2:12–13.

2. Analysis

Petitioner again relies on Schiraldi for the teachings asserted for the challenge over Chen, Schiraldi, and Chen II. Pet. 40. Petitioner asserts that Verma teaches using polyethylene oxides of different molecular weight to adjust film properties. *Id.* Petitioner asserts also that Verma discloses films containing polymers having differing molecular weights that are flexible and

disintegrate rapidly in water. *Id.* According to Petitioner, those teachings “would have motivated a person of ordinary skill in the art to make the films recited in the challenged claims.” *Id.* Specifically, Petitioner asserts that Verma would have provided a skilled artisan the particular ratios needed to control the structural properties of Schiraldi’s film and “the release rate of the active ingredient in order to achieve balance between dissolution and mucoadhesion.” *Id.* at 41.

Patent Owner asserts that Petitioner has not provided a reasonable motivation for combining the teachings of Schiraldi and Verma, or explained that those teachings could be combined. Prelim. Resp. 16–19. In particular, Patent Owner asserts that a person of skill in the art would not have combined the references because Verma is not directed to making a mucosally-adhesive film or any type of film that comprises a pharmaceutical active in the film. *Id.* at 17. According to Patent Owner, Verma is instead directed to making plastic exterior films for capsules that are subsequently filled with liquid drugs or granules and intended to be taken orally, i.e., swallowed. *Id.*

We agree with Patent Owner. Petitioner’s discussion of Verma excludes any mention that Verma is directed to films for use in manufacturing soft and hard shell capsules. Petitioner also does not reference any teaching or suggestion in Verma demonstrating that its disclosure is applicable to mucosally-adhesive water-soluble film products. Nor does the Petitioner reference any portion of Dr. Mumper’s declaration that squarely addresses that issue. Thus, Petitioner has not provided any persuasive argument or evidence that a person of ordinary skill in the art preparing a mucosally-adhesive water-soluble film, as disclosed by

Schiraldi, would have had a reason to consider or apply the teachings relating to manufacturing films for capsule shells that are intended to be administered and to deliver active agents in a completely different manner. Further, as Patent Owner has asserted, Petitioner also fails to provide evidence that a skilled artisan would have had a reasonable expectation that teachings relating to preparing a film used to manufacture capsules intended to deliver drugs systemically after being swallowed may be successfully applied to a film that delivers drugs by adhering to a wet mucosal surface in the oral cavity.

Accordingly, we determine that Petitioner has not demonstrated a reasonable likelihood of establishing that it would prevail in showing the unpatentability of independent claims 1 and 10, or their respective dependent claims 4–5, 8, 12–14, and 17, over the combination of Schiraldi and Verma.

D. Obviousness over Schiraldi, Verma, and Khan

Petitioner contends that claims 6–7, 9, 15–16, and 18 would have been obvious over the combination of Schiraldi, Verma, and Khan. Pet. 49–50. Patent Owner disagrees. Prelim. Resp. 15–19.

For this challenge, Petitioner relies upon the combination of Schiraldi and Verma in the same manner discussed *supra* regarding the challenge of independent claims 1 and 10. Petitioner relies on Khan only as providing the additional claim elements recited in claims 6–7, 9, 15–16, and 18, e.g., sweeteners or buffers. Consequently, we remain unpersuaded for the same reasons discussed regarding the ground involving the combination of Schiraldi and Verma.

Accordingly, we determine that Petitioner has not demonstrated a reasonable likelihood of establishing that it would prevail in showing the

unpatentability of claims 6–7, 9, 15–16, and 18 over the combination of Schiraldi, Verma, and Khan.

E. Obviousness over Yang

Petitioner contends that claims 1, 4–10, and 13–18 would have been obvious over Yang. Pet. 50–58. Patent Owner disagrees, asserting that Yang is not prior art. Prelim. Resp. 19–21. We agree with Patent Owner.

The parties dispute the priority date of the '150 patent. That dispute revolves around whether the '150 patent is entitled to the May 28, 2003 filing date of its provisional application, Application No. 60/473,902 (“the '902 application”). Petitioner asserts that the '902 application did not include a disclosure sufficient to show possession of the claim limitation reciting “the polyethylene oxide of low molecular weight comprises about 60% or more in the polymer component.” Pet. 21; Ex. 1001, claims 1 and 10. According to Petitioner, “[i]t was only the claims of the '150 patent itself, as amended during prosecution, that provided any disclosure of compositions containing . . . a polymer component comprising at least 60% low molecular weight PEO.” Pet. 21–22. Petitioner, however, does not address the following disclosure in the '902 application stating,

[f]or instance, certain film properties, such as fast dissolution rates and high tear resistance, may be attained by combining small amounts of high molecular weight PEOs with larger amounts of lower molecular weight PEOs. *Desirably, such compositions contain about 60% or greater levels of the lower molecular weight PEO* in the PEO-blend polymer component.

Ex. 1011, 29 (emphasis added). Based upon our review, that disclosure in the '902 application provides a written description sufficient to comply with 35 U.S.C. § 112, ¶ 1 with respect to specific percentage limitation raised by Petitioner. Thus, Petitioner has not established that Yang is prior art in view

of the May 28, 2003 priority date for the '150 patent claims. As the Patent Owner correctly asserted, the district court found, for a similar reason, that the '150 patent is entitled to a priority date of May 28, 2003, and that Yang, therefore, is not prior art. Prelim. Resp. 21 (citing Ex. 2009, 53).

Accordingly, we determine that Petitioner has not demonstrated a reasonable likelihood of establishing that that it would prevail in showing the unpatentability of claims 1, 4–10, and 13–18 over Yang.

III. CONCLUSION

For the foregoing reasons, we determine that the information presented in the Petition does not establish that there is a reasonable likelihood that Petitioner would prevail in showing that any of the challenged claims are unpatentable.

IV. ORDER

In consideration of the foregoing, it is hereby ordered that the Petition is *denied*.

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