IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RECKITT BENCKISER PHARMACEUTICALS INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC, Plaintiffs, v. DR. REDDY'S LABORATORIES S.A., and DR. REDDY'S LABORATORIES, INC., Defendants.	Civil Action No. 14-1451-RGA

TRIAL OPINION

Mary W. Bourke, Dana K. Severance, Daniel M. Attaway, WOMBLE CARLYLE SANDRIDGE & RICE, LLP, Wilmington, DE.

Attorneys for Plaintiffs.

Daniel A. Ladow, James M. Bollinger, Timothy P. Heaton, J. Magnus Essunger, TROUTMAN SANDERS LLP, New York, NY; Charanjit Brahma, TROUTMAN SANDERS LLP, San Francisco, CA; Robert E. Browne, Jr., TROUTMAN SANDERS LLP, Chicago, IL; Puja Patel Lea, TROUTMAN SANDERS LLP, Atlanta, GA; Jeffrey B. Elikan, Jeffrey Lerner, Erica N. Andersen, Ashley M. Kwon, COVINGTON & BURLING LLP, Washington, DC.

Attorneys for Plaintiffs Reckitt Benckiser Pharmaceuticals Inc. and RB Pharmaceuticals Limited

James F. Hibey, STEPTOE & JOHNSON LLP, Washington, DC; Cassandra A. Adams, STEPTOE & JOHNSON LLP, New York, NY.

Attorneys for Plaintiff MonoSol Rx, LLC

Richard D. Kirk, Stephen B. Brauerman, Sara E. Bussiere, BAYARD, P.A., Wilmington, DE; Elaine H. Blais, Robert Frederickson, III, Molly R. Grammel, Alexandra Lu, Kathryn Kosinski, GOODWIN PROCTER LLP, Boston, MA; Ira J. Levy, Robert V. Cerwinsky, GOODWIN PROCTER LLP, New York, NY; John Coy Stull, GOODWIN PROCTER LLP, Washington, DC.

Attorneys for Defendants Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc.

Aug. 31, 2017

Richard G. Andrews

ANDREWS, U.S. DISTRICT JUDGE:

Plaintiffs Reckitt Benckiser Pharmaceuticals, Inc.,[1] RB Pharmaceuticals Limited,[2] and MonoSol Rx, LLC (collectively, "Plaintiffs") bring this suit against Defendants Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL"[3]). This opinion addresses claims of infringement and invalidity with respect to U.S. Patent No. 8,017,150 (the "'150 patent").

The Court held a one-day bench trial with respect to this patent on November 7, 2016. (D.I. 298 ("Tr.")). The parties filed joint proposed findings of fact (D.I. 273), post-trial briefing with respect to infringement (D.I. 277; D.I. 286; D.I. 294), and post-trial briefing with respect to invalidity (D.I. 276; D.I. 287; D.I. 292). Having considered the documentary evidence and testimony, I make the following findings of fact and conclusions of law pursuant to Federal Rule of Civil Procedure 52(a).

I. BACKGROUND

Plaintiff Indivior is the holder of approved New Drug Application No. 22-410 for Suboxone® sublingual film, which is indicated for maintenance treatment of opioid dependence. (D.I. 228-2, Admitted Fact Nos. 13–14, 20). The active ingredients of Suboxone® sublingual film are buprenorphine hydrochloride and naloxone hydrochloride. (D.I. 228-2, Admitted Fact Nos. 15–18). Suboxone® sublingual film is available in four dosage strengths (buprenorphine

[1] Citations to "D.I.___" are to the docket in C.A. No. 14-1451 unless otherwise noted. Plaintiff Reckitt Benckiser Pharmaceuticals, Inc. is now known as Indivior Inc. (D.I. 228-2, Admitted Fact No. 2).

[2] Plaintiff Reckitt Benckiser Pharmaceuticals Limited is now known as Indivior UK Limited. (D.I. 228-2, Admitted Fact No. 4).

[3] DRL was substituted as a party in place of Teva Pharmaceuticals USA, Inc. following Teva's transfer of ownership of ANDA Nos. 205299 and 205806 to DRL. (D.I. 228-2, Admitted Fact No. 12 at n.2).

hydrochloride/naloxone hydrochloride): 2 mg/0.5 mg, 4 mg/1 mg, 8 mg/2 mg, and 12 mg/3 mg. (D.I. 228-2, Admitted Fact Nos. 16–18). Since the approval of NDA No. 22-410, Suboxone® Sublingual Film has been exclusively manufactured in the United States by Plaintiff MonoSol and exclusively sold in the United States by Plaintiff Indivior. (D.I. 228-2, Admitted Fact No. 19).

The '150 patent, entitled "Polyethylene Oxide-Based Films and Drug Delivery Systems Made Therefrom," issued on September 13, 2011. (D.I. 228-2, Admitted Fact No. 24). The '150 patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalences Evaluations (the "Orange Book") as covering Suboxone® Sublingual Film. (D.I. 228-2, Admitted Fact No. 26). MonoSol owns the '150 patent and Indivior is an exclusive licensee of the '150 patent. (D.I. 228-2, Admitted Fact No. 25).

Plaintiffs are asserting independent claim 1 and dependent claims 4, 5, 8, and 9 of the '150 patent against DRL. (D.I. 273 at p. 110). Claim 1 of the '150 patent reads:

> 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 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.

(JTX-1 ("'150 patent"), claim 1).

II. LEGAL STANDARDS

A. Infringement

A patent is infringed when a person "without authority makes, uses, offers to sell, or sells any patented invention, within the United States . . . during the term of the patent . . . ." 35 U.S.C. § 271(a). A two-step analysis is employed in making an infringement determination. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). First, the court must construe the asserted claims to ascertain their meaning and scope. *See id.* The trier of fact must then compare the properly construed claims with the accused infringing product. *See id.* This second step is a question of fact. *Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed. Cir. 1998).

"Literal infringement of a claim exists when every limitation recited in the claim is found in the accused device." *Kahn v. Gen. Motors Corp.*, 135 F.3d 1472, 1477 (Fed. Cir. 1998). "If any claim limitation is absent from the accused device, there is no literal infringement as a matter of law." *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000). If an accused product does not infringe an independent claim, it also does not infringe any claim depending thereon. *See Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1553 (Fed. Cir. 1989). However, "[o]ne may infringe an independent claim and not infringe a claim dependent on that claim." *Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352, 1359 (Fed. Cir. 2007) (internal quotation marks omitted). A product that does not literally infringe a patent claim may still infringe under the doctrine of equivalents if the differences between an individual limitation of the claimed invention and an element of the accused product are insubstantial. *See Warner–*

Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 39–40 (1997). The patent owner has the burden of proving infringement by a preponderance of the evidence. *See SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988).

B. Obviousness

The presumption that all patents are valid is the starting point for any obviousness determination. 35 U.S.C. § 282. A patent claim is invalid as obvious under 35 U.S.C. § 103 "if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains." *Id.* § 103(a); *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406–07 (2007). Obviousness is a question of law that depends on the following factual inquiries: (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the relevant art; and (4) any objective indicia of nonobviousness. *See KSR*, 550 U.S. at 406; *see also Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1347 (Fed. Cir. 2012). A court is required to consider secondary considerations, or objective indicia of nonobviousness, before reaching an obviousness determination, as a "check against hindsight bias." *See In re Cyclobenzaprine Hydrochloride Extended–Release Capsule Patent Litig.*, 676 F.3d 1063, 1078–79 (Fed. Cir. 2012). Relevant secondary considerations include commercial success, long felt but unsolved needs, failure of others, praise, unexpected results, and copying, among others. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966); *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 662–63 (Fed. Cir. 2000); *Tex. Instruments, Inc. v. U.S. Int'l Trade Comm'n*, 988 F.2d 1165, 1178 (Fed. Cir. 1993).

"Generally, a party seeking to invalidate a patent as obvious must demonstrate . . . that a skilled artisan would have had reason to combine the teaching of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success from doing so." *In re Cyclobenzaprine Hydrochloride*, 676 F.3d at 1068–69. "The Supreme Court has warned, however, that, while an analysis of any teaching, suggestion, or motivation to combine known elements is useful to an obviousness analysis, the overall obviousness inquiry must be expansive and flexible." *Id.* at 1069. The improvement over prior art must be "more than the predictable use of prior art elements according to their established functions." *KSR*, 550 U.S. at 417. Evidence of obviousness, however, especially when that evidence is proffered in support of an "obvious-to-try" theory, is insufficient unless it indicates that the possible options skilled artisans would have encountered were "finite," "small," or "easily traversed," and "that skilled artisans would have had a reason to select the route that produced the claimed invention." *In re Cyclobenzaprine Hydrochloride*, 676 F.3d at 1072. Obviousness must be proven by clear and convincing evidence. *Id.* at 1078.

III. DISCUSSION

A. Infringement

1. Findings of Fact

1. A person of ordinary skill in the art ("POSA") would understand that only polyethylene oxide ("PEO") and hydrophobic cellulosic polymers ("HCPs") are actually claimed by the patent.
2. The specification of the '150 patent identifies polyvinyl pyrrolidone ("PVP") as an alternative to HCP in a list of useful "Film-Forming Polymers."
3. Example EA in the '150 patent specification—which is described as an "example of the present invention"—uses a polymer blend of PEO and PVP.
4. Figure 38 in the '150 patent specification describes "compositions of the invention" that include PEO or PEO/polymer blends.

5. Examples EI and EJ, which are listed in Figure 38, use PVP as an alternative to HCP in forming the PEO/polymer-blend films of the alleged invention of the '150 patent.

6. A POSA, understanding the patent as whole, would find that PVP was disclosed as an alternative to the HCP element in the asserted claims.

2. Conclusions of Law

The asserted claims require a water-soluble polymer component of PEO in combination with a HCP. The water-soluble polymer component comprises greater than 75% PEO and up to 25% HCP. The PEO component comprises low molecular weight PEOs and high molecular weight PEOs. A certain amount of low molecular weight PEO is required by the claims. (*See* '150 patent, claim 1).

Plaintiffs argue that the sole infringement dispute is whether DRL, by substituting PVP for HCP in DRL's ANDA, infringes via the doctrine of equivalents. Defendants argue that Plaintiffs cannot apply the doctrine of equivalents to capture DRL's ANDA products because the patentees disclosed, but did not claim, PVP as an alternative to HCP.

"[O]ne of ordinary skill in the art should be able to read a patent, to discern which matter is disclosed and discussed in the written description, and to recognize which matter has been claimed." *PSC Computer Prod., Inc. v. Foxconn Int'l, Inc.*, 355 F.3d 1353, 1359 (Fed. Cir. 2004). "The presumption is, and such is generally the fact, that what is not claimed was not invented by the patentee, but was known and used before he made his invention. But, whether so or not, his own act has made it public property, if it was not so before." *Mahn v. Harwood*, 112 U.S. 354, 361 (1884). "The ability to discern both what has been disclosed and what has been claimed is the essence of public notice." *PSC*, 355 F.3d at 1360. "It tells the public which products or processes would infringe the patent and which would not." *Id.* "Were the patentee allowed to reclaim some specifically-disclosed-but-unclaimed matter under the doctrine of equivalents, the public would have no way of knowing which disclosed matter infringed and

which did not." *Id.* "Such a reclamation would eviscerate the public notice function of patents and create uncertainty in the law." *Id.*

"[I]f one of ordinary skill in the art can understand the unclaimed disclosed teaching upon reading the written description, the alternative matter disclosed has been dedicated to the public." *Id.* "This 'disclosure-dedication' rule does not mean that any generic reference in a written specification necessarily dedicates all members of that particular genus to the public." *Id.* "The disclosure must be of such specificity that one of ordinary skill in the art could identify the subject matter that had been disclosed and not claimed." *Id.*

Plaintiffs argue that because there is no passage or example in the '150 patent specification that specifically discloses a combination of low and high molecular weight PEOs with PVP, the dedication-disclosure rule does not apply. I disagree. It would be clear to a POSA reading the patent as a whole that PVP is disclosed as an alternative to the HCP element of the asserted claims. (Tr. 260:3–18). The strongest evidence that PVP can be used as an alternative to HCP is in the part of the specification where PEO, HCP, and PVP are listed as examples of useful water-soluble film-forming polymers. ('150 patent, 15:44–56).[4] Dr. Mathias, Plaintiffs' expert, relied on the same disclosure to argue that PVP serves the same purposes as HCPs. (Tr. 132:3–133:16).

---

[4] Column 15, lines 44 to 56 of the '150 patent provides:

> The polymer may be water soluble, water swellable, water insoluble, or a combination of one or more either water soluble, water swellable or water insoluble polymers. The polymer may include cellulose or a cellulose derivative. Specific examples of useful water soluble polymers include, but are not limited to, polyethylene oxide (PEO), pullulan, hydroxypropylmethyl cellulose (HPMC), hydroxyethyl cellulose (HPC), hydroxypropyl cellulose, polyvinyl pyrolidone (sic), carboxymethyl cellulose, polyvinyl alcohol, sodium aginate, polyethylene glycol, xanthan gum, tragancanth gum, guar gum, acacia gum, arabic gum, polyacrylic acid, methylmethacrylate copolymer, carboxyvinyl copolymers, starch, gelatin, and combinations thereof.

Further support is found in Example EA of the '150 patent, which relates to an "example of the present invention" that "describes films that include PEO and polyvinyl pyrrolidone (PVP) polymeric blends." ('150 patent, 51:49–51). This example discloses that "the polymer component of the films contained about 80% PEO and 20% PVP, or a ratio of 4:1 PEO to PVP." (*Id.*, 51:53–54). Again, Dr. Mathias uses Example EA to argue that PVP functions in an equivalent manner to HCPs. (Tr. 135:1–137:2).

Examples EI and EJ in Figure 38 also support the fact that PVP is an alternative to HCP. These examples are described as having similar properties to films made with polymer components comprised of PEO and HCP. (Tr. 273:18–275:5). Dr. Mathias relies on these examples to argue that PVP is the equivalent to HCP. (Tr. 137:21–140:15).

Plaintiffs note that these three references only combine PVP with a single grade of PEO. Further, Plaintiffs note that Examples EI and EJ use only a low molecular weight PEO and contain a lower percentage of the total PEO than that which is required in the polymer component of claim 1. Even if this is true, I think that when these examples are read in conjunction with column 15, lines 44 to 56 of the specification, a POSA would still understand that PVP was adequately disclosed as an alternative to the HCP element of the claims. (Tr. 276:6–277:13).

Plaintiffs argue that *Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co.*, 285 F.3d 1046 (Fed. Cir. 2002) (en banc) is distinguishable. In *Johnson*, the specification provided, "While aluminum is currently the preferred material for the substrate, other metals, such as stainless steel or nickel alloys may be used." *Johnson*, 285 F.3d at 1055. The court held, "Having disclosed without claiming the steel substrates, [Plaintiff] cannot now invoke the doctrine of equivalents to extend its aluminum limitation to encompass steel." *Id.* The facts here are analogous to those in

Johnson. Here, there is a portion of the specification where HCPs and PVP are listed as examples of useful water-soluble film-forming polymers. PVP is akin to steel and HCP is akin to aluminum. *See also PSC*, 355 F.3d at 1360 ("We agree with the district court, however, that the specific disclosure that '[o]ther prior art devices use molded plastic and/or metal parts that must be cast or forged which again are more expensive metal forming operations,' . . . dedicated the alternative use of plastic parts to the public."); *Aventis Pharm., Inc. v. Barr Labs., Inc.*, 335 F. Supp. 2d 558, 578 (D.N.J. 2004) ("By disclosing but not claiming povidone, crospovidone, and sodium starch glycolate, the patents have dedicated these ingredients to the public, and cannot now reclaim these excipients through application of the doctrine of equivalents."); *In re Bendamustine Consol. Cases*, 2015 WL 1951399, at *2 (D. Del. Apr. 29, 2015) ("By claiming only TBA from among the listed organic solvents, the patentee effectively disclaimed the remaining solvents in the list and cannot employ the doctrine of equivalents to bring them back within the scope of the '190 and '863 patents.").

Because I find that the dedication-disclosure rule applies here, Plaintiffs fail to show that DRL infringes the '150 patent.

B. Validity

Defendants argue that the '150 patent is not entitled to the 2003 priority date of the '902 application and therefore that all asserted claims are obvious in view of Yang (2005). Defendants alternatively argue that the asserted claims of the '150 patent are invalid as obvious even with a 2003 priority date.

1. Findings of Fact

1. A POSA would include someone with a bachelor's degree in pharmaceutical sciences, chemistry, or a related field, plus two to five years of relevant experience in developing drug formulations, including orally dissolving and film strip dosage forms.

2. A POSA would understand the '902 application to use the term "polymer component" to refer to all polymers in the formulation, including the low molecular weight PEO, high molecular weight PEO, and any HCP.

3. A POSA would look beyond the Summary of the Invention of the '902 application, and find that the '902 application as a whole discloses hydrophilic cellulosic polymer in the polymer component.

4. The written description reasonably conveys to a POSA that the inventors had possession of the invention where the water-soluble polymer component is comprised of low and high molecular weight PEO in combination with HCP and where the low molecular weight PEO is about 60% or more of the polymer component as of the filing date.

5. Yang is not prior art.

6. Schiraldi is directed to mucoadhesive film compositions for delivery of certain drugs in the mouth.

7. Verma is directed to alkylene oxide polymer compositions having particular molecular weight distributions.

8. A POSA would not be motivated to combine Schiraldi and Verma because Verma is mainly directed at soft gel capsules and is directed to a broad variety of applications such as bath oil beads and the delivery of inks, which are far removed from the area of mucoadhesive films.

9. Even if a POSA were motivated to combine Schiraldi and Verma, substantial modifications would still need to be made in order to achieve the claimed films.

10. Schiraldi teaches away from the claimed invention, for example, by strongly recommending that one begin with PEO with molecular weights of three to five million.

11. A POSA would not have a reasonable expectation of success from combining Schiraldi and Verma to achieve the film of Claim 1 of the '150 patent.

12. A POSA would find that the claimed film containing an analgesic opiate and possessing desirable properties of mucoadhesion and water solubility was unexpected.

13. Defendants fail to show that the '150 patent is obvious.

2. Conclusions of Law

a) Person of Ordinary Skill in the Art

A POSA would include someone with a bachelor's degree in pharmaceutical sciences, chemistry, or a related field, plus two to five years of relevant experience in developing drug

formulations, including orally dissolving and film strip dosage forms. (Tr. 261:17–262:15, 308:8–19, 369:3–23, 368:23–369:23).

b) Priority Date of April 22, 2008

Application Serial No. 12/107,389 that issued as the '150 patent was filed on April 22, 2008 as a continuation-in-part tracing back to Provisional Application No. 60/473,902. (D.I. 228-2, Admitted Fact No. 190; JTX-1 at 1). The '902 application was filed on May 28, 2003. (D.I. 228-2, Admitted Fact No. 192; JTX-10 at 5). Defendants argue that Yang (the published version of the '150 patent's parent application) is prior art because the '150 patent is not entitled to the priority date of the '902 application. Defendants argue that the '902 application failed to adequately describe the requirement of HCP in the polymer component of the claimed invention. Defendants further argue that the '902 application fails to convey possession of any polymer component that includes a polymer component with a low molecular weight PEO, a high molecular weight PEO, and an HCP where the low molecular weight PEO is at least 60% of the polymer component.

To be entitled to the filing date of an earlier patent application, the earlier application must contain a disclosure that complies with 35 U.S.C. § 112, ¶ 1. *See* 35 U.S.C. § 120; *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571 (Fed. Cir. 1997). Section 112, ¶ 1 provides that:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112, ¶ 1.

The '902 application discloses the following:

> For 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 PEGs. Desirably, such compositions contain about 60% or greater levels of the lower molecular weight PEO in the PEO-blend polymer component.
>
> To balance the properties of adhesion prevention, fast dissolution rate, and good tear resistance, desirable film compositions may include about 50% to 75% low molecular weight PEO, optionally combined with a small amount of a high molecular weight PEO, with the remainder of the polymer component containing a hydrophilic cellulosic polymer (HPC or HPMC).

(JTX-10 at 35). Reviewing these passages in their entirety, a POSA would understand the '902 application to use the term "polymer component" to refer to all polymers in the formulation, including the low molecular weight PEO, high molecular weight PEO and any HCP. (Tr. 296:18-397:2, 397:20–23, 398:5–23, 399:18–21). Thus, the words, "polymer component" in the phrase, "such compositions contain about 60% or greater levels of the lower molecular weight PEO in the PEO-blend polymer component," include HPC. (Tr. 397:20–23).

Examples DT and DU of the '902 application disclose formulations where the polymer component includes low and high molecular weight PEOs, along with HCP. Although the examples do not expressly indicate that the polymer component contains at least 60% low molecular weight PEO (JTX-10 at 85, table 22), this does not evince a lack of written description in light of the disclosure discussed above. Defendants argue that the Summary of the Invention of the '150 patent contains language that explicitly requires the inclusion of HCP in the polymer component whereas the Summary of the Invention in the '902 application does not. This difference is not persuasive as a POSA would look beyond the Summary of the Invention of the '902 application and find that the '902 application as a whole discloses HCP in the polymer component.

The written description reasonably conveys to a POSA that the inventors had possession of the invention where the water-soluble polymer component is comprised of low and high molecular weight PEO in combination with HCP and where the low molecular weight PEO is about 60% or more of the polymer component as of the filing date. (Tr. 394:9–401:10, 413:2–414:13). Thus, the '150 patent is entitled to the priority date of May 28, 2003. Yang is therefore not prior art.

Defendants have not established proof by clear and convincing evidence that the '150 patent is obvious over Yang.[5]

c) Priority Date of 2003

(1) Scope and Content of the Prior Art

(a) Background

As of 2003, pharmaceutical film technology remained in a nascent stage. (Tr. 369:13–370:17). The first prescription pharmaceutical film was not approved until 2009. (Tr. 370:5–6). Suboxone®, the first prescription sublingual film, was approved by the FDA in 2010. (Tr. 370:9–12).

As of 2003, the state of the art was that people were focusing on high molecular weight polymers, such as polymers with a molecular weight of three to five million, which had the property of crystallization. (Tr. 371:24–372:8). Crystallization imparts to films hardness and inflexibility and detracts from solubility. (Tr. 372:9–13). To control crystallinity, one strategy was to add plasticizers, such as alcohols. The addition of plasticizers changes crystallization and results in a more amorphous substance. (Tr. 373:2–20). There were limitations to the extent that

[5] Plaintiffs argue that 35 U.S.C. § 121 further serves to prevent the use of Yang as prior art. I do not need to reach this issue in light of my finding that Yang is not prior art.

alcohol was used as alcohol denatures proteins. (Tr. 373:13–20). Another strategy was to add soluble polymers such as cellulosic polymers. Entanglements between PEO and cellulosic polymers decrease crystallization and impart flexibility to the film. (Tr. 374:5–17).

(b) Prior Art References

Schiraldi (1987) is directed to mucoadhesive film compositions for the delivery of certain drugs in the mouth. (Tr. 310:7–10). Schiraldi discloses that the film consists "essentially of 40-95% by weight of a hydroxypropyl cellulose, 5-60% of a homopolymer of ethylene oxide, 0-10% of a water-insoluble polymer such as ethyl cellulose, propyl cellulose, polyethylene and 2-10% of a plasticizer . . . ." (DTX-35, Abstract). Schiraldi thus discloses the combination of HCP ("hydroxypropyl cellulose") and PEO ("homopolymer of ethylene oxide") with other ingredients in films. (Tr. 310:11–311:11, 355:12–17). Schiraldi teaches that the PEO "has a relatively high molecular weight, i.e., above 100,000 and preferably above 3,000,000." (DTX-35, 4:25–27). It further teaches that PEO with a molecular weight of approximately 4,000,000–5,000,000 is the most preferred. (*Id.*, 4:29–31). Schiraldi claims PEO having a molecular weight from 3,000,000–5,000,000. (DTX-35, Claim 1). Schiraldi thus teaches the use of very high molecular weight PEO. Schiraldi does not expressly disclose the combination of low and high molecular weight PEOs required by the '150 patent. (Tr. 365:7–366:10, 375:7–376:8, 380:12–22). Schiraldi teaches that by varying the ratios of the water-soluble and water-insoluble compounds, "both the solubility and the adhesive properties of each layer of film may be controlled." (DTX-35, 3:25–27). A POSA would not understand this to teach varying the ratios of soluble polymers such as HPMC and PEO with respect to each other. (Tr. 377:22–380:8). Schiraldi discloses that its films may contain: "Anesthetics/Analgesics dyclonine HCL, phenol, aspirin, phenacetin,

acetaminophen, potassium nitrate, etc." (DTX-35, 3:41–44). Schiraldi does not expressly disclose opiates. (Tr. 377:16–21).

Verma is directed to alkylene oxide polymer compositions having particular molecular weight distributions. (JTX-21, Abstract). The preferred use for these compositions is in making soft gel capsules. (*Id.*, 5:22–24). These compositions could also be used in making hard shell capsules. (*Id.*, 5:31–33). These shells are not required to dissolve in the oral cavity. It is not required to be mucoadhesive. These shells can be used for swallowing. (Tr. 381:18–383:3). They can also can be used for hair care, skin care, as bath oil beads, fragrances, timed release ingredients, paint balls, and the delivery of inks. (JTX-21, 6:14–27). Verma discloses polyethylene oxide. (Tr. 314:3–5). It teaches that polyethylene oxide polymers can be combined with other types of polymers such as cellulose derivatives. (Tr. 314:15–21). Verma does not expressly disclose combining PEOs of different molecular weights with a hydrophilic cellulosic polymer. (Tr. 389:9–14; JTX-21 at 11:58–63, Tables 1–4). While Verma discloses the combination of different grades of polyethylene oxide such as polyox WSR-750 (molecular weight of 300,000) and polyox WSR-1105 (molecular weight of 900,000) (Tr. 315:3–11), the disclosure is not discussed in the text of the patent and is among Verma's twenty-four examples of formulations for its capsule shells. (Tr. 357:6–358:9, 386:24–387:10; JTX-21). Verma does not disclose the low and high molecular weight PEOs in the claimed amounts and ratios. (Tr. 385:14–19, 389:9–14, 389:21–390:6). Verma does not teach that this combination confers any special characteristics, such as mucoadhesion, flexibility, and rapid dissolution in the oral cavity. (Tr. 382:20–383:6, 386:5–17).

(2) Comparing Prior Art and Claimed Subject Matter

The claims describe the film products as a "mucosally-adhesive" and "water-soluble." (JTX-1 at 57:36–54). I do not think a POSA would be motivated to combine Schiraldi and Verma because Verma is mainly directed at soft gel capsules and to a broad variety of applications such as bath oil beads and the delivery of inks—applications which are far removed from the area of mucoadhesive films.

Assuming that a POSA would be motivated to combine Schiraldi and Verma, substantial modifications would still need to be made in order to achieve the claimed films. One would have to adjust the 40/60 single grade PEO/HCP ratio of Schiraldi to a 75/25 ratio. One would have to understand Verma to teach the 300,000 and 900,000 PEO combination, which was not prominently highlighted in Verma, and ignore that Schiraldi taught a single grade of PEO. One would have to understand that even though Schiraldi most prefers a single grade of PEO from three to five million, one should look to PEO grades below one million. One would also have to implement 60% of the polymer component weight as the low molecular weight PEO. There is no reason other than hindsight to guide a POSA to implement all these modifications.

Indeed, Schiraldi teaches away from the claimed invention. Even though Schiraldi does say that the single grade of PEO could be greater than 100,000 in molecular weight, Schiraldi directs a POSA to molecular weights of three to five million. Schiraldi does not encourage a POSA to spend time experimenting with molecular weights below one million. Schiraldi teaches the use of too much HPC at 40–95% instead of the claimed "up to 25%." It is also significant that Schiraldi teaches the use of plasticizers and insoluble components because this teaches away from the heart of the invention.

This is a case where Defendants' theory of obviousness requires cherry-picking elements of the prior art and is the product of hindsight bias. A POSA would not have a reasonable expectation of success in achieving the film of Claim 1 of the '150 patent. It follows that the asserted dependent claims have also not been shown to be obvious.

Thus, I am not persuaded that Defendants have met their burden of showing obviousness.[6]

IV. CONCLUSION

For the foregoing reasons, Plaintiffs failed to meet their burden of showing that DRL infringes the asserted claims of the '150 patent. Defendants failed to meet their burden of showing by clear and convincing evidence that any asserted claims of the '150 patent is invalid as obvious.

Plaintiffs are directed to submit an agreed-upon form of final judgment within two weeks.

[6] Plaintiffs did not introduce any evidence of secondary considerations of nonobviousness. Secondary considerations therefore play no part in the analysis.