Trials@uspto.gov
571-272-7822

Paper 72
Entered: July 8, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PURDUE PHARMA L.P.,
Petitioner,

v.

DEPOMED, INC.,
Patent Owner.

Case IPR2014-00377
Patent 6,635,280 B2

Before ERICA A. FRANKLIN, GRACE KARAFFA OBERMANN, and TINA E. HULSE, *Administrative Patent Judges.*

HULSE, *Administrative Patent Judge.*

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

Purdue Pharma L.P. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1, 8–15, 43, 45, and 46 of U.S. Patent No. 6,635,280 B2 (Ex. 1001, "the '280 patent"). Paper 1 ("Pet."). Depomed, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 8 ("Prelim. Resp."). On July 10, 2014, we instituted an *inter partes* review of claims 1, 8–10, 13–15, 43, 45, and 46 on certain grounds of unpatentability alleged in the Petition. Paper 9 ("Dec. Inst."), 25. Patent Owner timely filed a Response (Paper 24, "PO Resp."), to which Petitioner timely filed a Reply (Paper 35, "Pet. Reply").

Both parties filed motions to exclude certain exhibits and testimony. Paper 41 (Petitioner); Paper 48 (Patent Owner). Both parties opposed the other's motion to exclude. Paper 56 (Patent Owner Opposition); Paper 51 (Petitioner Opposition). And both parties filed reply briefs in support of their motions to exclude. Paper 58 (Petitioner Reply); Paper 59 (Patent Owner Reply).

Patent Owner also filed a Motion for Observation (Paper 46) on certain cross-examination testimony of Petitioner's declarant Dr. Eric M. Gaier, and Petitioner filed a Response (Paper 52).

A consolidated oral hearing for this proceeding and Cases IPR2014-00378 and IPR2014-00379 was held on March 19, 2015, a transcript of which has been entered in the record.[1] Paper 71 ("Tr.")

---

[1] Petitioner and Patent Owner filed Objections to Demonstrative Exhibits. Paper 66 (Patent Owner); Paper 67 (Petitioner). In this Final Written Decision, we rely directly on the arguments presented properly in the

We have jurisdiction under 35 U.S.C. § 6(c). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

For the reasons that follow, we determine that Petitioner has not shown by a preponderance of the evidence that claims 1, 8–10, 13–15, 43, 45, and 46 of the '280 patent are unpatentable.[2]

A. Related Proceedings

Petitioner and Patent Owner identify various district court actions involving the '280 patent, including an action involving the parties titled *Depomed, Inc. v. Purdue Pharma L.P.*, No. 3:13-00571 (D.N.J.). Pet. ix; Paper 5 at 2–3.

Petitioner has also filed two related petitions for *inter partes* review of U.S. Patent No. 6,340,475 B2, which is the parent of the '280 patent. *See* IPR2014-00378, IPR2014-00379. We issue Final Written Decisions in those two related proceedings concurrently herewith.

B. The '280 Patent (Ex. 1001)

The '280 patent relates to drugs formulated as unit oral dosage forms by incorporating them into polymeric matrices comprised of hydrophilic polymers that swell upon imbibition of water to a size large enough to promote gastric retention of the drug during the fed mode. Ex. 1001,

---

parties' briefs and the evidence of record. The demonstrative exhibits were only considered to the extent they are consistent with those arguments and evidence.

[2] On February 20, 2015, Patent Owner objected to Petitioner's use of a condensed font in Petitioner's Reply paper. Petitioner, however, appears to have used the same condensed font throughout this proceeding. *Compare* Pet. *with* Pet. Reply (using same font). In light of Patent Owner's late objection, we deem the objection to be waived.

Abstract. Drugs administered by conventional tablets generally become available to body fluids at a high rate initially, followed by a rapid decline. *Id.* at 1:31–33. To address that issue, controlled drug delivery systems were introduced in the 1970's. *Id.* at 1:35–37. Many of the controlled delivery systems utilize hydrophilic, polymeric matrices that provide controlled release of sparingly soluble drugs. According to Specification, however, such matrices do not provide adequate control of drug release for highly soluble drugs. *Id.* at 1:45–50.

The claimed invention allows drugs that are highly soluble in water to be administered orally in a way that will prolong their release rate throughout the duration of the fed mode. *Id.* at 5:32–36. This prolonged release rate reduces the problem of transient overdosing, and controls the dosage to safer and more effective levels over an extended period of time. *Id.* at 5:36–41. Moreover, the Specification states that particles exceeding about 1 cm in size are larger than the pylorus and are retained in the stomach for approximately 4 to 6 hours. *Id.* at 11:66–12:2. The Specification states that these benefits are due, in part, to using a polymeric matrix that is water-swellable rather than just hydrophilic, that has an erosion rate substantially slower than its swelling rate, and that releases the drug primarily by diffusion rather than erosion. *Id.* at 5:57–62. Preferred polymeric matrices include water-swellable polymers such as hydroxypropylmethylcellulose ("HPMC") and poly(ethylene) oxide ("PEO"). *Id.* at 7:54–8:51.

C. Illustrative Claims

Independent claims 1 and 43 are illustrative and are reproduced below:

1. A controlled-release oral drug dosage form for releasing a drug whose solubility in water is greater than one part by weight of said drug in ten parts by weight of water, said dosage form comprising one or more polymers forming a solid polymeric matrix with said drug incorporated therein at a weight ratio of drug to polymer of from 15:85 to 80:20, said dosage form being one that when swollen in a dimensionally unrestricted manner as a result of imbibition of water is of a size exceeding the pyloric diameter in the fed mode to promote retention in the stomach during said fed mode, that releases said drug into gastric fluid by the dissolution and diffusion of said drug out of said matrix by said gastric fluid, that upon immersion in gastric fluid retains at least about 40% of said drug one hour after such immersion and releases substantially all of said drug after such immersion, and that remains substantially intact until substantially all of said drug is released.

43. A method of administering to a subject a drug that is therapeutic to said subject when absorbed in the stomach where said drug has at least one ionized group in the pH range 5 through 8, said method comprising orally administering to said subject a dosage form of said drug while said subject is in a fed mode, said dosage form comprising one or more polymers forming a solid polymeric matrix with said drug incorporated therein at a weight ratio of drug to polymer of from 0.01:99.99 to 80:20, said polymeric matrix being one that:

(a) when swollen in a dimensionally unrestricted manner as a result of imbibition of gastric fluid is of a size exceeding the pyloric diameter in the fed mode to promote retention in the stomach during said fed mode,

(b) releases said drug into gastric fluid by the dissolving of said drug by said gastric fluid and either erosion of said matrix or diffusion of said dissolved drug out of said matrix,

(c) retains at least about 40% of said drug one hour after such immersion in gastric fluid, and

(d) releases substantially all of said drug within about ten hours after such immersion,

thereby extending the release rate of said drug with time during said fed mode while releasing substantially all of said drug within said stomach where said drug is maintained in an acidic environment.

D. Grounds of Unpatentability Instituted for Trial

We instituted trial based on the following grounds of unpatentability:

Claims	**Basis**	**References**
1, 8, 9, 13–15, 45, and 46	§ 103	Baveja,[3] the '837 patent,[4] and the '548 patent[5]
10	§ 103	Baveja, Kim,[6] the '837 patent, and the '548 patent
43	§ 103	Baveja, the '837 patent, and Colombo[7]

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); *In re Cuozzo Speed Techs., LLC*, 778 F.3d 1271, 1279–81 (Fed. Cir. 2015). Under that standard, and absent any special definitions, we give

---

[3] Baveja et al., *Zero-Order Release Hydrophilic Matrix Tablets of β-adrenergic Blockers*, 39 INT'L J. OF PHARM. 39–45 (1987) (Ex. 1008).
[4] John W. Shell, US 5,582,837, issued Dec. 10, 1996 (Ex. 1010).
[5] Edgren et al., US 4,871,548, issued Oct. 3, 1989 (Ex. 1017).
[6] Cherng-ju Kim, *Drug Release from Compressed Hydrophilic POLYOX-WSR Tablets*, 84 J. PHARM. SCIENCES 303-306 (1995) (Ex. 1019).
[7] Colombo et al., *Drug Release Modulation by Physical Restrictions of Matrix Swelling*, 63 INT'L J. OF PHARM. 43-48 (1990) (Ex. 1009).

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).

1. Prior Construed Claim Terms

We construed the following claim terms in the Decision to Institute.

Claim Term	**Claim(s)**	**Construction**
"gastric fluid"	1, 43	"[b]oth the fluid in the stomach and simulated or artificial fluids recognized by those skilled in the art as a suitable model for the fluid of the human stomach" (Dec. Inst. 6–7)
"releases substantially all of said drug after such immersion"	1	"[a]t least 80% of the drug has been released" (Dec. Inst. 7)
"releases substantially all of said drug within about ten hours after such immersion"	43	"at least 80% of the drug has been released after ten hours of immersion in gastric fluid" (Dec. Inst. 7)
"substantially intact"	1	"a polymeric matrix in which the polymer portion substantially retains its size and shape without deterioration due to becoming solubilized in the gastric fluid or due to breakage into fragments or small particles" (Dec. Inst. 7–8)

Dec. Inst. 6–8.

Because nothing in the full record developed during trial persuades us to deviate from our prior constructions, we adopt those constructions for purposes of this Decision.

Two of the claim terms, however, require additional discussion at this stage of the proceeding:

2. "substantially all"

Patent Owner asserts that the term "substantially all," as it appears in various claim phrases in claims 1, 43, and 46, should be construed as "at least 80%." PO Resp. 15–16. Patent Owner notes that this construction would be consistent with our prior constructions of "releases substantially all of said drug after such immersion" and "releases substantially all of said drug within about ten hours after such immersion." Dec. Inst. 7. Petitioner does not object to Patent Owner's proposed construction in its Reply.

Based on the information presented and for the same reasons stated in our Decision to Institute (*id.*), we determine that the broadest reasonable interpretation of "substantially all" as used in the claims is "at least 80%."

3. "releases said drug . . . by the dissolution and diffusion of said drug out of said matrix"

The parties dispute the construction of the term "releases said drug . . . by the dissolution and diffusion of said drug out of said matrix" (i.e., the "dissolution and diffusion" limitation) in claim 1. We did not construe this term in the Decision to Institute for this proceeding. As Petitioner notes, however, we construed this term in related case IPR2014-00656, which also involves the '280 patent. Pet. Reply 1. In the Decision to Institute in that case, we preliminarily construed the term according to its plain and ordinary meaning and declined to limit claim 1 to require that drug release occurs

"primarily" by diffusion. *Endo Pharms. Inc. v. Depomed Inc.*, Case IPR2014-00656, slip op. at 9–10 (PTAB Sept. 29, 2014) (Paper 12).

Here, Patent Owner contends that the term should be construed as "rapid dissolution of the drug, followed by slow diffusion of the drug out of the water-swollen matrix, such that the drug is released at a rate controlled by the rate of diffusion." PO Resp. 16. Alternatively, Patent Owner proposes that the plain and ordinary meaning of the term is "dissolution liberates the drug molecule for release and subsequent diffusion controls the release of drug out of the matrix." *Id.* at 18. Petitioner, on the other hand, contends that our construction in the related case was correct, and that the plain and ordinary meaning of the term is "dissolution of the drug in the matrix followed by diffusion of the drug out of the matrix." Pet. Reply 2.

The main difference between the parties' constructions is whether diffusion must control the rate of release of drug out of the matrix. After considering the parties' arguments, we adopt Petitioner's construction as the broadest reasonable interpretation consistent with the Specification.

To construe the term, we start with the language of the claim. Claim 1 recites a "controlled-release oral drug dosage form" that "releases said drug into gastric fluid by the dissolution and diffusion of said drug out of said matrix by said gastric fluid." We determine that nothing in the claim language requires that the drug release be "at a rate controlled by the rate of diffusion," as Patent Owner asserts. To the extent Patent Owner suggests that its construction is dictated by the fact that the claim recites a "controlled-release" drug formulation for a highly soluble drug, we are not persuaded. In particular, we note that Patent Owner's own declarant,

Dr. Harold B. Hopfenberg, testified that those parameters do not necessarily require release by dissolution and diffusion:

> Q: Is it your opinion that, if you use a swellable polymer in a highly soluble drug and you get extended release that meets the requirements of Claim 1, that you must necessarily be releasing by dissolution and diffusion?
>
> A. Could you repeat that?
>
> (The record was read by the reporter.)
>
> THE WITNESS: No.

Ex. 1072, 44:17–24.

Patent Owner also argues that the Specification supports its narrowed construction. For example, Patent Owner asserts that the "focus of the '280 Patent is on slowing the rate of diffusion." PO Resp. 16. Patent Owner also notes that the Specification "states the invention disclosed 'is achieved by using a formulation in which the drug is incorporated in a polymeric matrix that is water-swellable rather than merely hydrophilic, that has an erosion rate that is substantially slower than its swelling rate, and that releases the drug primarily by diffusion.'" *Id.* at 17 (quoting Ex. 1001, 5:57–62).

We are not persuaded. Our reviewing court has warned that, "[a]bsent claim language carrying a narrow meaning, the PTO should only limit the claim based on the specification or prosecution history when those sources *expressly disclaim* the broader definition." *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004) (emphasis added). Here, the Specification does not expressly disclaim other mechanisms of drug release that are not controlled by diffusion. Indeed, most of the '280 patent claims are directed to drug dosage forms that release the drug by erosion or diffusion, reciting that the dosage form "releases said drug into gastric fluid by the dissolving of said

drug by said gastric fluid and either erosion of said matrix or diffusion of said dissolved drug out of said matrix." Ex. 1001, claim 43; *see also* independent claims 19, 22, 24, 27, 28, 29, 30, 32, 33, 34, 37, 38, 39, 40, 42, 44 (reciting similar "erosion or diffusion" limitations). Thus, to the extent Patent Owner asserts those claims have sufficient written description support, the '280 patent Specification clearly is not limited to dosage forms where drug release is controlled by the rate of diffusion.

Finally, our reviewing court "counsels the PTO to avoid the temptation to limit broad claim terms solely on the basis of specification passages." *Bigio*, 381 F.3d at 1325. Accordingly, while the Specification's "Summary of the Invention" may state that the drug formulation "releases the drug primarily by diffusion" (Ex. 1001, 5:56–62), we decline to import that limitation from the Specification. *See Bigio*, 381 F.3d at 1325 (affirming Board's construction that declined to limit "hair brush" to scalp hair brushes despite statements in the "Objects of the Invention").

Patent Owner alternatively argues that a person of ordinary skill in the art would have understood the plain and ordinary meaning of claim 1 to require that "dissolution liberates the drug molecule for release and subsequent diffusion controls the release of drug out of the matrix." PO Resp. 17–18. We are not persuaded. As explained above, nothing in the claim language requires that diffusion must control the release of the drug. And, contrary to Patent Owner's suggestion, the testimony by Petitioner's declarant, Dr. Roland Bodmeier, that drug "is released by diffusion" does not amount to an admission that drug release is *controlled* by the rate of diffusion. *See id.* Rather, Dr. Bodmeier's testimony is consistent with our interpretation of the plain and ordinary meaning of the claim.

Upon considering the parties' arguments and evidence, we determine that the broadest reasonable interpretation of "releases said drug . . . by the dissolution and diffusion of said drug out of said matrix" is "releases the drug by dissolution of the drug in the matrix followed by diffusion of the drug out of the matrix."

B. Principles of Law

To prevail in its challenges to the patentability of the claims, Petitioner must prove unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter 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 to which said subject matter pertains. *KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

"[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR*, 550 U.S. at 418. "[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine elements in the way the claimed new invention does." *Id.* Moreover, a person of ordinary skill in the art must have had a

reasonable expectation of success of doing so. *PAR Pharm., Inc. v. TWi Pharms., Inc.*, 773 F.3d 1186, 1193 (Fed. Cir. 2014).

We analyze the instituted grounds of unpatentability in accordance with the above-stated principles.

C. The '837 Patent Is Applicable Prior Art

As an initial matter, Patent Owner asserts that the '837 patent—which is involved in every instituted ground of obviousness—is not applicable prior art to the product claims of the '280 patent.[8] PO Resp. 24. The '837 patent issued on December 10, 1996, to John W. Shell (the first-named inventor of the '280 patent), and is assigned to Patent Owner. Ex. 1010, cover page. Patent Owner argues that, as prior art under 35 U.S.C. § 102(e), the '837 patent cannot preclude patentability under 35 U.S.C. § 103(c). *Id.*

Section 103(c) states, in part:

> (1) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.

35 U.S.C. § 103(c)(1). Patent Owner argues that the '837 patent "fails to invalidate the Product Claims of the '280 Patent because it has the same inventor as the '280 Patent and is assigned to Patent Owner Depomed." PO Resp. 24. In its Motion to Exclude, Patent Owner further argues that

---

[8] The involved product claims of the '280 patent are claims 1, 8–10, 13–15, 45, and 46. Patent Owner admits that the '837 patent constitutes prior art under 35 U.S.C. § 102(b) with respect to method claim 43. *See* Tr. 75:15–21 (agreeing the method claims are entitled to a 1999 benefit date).

because Petitioner did not assert that the '837 patent was prior art under any provision other than § 102(e) with respect to the product claims, § 103(c) acts to prevent the use of the '837 patent for showing unpatentability under § 103(a). Paper 48, 2–3.

In response, Petitioner argues that the '837 patent is also prior art under 35 U.S.C. § 102(a) because it issued before the '280 patent filing date and has different inventive entities. Pet. Reply. 2–3. Because § 103(c) does not apply to references that are § 102(a) prior art, Petitioner argues that the '837 patent is applicable prior art. *Id.*

Under § 103(c)(1), the '837 patent cannot preclude patentability unless it "qualifies as prior art *only* under one or more of subsections (e), (f), and (g) of section 102." 35 U.S.C. § 103(c)(1) (emphasis added). As noted by Petitioner, the '837 patent is also prior art under 35 U.S.C. § 102(a). Patent Owner does not dispute this. Thus, the plain language of § 103(c)(1) suggests that the '837 patent is applicable as § 102(e) prior art for purposes of obviousness. Patent Owner's complaint that the Petition did not identify the '837 patent as § 102(a) prior art is immaterial to whether the reference, in fact, qualifies as § 102(a) prior art. Petitioner's reliance on the '837 patent as §102(e) art in the Petition was sufficient to place Patent Owner on full and fair notice that Petitioner was applying the reference in the grounds. Patent Owner does not persuade us that the alleged misidentification in any way prejudiced Patent Owner's defense of its interests in this proceeding. Under these circumstances, we are not persuaded by Patent Owner's argument that we should exclude the '837 patent from the challenges asserted in this proceeding.

We now address the substantive challenges to the instituted claims.

D. The Level of Ordinary Skill in the Art

In large part, the parties agree as to the level of ordinary skill in the art. Pet. 10; PO Resp. 11. Both agree that a person of ordinary skill in the art would be a person with a Ph.D. degree in at least pharmaceutical science, chemistry, or chemical engineering along with at least two years of industry experience in the development of controlled-release oral dosage forms. Pet. 10; PO Resp. 11. Both also agree that a person of ordinary skill in the art may have an equivalent level of skill through similar education, training, and industry experience. Pet. 10; PO Resp. 11. In light of the parties' agreement, we adopt that description of the level of ordinary skill in the art for purposes of this proceeding.

E. Obviousness over Baveja, the '837 Patent, and the '548 Patent

Petitioner asserts that claims 1, 8, 9, 13–15, 45, and 46 of the '280 patent are unpatentable as obvious over Baveja, the '837 patent, and the '548 patent. Pet. 32–44; Pet. Reply 3–10. Petitioner relies on the Declaration of Dr. Bodmeier. Ex. 1016 ¶¶ 121–37. Patent Owner disagrees with Petitioner's assertions (PO Resp. 29–42), relying on the Declaration of Dr. Hopfenberg (Ex. 2010 ¶¶ 164–78).

1. Baveja (Ex. 1008)

Baveja discloses a dosage form comprised of a swellable hydrophilic matrix that exhibits zero-order (i.e., constant) release of a drug. Ex. 1008, Summary. Baveja uses β-adrenergic blockers propranolol hydrochloride, alprenolol hydrochloride, and metoprolol tartrate as model drugs. *Id.* at 40. Baveja describes tablets with different ratios of HPMC, sodium carboxymethylcellulose ("Na CMC"), and drug, which are then subjected to an in vitro dissolution study. The in vitro dissolution study involves placing

the tablets into a dissolution rate test apparatus with diluted HCl (pH 3.0) for three hours and then in 0.2 M phosphate buffer (pH 7.4) for another 9 hours. *Id.*

The results of the dissolution studies for tablets formed from just HPMC and drug are shown in Figures 1–3. For example, Figure 2 is reproduced below:

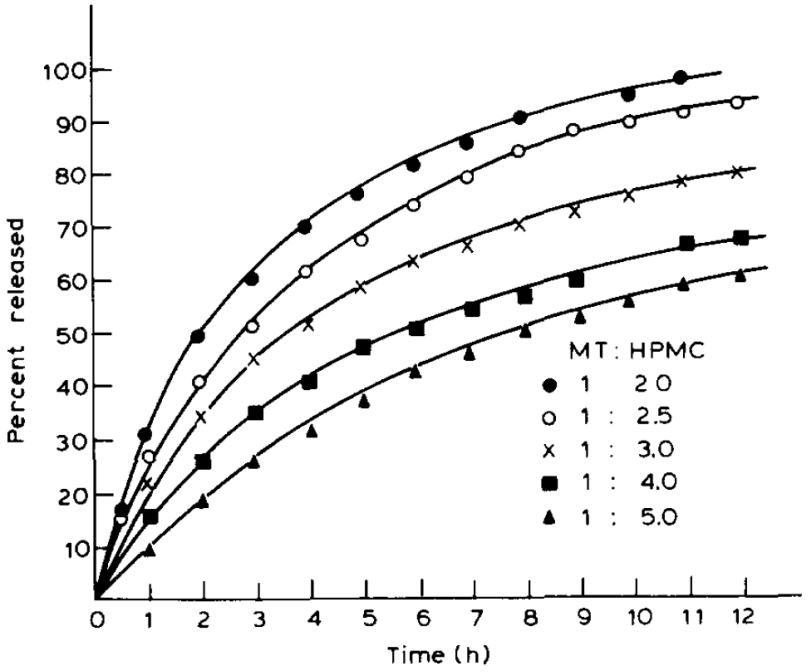

Fig. 2. Release of metoprolol tartrate (cumulative percent) as a function of time from tablets containing drug: HPMC in the ratios given.

Figure 2 illustrates the cumulative percent of metoprolol tartrate released as a function of time from tablets containing metoprolol tartrate and HPMC in the ratios shown. *Id.* at 41.

As explained by Baveja, the rate of release of the tablets made of drug and HPMC decreases with time, which may be due to "an increase in diffusional path length for the drug[,] which in turn may be due to slower

erosion rate of the rubbery layer and faster advancement of swelling front into the glassy polymer." *Id.*

Baveja also describes tablets formed from HPMC, Na CMC, and drug in varying amounts that exhibit a nearly zero-order rate of release. *Id.*, Abstract.

2. The '837 Patent (Ex. 1010)

The '837 patent relates to the field of alkyl-substituted cellulose-based sustained-release drug dosage forms. Ex. 1010, 1:17–19. Specifically, the dosage form disclosed in the '837 patent comprises a plurality of solid particles of a drug dispersed within a non-crosslinked alkyl-substituted cellulose that "swells unrestricted dimensionally via imbibition of water from gastric fluid to increase the size of the particles to promote gastric retention of the pellets in fed-mode induced patients." *Id.* at 1:58–65. The '837 patent teaches that the particles will normally swell to a size of about 6 to 18 mm. *Id.* at 5:8–12. According to the '837 patent specification, the dosage form is particularly useful for delivering drugs in a sustained manner within the stomach. *Id.* at 2:39–43.

The '837 patent also discloses drug release experiments using drug dosage forms comprised of hydroxypropylcellulose ("HPC") and aspirin ("ASA"). *Id.* at 7:25–57. The results of the drug release experiments, which were performed in simulated gastric fluid, are shown in Figure 1, which is reproduced below.

Fig. 1

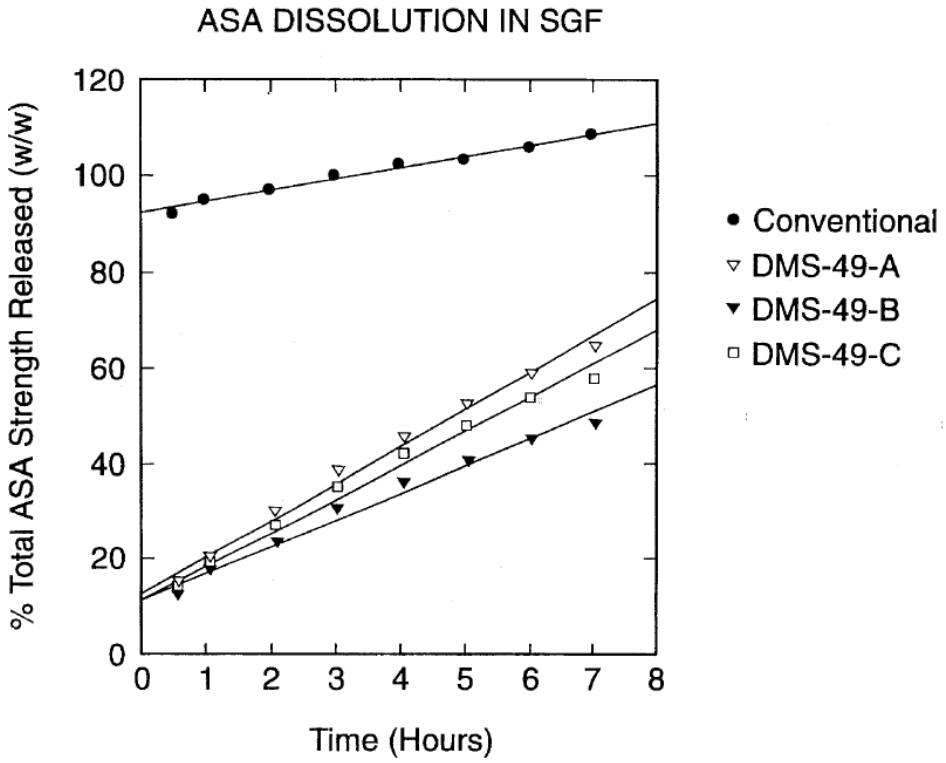

Figure 1 depicts the percentage of aspirin released over time for the various drug formulations tested, including conventional aspirin without HPC. *Id.* at 7:47–52. The release of aspirin was measured at various intervals up to seven hours. *Id.*

3. The '548 Patent (Ex. 1017)

The '548 patent issued on October 3, 1989, and relates to a controlled-release dosage form comprising a drug and at least two different cellulose ethers. Ex. 1017, 1:12–16. According to the '548 patent specification, "[an] object of the present invention is to provide a dosage form of delivering a drug in the gastrointestinal tract that substantially avoids a premature disintegration." *Id.* at 3:1–4. The '548 patent specification also states that the disclosed invention "delivers a drug at a rate of dosage form release that

corresponds to the rate of change of the integrity of the dosage form over a prolonged period of at least eight hours." *Id.* at 3:4–7.

Moreover, the dosage form uses cellulose ethers, which swell extensively when hydrated and lessens direct drug contact with mucosal tissues. *Id.* at 11:23–26. The drug delivery matrix is suitable for gastric retention over the releasing lifetime of the dosage system. *Id*. at 10:65–68. Furthermore, "when all the drug is released, the system bioerodes into innocuous particles and dissolved polymers that pass from the gastrointestinal tract." *Id.* at 10:68–11:3.

4. Analysis

Petitioner asserts that claims 1, 8, 9, 13–15, 45, and 46 of the '280 patent are unpatentable as obvious over Baveja, the '837 patent, and the '548 patent. We have reviewed the arguments and evidence presented by both parties, and we are not persuaded that Petitioner has shown by a preponderance of the evidence that the claims would have been obvious over the cited references.

Petitioner argues that "[t]he only difference between the disclosure in Baveja and claim 1, is that Baveja does not expressly disclose certain inherent properties and release characteristics of its formulations." Pet. 32–33. Specifically, Petitioner asserts that two limitations of claim 1 are disclosed inherently, not expressly, in Baveja: (1) "dosage form being one that when swollen in a dimensionally unrestricted manner as a result of imbibition of water is of a size exceeding the pyloric diameter in the fed mode to promote retention in the stomach during said fed mode" (i.e., the "swelling" limitation) (Pet. 35–36); and (2) "remains substantially intact

until substantially all of said drug is released" (i.e., the "substantially intact" limitation) (*id.* at 36).

Looking first at the limitations that Petitioner contends are expressly disclosed, Patent Owner disagrees with Petitioner's contentions, arguing that Baveja also does not disclose, either expressly or inherently, drug release by "dissolution and diffusion." PO Resp. 30–32. Indeed, Patent Owner contends that Baveja actually teaches away from drug release by dissolution and diffusion because it describes the dosage form relied upon by Petitioner as having a "major disadvantage" because it does not exhibit zero-order release. *Id.* (citing Ex. 1008, 40). We find, however, that Baveja teaches "dissolution and diffusion" expressly when it states that "Figs. 1–3 reveal that the rate of release decreased with time and this may be due to an increase in diffusional path length for the drug which in turn may be due to slower erosion rate of the rubbery layer and faster advancement of swelling front into the glassy polymer." Ex. 1008, 41. Moreover, the fact that Baveja may prefer dosage forms that exhibit zero-order release, over those that do not, does not teach away from the claimed invention. *See In re Mouttet*, 686 F.3d 1322, 1334 (Fed. Cir. 2012) ("This court has further explained that just because better alternatives exist in the prior art does not mean that an inferior combination is inapt for obviousness purposes.").

For the remaining limitations of claim 1 that Petitioner contends are expressly disclosed, based on the evidence presented, we are persuaded that Petitioner has established that Baveja teaches those limitations expressly. Pet. 16–18; Ex. 1016 ¶¶ 74–76, 83–86. We further agree with Petitioner that Baveja does not expressly disclose the "swelling" limitation and the "substantially intact" limitation. *See* Pet. 16–18.

Petitioner, however, asserts that Baveja inherently teaches the "swelling" and "substantially intact" limitations. Pet. 35–36. To prove inherency, Petitioner must establish that "the missing descriptive matter is necessarily present in the thing described in the reference." *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999). We are not persuaded that Petitioner has met this test for either limitation.

Regarding the "swelling" limitation, Petitioner asserts that Baveja discloses a tablet that is 11 mm in diameter prior to imbibition of water and contains 25% alprenolol HCl and 75% HPMC. Pet. 16–17 (citing Ex. 1016 ¶ 78); *see* Ex. 1008, Fig. 1. Petitioner concludes that Baveja inherently discloses a dosage form that swells in a dimensionally unrestricted manner to a size exceeding the pyloric diameter and that will promote retention in the stomach during the fed mode. Pet. 35 (citing Ex. 1016 ¶ 123). Petitioner bases its argument in part on the '280 patent Specification's disclosure that "[p]articles exceeding about 1 cm in size are thus retained in the stomach for approximately 4 to 6 hours." Ex. 1001, 12:1–3. Although Baveja does disclose a "swelling front" (Ex. 1008, 41), we are not persuaded that Petitioner has shown sufficiently that Baveja inherently teaches the entirety of the "swelling" limitation. Specifically, we are not persuaded that Petitioner has shown that Baveja necessarily teaches swelling in a "dimensionally unrestricted manner to a size exceeding the pyloric diameter" or that "will promote retention in the stomach during the fed mode." PO Resp. 37–39. As Patent Owner asserts, Baveja discloses only a single dimension of the dosage form—the diameter—and is silent as to the thickness of the dosage form. *Id.* at 37; Ex. 2010 ¶ 111.

As for the "substantially intact" limitation, Petitioner argues that Baveja's formulation would inherently remain substantially intact. Pet. 36. As support, Petitioner relies on both the testimony of Dr. Bodmeier and the test results of Dr. Kinam Park. *Id.* According to Petitioner, Dr. Park re-created two formulations in Baveja to determine the release kinetics and swelling properties of the dosage forms. Pet. 19. As explained in our Decision to Institute, however, because Dr. Park did not provide evidence of a positive control, we cannot conclude with sufficient certainty that Dr. Park's dosage forms were, in fact, the same dosage forms disclosed by Baveja. Dec. Inst. 11. During oral argument, Petitioner accepted our finding. Tr. 29:21–22 ("We accept the Board's conclusion regarding the prior test results . . . ."). And, as explained in our Decision to Institute, we do not give persuasive weight to Dr. Bodmeier's unsupported opinion that the Baveja tablets will remain substantially intact. Dec. Inst. 11–12. Accordingly, we are not persuaded that Baveja inherently teaches the "substantially intact" limitation.

Petitioner provides, however, alternative sources for teaching these two limitations missing from Baveja. First, Petitioner asserts that the '837 patent discloses expressly the "swelling" and "substantially intact" limitations. Pet. 37–38. We agree. The '837 patent discloses that the dosage form "swells unrestricted dimensionally via imbibition of water from gastric fluid to increase the size of the particles to promote gastric retention of the pellets in fed-mode induced patients." Ex. 1010, 1:62–66. The '837 patent also discloses that the drugs are dispersed in the "selected alkyl-substituted cellulose such as hydroxyethylcellulose or hydroxy propylcellulose," and that "because these polymers dissolve very slowly in

gastric fluid, the particles maintain their integrity over at least a substantial portion (i.e., at least about 90% and preferably over 100% of the intended dosing period)." *Id.* at 4:31–46.

Second, Petitioner asserts that the '548 patent teaches the "swelling" and "substantially intact" limitations. Pet. 41. We are not persuaded, however, that the cited portions of the '548 patent teach or suggest either of these limitations. For example, as Patent Owner notes (PO Resp. 39), Petitioner points to nothing in the '548 patent that suggests the dosage form swells in a "dimensionally unrestricted manner" to a size exceeding the pyloric diameter "in fed mode," as required by the "swelling" limitation. Nor are we persuaded that the '548 patent's teaching that the dosage form "exhibit[s] better mechanical integrity" teaches or suggests a dosage form that remains "substantially intact," as defined by the Specification, particularly in light of the '548 patent's disclosure of drug release by erosion. *See* Ex. 1017, 3:1–7 (describing drug release at a rate that "corresponds to the rate of change of the integrity of the dosage form over a prolonged period of at least eight hours").

Notwithstanding our findings with respect to the '548 patent, we are persuaded that Petitioner has established that each limitation of claim 1 was known in the art, as evidenced by the teachings of Baveja and the '837 patent. A patent, however, "is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR*, 550 U.S. at 418. Petitioner must also show that there was a reason to combine those elements to achieve the claimed invention with a reasonable expectation of success. *See PAR Pharm.*, 773 F.3d at 1193. To make that determination, we can look to "interrelated teachings of multiple patents; the

effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art." *Id.* We can also look to the nature of the problem to be solved. *In re Gartside*, 203 F.3d 1305, 1319 (Fed. Cir. 2000) (holding that suggestion to combine "may come from, *inter alia*, the teachings of the references themselves and, in some cases, from the nature of the problem to be solved"). After considering the parties' arguments and evidence, however, we are not persuaded that Petitioner has made a sufficient showing that a person of ordinary skill would have combined the teachings in the manner contended by Petitioner.

Petitioner argues that a person of ordinary skill in the art would have been led to combine the teachings of Baveja and the '837 patent for several reasons.[9] Pet. 38 (citing Ex. 1016 ¶¶127, 131). First, Petitioner argues that the references have interrelated teachings. According to Petitioner, both references are directed to controlled-release dosage forms that contain HPMC with similar drug-to-polymer weight ratios. *Id.*; Ex. 1016 ¶ 127. For example, claim 1 of the '837 patent recites a drug to polymer ratio of about 1:9 to 9:1. Ex. 1010, claim 1. Baveja's matrix contains a drug-to-polymer ratio that falls within the weight ratio range claimed by the '837 patent. Pet. 38 (citing Ex. 1008, Figs. 1 and 2); Ex. 1016 ¶ 127. Moreover, Petitioner argues that both references teach drug formulations for high

[9] Petitioner also argues that a person of ordinary skill in the art would have been motivated to combine Baveja and the '548 patent to achieve the claimed invention. Pet. 41–42. Because we are not persuaded that the '548 patent teaches the "swelling" and "substantially intact" limitations, we do not address further the proposed combination of Baveja and the '548 patent.

solubility drugs. Pet. 38; Ex. 1016 ¶ 128. Petitioner and its declarant, Dr. Bodmeier, assert also that "the advantages of formulations retained in the stomach and techniques for creating swellable polymer formulations retained in the stomach, were well known by a [person of ordinary skill in the art]." Pet. 36; Ex. 1016 ¶¶ 123, 51–57. Petitioner then concludes that "it would be natural for a POSA to combine the teachings of these two references to arrive at the formulation in claim 1 of the '280 patent." Pet. 39; Ex. 1016 ¶ 128.

Second, Petitioner argues that a person of ordinary skill in the art would have a reason to combine Baveja and the '837 patent given the nature of the problem to be solved: "to formulate a swellable, controlled release oral dosage form for releasing a high solubility drug with particular release kinetics and that will remain substantially intact and be retained in the stomach during the fed mode." Pet. 41 (citing Ex. 1016 ¶ 131). As such, Petitioner argues that a person of ordinary skill in the art reading Baveja would look to the '837 patent "to confirm that the same polymer will in fact be retained in the stomach and remain substantially intact." *Id.* (citing Ex. 1016 ¶ 131).

In response, Patent Owner argues that Petitioner has failed to demonstrate a motivation to combine the cited references with a reasonable expectation of success. Patent Owner challenges Dr. Bodmeier's statement that it would be "natural" to combine Baveja and the '837 patent. PO Resp. 40. According to Patent Owner, Dr. Bodmeier fails to provide any substantive evidence to support his testimony that it would take him "a week" to come up with the claimed invention. *Id.* at 41 (quoting Ex. 2018, 80:19–81:8). In contrast to Dr. Bodmeier's testimony, Patent Owner notes

that Jenny-Louie Helm, an inventor of the '280 patent ("Inventor Helm"), testified that it "took years of research and testing in the laboratory to manipulate different variables, such as type of polymer, molecular weight, particle size, dosage size, matrix chemical structure, and manufacturing processes, to come up with the claimed inventions." *Id.*; Ex. 2016 ¶ 21 (Helm Decl.) ("It took me three years testing various polymers with guidance of Dr. Shell to achieve the Captopril formulation that contained the aspects of the claims of the '475 and '280 Patents."). Consistent with Inventor Helm's testimony, Patent Owner asserts that its declarant, Dr. Hopfenberg, testified that a person of ordinary skill in the art would not have reasonably expected to successfully achieve the claimed invention given that a "vast array of structural considerations affect polymer and matrix properties." PO Resp. 42 (citing Ex. 2010 ¶ 59).

On the record developed at trial, we are not persuaded that Petitioner has shown by a preponderance of the evidence that a person of ordinary skill in the art would have had a reason to combine the references with a reasonable expectation of success. Although the references may have interrelated teachings, as Petitioner asserts, Petitioner has not explained persuasively *how or why* a person of ordinary skill in the art would have combined the "swelling" and "substantially intact" features of the '837 patent formulation with the formulation of Baveja.

In its Reply, Petitioner asserted another reason to combine the cited references:

> A [person of ordinary skill in the art] would look to (1) Baveja to learn how to adjust the rate of high solubility drug release by varying the drug-to-polymer (HPMC) weight ratio and (2) either the '837 or the '548 patent to confirm that the same type

> of polymer used in Baveja will (a) swell in a dimensionally unrestricted manner to a size exceeding the pyloric diameter, (b) be retained in the stomach during the fed mode, and (c) remain substantially intact until all of the drug is released.

Pet. Reply 8–9; Ex. 1016 ¶¶ 122–36. But here, again, Petitioner speaks in generalizations and does not explain persuasively *why* a person of ordinary skill in the art, learning from Baveja how to adjust the rate of drug release by varying the drug-to-polymer weight ratio, would need or want to look to the '837 patent to "confirm" the "swelling" and "substantially intact" properties. *See InTouch Techs., Inc. v. VGO Commc'ns, Inc.*, 751 F.3d 1327, 1351 (Fed. Cir. 2014) (reversing district court's judgment of invalidity where expert's testimony "was vague and did not articulate reasons why a person of ordinary skill in the art at the time of the invention would combine these references").

To the extent Petitioner relies on the nature of the problem to be solved to supply the reason for the combination, we remain unpersuaded. Petitioner's recitation of the nature of the problem to be solved is essentially a recitation of claim 1 itself: "to formulate a swellable, controlled release oral dosage form for releasing a high solubility drug with particular release kinetics and that will remain substantially intact and be retained in the stomach during the fed mode." Pet. 41. As our reviewing court has recently reminded us, however, "[d]efining the problem in terms of its solution reveals improper hindsight in the selection of the prior art relevant to obviousness." *Insite Vision, Inc. v. Sandoz, Inc.*, 783 F.3d 853, 859 (Fed. Cir. 2015) (quoting *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 881 (Fed. Cir. 1998)). As such, the Federal Circuit stated that when considering the reason to combine, "the problem examined is not the

specific problem solved by the invention." *Id.* (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). Here, the claim represents the specific problem solved by the invention, rather than the general problem facing the inventors. Thus, we find that by defining the nature of the problem to be solved as the specific problem solved by the invention, Petitioner has relied on impermissible hindsight to supply the reason to combine Baveja and the '837 patent. *Id.* (affirming the district court's recognition that "an overly narrow 'statement of the problem [can] represent[] a form of prohibited reliance on hindsight, [because] [o]ften the inventive contribution lies in defining the problem in a new revelatory way'") (quoting *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1377 (Fed. Cir. 2012) (alterations in original)).

Even if we were to find that Petitioner has established that a person of ordinary skill in the art would have had a reason to combine the teachings of Baveja and the '837 patent, we are still not persuaded that Petitioner has established that a person of ordinary skill in the art would have had a reasonable expectation of success in doing so.

Petitioner argues that, at the time of the invention, a person of ordinary skill in the art "understood how to achieve" the claimed drug formulation. Pet. 36–37. For example, Petitioner and its declarant argue that a person of ordinary skill in the art would have known "techniques for creating swellable polymer formulations retained in the stomach." Pet. 35–36; Ex. 1016 ¶¶ 51–57, 123. Petitioner also argues that a person of ordinary skill in the art would have known how to construct a matrix that would remain intact because it was well known that "increasing the viscosity of HPMC (based on grade) or the concentration (by altering the drug-to-polymer weight ratio) strengthens the matrix, resulting in a dosage form that

would remain physically intact over the dosing period." Pet. 36–37; Ex. 1016 ¶¶ 61– 65, 125.

We are not persuaded that a person of ordinary skill in the art would have had a reasonable expectation of success, in part, because both parties' declarants testified about the number of formulation considerations at play when preparing a drug formulation. For example, Petitioner's declarant testified that there were formulation considerations such as "molecular weight, chemical substitution, particle size, hydration rate effect, polymer content, dosage form, dosage size and manufacturing processes." Ex. 1016 ¶ 41. Similarly, Patent Owner's declarant stated that "[a] person of ordinary skill in the art understands that formulation of a polymer matrix involves a vast array of interacting 'formulation considerations' affecting polymer and matrix properties." Ex. 2010 ¶ 161. Despite this testimony from its own declarant (as confirmed by Patent Owner's declarant), we find that Petitioner does not address sufficiently why a person of ordinary skill in the art would believe it could modify the formulation of Baveja to incorporate the "swelling" and "substantially intact" features of the '837 patent without, for example, affecting the other desired properties of the original Baveja formulation (e.g., the drug release profile). Petitioner has not identified any combinations of Baveja and the '837 patent that would be most promising to try. As such, we reach the same conclusion as the Federal Circuit in *Leo Pharmaceutical Products, Ltd. v. Rea*, 726 F.3d 1346, 1357 (Fed. Cir. 2013). That is, we find that, "[w]ithout a reasonable expectation of success or clues pointing to the most promising combinations, an artisan could have spent year experimenting without success." *Id.*

Finally, during cross-examination, Dr. Bodmeier testified that it would take him "within a week" to come up with the claimed formulations. *See* PO Resp. 41; Ex. 2018, 80:19–81:8. In its Reply, Petitioner also argues that "[e]ven if the Board accepts that Dr. Park's tablets are not identical to Baveja's tablets, Baveja's disclosures led Dr. Park to create dosage forms that fall within the scope of claim 1 using techniques well-known to a POSA, . . . confirming that the claims are obvious over Baveja." Pet. Reply 5.

The problem with both Dr. Bodmeier's testimony and Dr. Park's test results is that neither testified from the perspective of a person of ordinary skill in the art *at the time of the invention*. Specifically, Dr. Bodmeier's testimony was as follows:

> Q. Could you give me an estimate on how long in the lab it would take you, a day, two weeks of experimentation to come up with the formulations of the '280 patent?
>
> A. Yes. Obviously compare to other patents, you know, this is not a claim to a specific drug, you know. It's to a drug class. So I think to develop a gastro retentive system which is mechanically stable and has release profiles, for example, shown in the examples or in Baveja, I think you can do that within a week.

Ex. 2018, 80:19–81:8.

And Dr. Park attested that, "[i]n performing the testing set forth in this Declaration, [he] considered and relied upon [his] education, background, and years of experience in the field of pharmaceutical sciences." Ex. 1020 ¶ 13. Thus, even if we did accept Dr. Bodmeier and Dr. Park's testimony as true, both are irrelevant to our obviousness analysis. *InTouch Techs.*, 751 F.3d at 1352 (stating expert's testimony as to what a skilled artisan could

accomplish at the time the testimony was given "is not the relevant inquiry" to what a skilled artisan would have understood as of the time of the invention).

After considering the parties' arguments and the supporting evidence, we determine that Petitioner has not shown by a preponderance of the evidence that claims 1, 8, 9, 13–15, 45, and 46 are unpatentable as obvious over Baveja, the '837 patent, and the '548 patent.

F. Obviousness of Claim 10 over Baveja, Kim, the '837 Patent, and the '548 Patent

Petitioner asserts that claim 10 of the '280 patent is unpatentable as obvious over Baveja, Kim, the '837 patent, and the '548 patent, relying on the Declaration of Dr. Bodmeier. Pet. 44–47; Pet. Reply 10; Ex. 1016 ¶¶ 158–63. Patent Owner disagrees with Petitioner's assertions (PO Resp. 42–44), relying on the Declaration of Dr. Hopfenberg (Ex. 2010 ¶¶ 179–87).

1. Kim (Ex. 1019)

Kim discusses drug release from compressed tablets manufactured with a powder mixture of poly(ethylene oxide) ("PEO"), a drug, and magnesium stearate. Ex. 1019, 303. In one example, Kim describes a dosage form wherein the PEO has an average molecular weight of 4,000,000. *Id.*

2. Analysis

Claim 10 of the '280 patent depends from claim 1 and further requires a polymeric matrix formed of PEO at a molecular weight of at least about 4,000,000. Ex. 1001, claim 10. As determined above, we find that the combination of Baveja and the '837 patent teaches each limitation of

claim 1. We also find that Kim teaches the additional limitation of claim 10, which Patent Owner does not dispute. PO Resp. 42–44.

Because claim 10 depends from claim 1, we determine, for the same reasons stated above, that Petitioner has failed to establish that a person of ordinary skill in the art would have had a reason to combine the teachings of Baveja, the '837 patent, and Kim to achieve the claimed invention with a reasonable expectation of success.

After considering the parties' arguments and the supporting evidence, we determine that Petitioner has not shown by a preponderance of the evidence that claim 10 is unpatentable as obvious over Baveja, Kim, and the '837 patent.

G. Obviousness over Baveja, the '837 Patent, and Colombo

Petitioner asserts that claim 43 of the '280 patent is unpatentable as obvious over Baveja, the '837 patent, and Colombo, relying on the Declaration of Dr. Bodmeier. Pet. 58–60; Pet. Reply 10–13; Ex. 1016 ¶¶ 188–97. Patent Owner disagrees with Petitioner's assertions (PO Resp. 44–49), relying on the Declaration of Dr. Hopfenberg (Ex. 2010 ¶¶ 188–99).

1. Colombo (Ex. 1009)

Colombo relates to swellable matrix systems in the form of a tablet comprising a mixture of the drug diltiazem, HPMC, ethylcellulose, and mannitol. Ex. 1009, 44. Colombo discloses three different matrices: Case 0, the plain matrix; Case 1, the matrix coated with cellulose acetate propionate ("CAP") on one face; and Case 2, the matrix coated with CAP on both faces. *Id*. Colombo describes "[s]welling and release experiments" in which the matrices were swollen in deionized water for 120 minutes, and the

drug release measurements were obtained concomitantly with the matrix swelling observations. *Id.*

Colombo describes and depicts the morphological changes in the matrices over time, observing that, in the uncoated system (Case 0), "[v]ery quickly (after 15 min) the swelling of the matrix moves both in axial and radial directions." *Id.* Colombo also discloses the drug release profiles of the systems. *Id.* at 45. Figure 5 of Colombo is reproduced below:

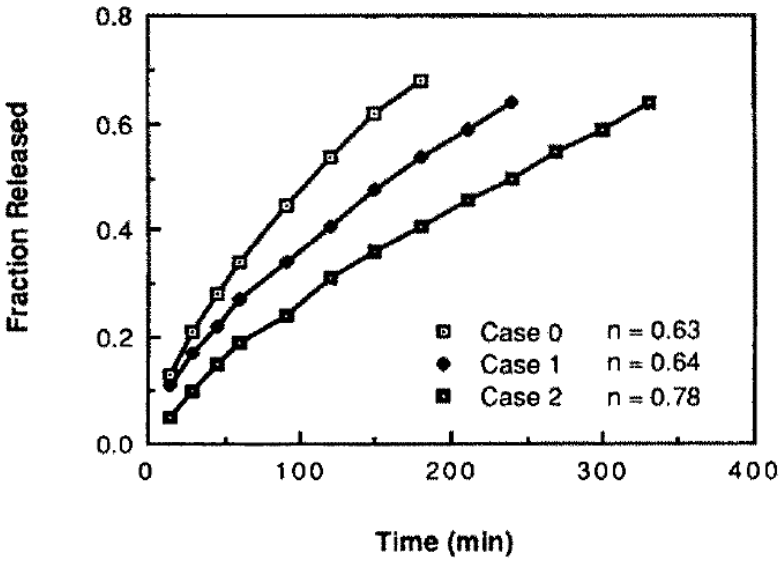

Fig. 5. Drug release profiles of the systems. Calculated values of exponent *n* of Eqn 2 are also shown.

Figure 5 depicts the fraction of diltiazem released over time for the Case 0, Case 1, and Case 2 matrices.

2. Analysis

Petitioner asserts that the subject matter of claim 43 of the '280 patent would have been obvious over the teachings of Baveja, the '837 patent, and Colombo. Pet. 58–60. Petitioner argues that Colombo and Baveja each "disclose the limitations set forth in claim 43, except for the method of administration, which is expressly disclosed by the '837 patent." *Id.* at 58. Petitioner further contends that a person of ordinary skill in the art would

have been motivated to combine the teachings of the '837 patent with Baveja and Colombo given the nature of the problem to be solved (identified above) and the interrelated teachings of the art. *Id.* at 58–59.

As explained above, we are not persuaded that Baveja teaches inherently the "swelling" limitation. Similarly, we are not persuaded that Colombo teaches this limitation, either. Colombo teaches studies in which the matrices were swollen in deionized *water*. Ex. 1009, 44. Petitioner directs us to no persuasive evidence that Columbo's matrices swell by "imbibition of *gastric fluid*," as required by the claims. That is, Petitioner has not established that deionized water is an "artificial fluid[] recognized by those skilled in the art as a suitable model for the fluid of the human stomach," as required by our construction of "gastric fluid." Thus, we are not persuaded that Colombo teaches the "swelling" limitation, either expressly or inherently.

We are also not persuaded that Colombo teaches "releas[ing] substantially all of said drug within about ten hours after such immersion." Figure 5 of Colombo does not show any formulation that ever releases at least 80% of the drug, as required by the claims. Ex. 1009, Fig. 5.

Nevertheless, we are persuaded that Petitioner has established that each limitation of claim 43 was known in the art, as evidenced by the teachings of Baveja, the '837 patent, and Colombo. For the same reasons stated above with respect to claim 1, however, we find that Petitioner has not shown sufficiently that a person of ordinary skill in the art would have had a reason to combine the references to achieve the claimed invention with a reasonable expectation of success. Once again, Petitioner frames the nature of the problem to be solved too narrowly, indicating a hindsight bias. *See*

Insite Vision, 783 F.3d at 859. Moreover, as Patent Owner argues, Petitioner "fails to prove that coming up with the invention of Claim 43 by combination of prior art references took just routine experimentation by one of skill in the art." PO Resp. 49. We find that Petitioner does not explain persuasively why a person of ordinary skill in the art would have had a reasonable expectation of success beyond just the knowledge that each limitation of the claim was known in the art at the time of the invention.

After considering the parties' arguments and the supporting evidence, we determine that Petitioner has not shown by a preponderance of the evidence that claim 43 is unpatentable as obvious over Baveja, the '837 patent, and Colombo.

H. Secondary Considerations of Nonobviousness

In light of our determination that Petitioner has not shown by a preponderance of the evidence that any of the challenged claims are unpatentable as obvious, we need not reach the merits of Patent Owner's evidence of secondary considerations of nonobviousness.

III. MOTIONS TO EXCLUDE EVIDENCE

Both parties filed motions to exclude evidence offered by the other side. The party moving to exclude evidence bears the burden of proving that it is entitled to the relief requested—namely, that the material sought to be excluded is inadmissible under the Federal Rules of Evidence ("FRE"). *See* 37 C.F.R. §§ 42.20(c), 42.62(a). We address each party's motion in turn.

1. Petitioner's Motion to Exclude Evidence

Petitioner moves to exclude portions of Dr. Hopfenberg's declaration and a claim chart for Gralise® (Ex. 2013) as improperly incorporated by reference and as irrelevant because they are improperly incorporated.

Paper 41, 3–6. We decline to do so. As explained in our prior Order (Paper 30), to the extent any such violations have occurred, we have not considered such evidence in reaching our decision. Therefore, we dismiss Petitioner's motion as moot.

Petitioner also moves to exclude certain testimony of Inventor Helm. Paper 41, 10–13. We decline to do so. To the extent we have relied on the testimony of Inventor Helm, that testimony was based on her own work. *See* Ex. 2016 ¶ 21 (testifying how long it took her to develop an embodiment of the claims). Such testimony based on her own personal knowledge is relevant and proper lay witness testimony under FRE 701, 602, and 401/402/403. Accordingly, we deny Petitioner's motion as to this evidence.

Petitioner also moves to exclude certain evidence relating to Patent Owner's assertions of commercial success, licensing, long-felt but unmet need, and unexpected results. Paper 41, 6–15. Given our determination that we need not reach Patent Owner's evidence of secondary considerations, we need not reach the merits of Petitioner's Motion to Exclude and dismiss the motion as moot.

2. Patent Owner's Motion to Exclude Evidence

Patent Owner moves to exclude the '837 patent as irrelevant to the product claims in this proceeding because it allegedly does not constitute prior art. Paper 48, 1–3. We have addressed this argument and deny Patent Owner's motion to exclude the '837 patent for the reasons stated above.

Patent Owner also moves to exclude (1) Exhibits 1022, 1023, 1062, and 1063 (*id.* at 3–7); (2) Exhibit 1071 and the related testimony of Dr. Bodmeier (*id.* at 11–13); and (3) portions of the cross-examination testimony of Dr. Eric Gaier (*id.* at 13–16). Because we did not rely on any

of these exhibits or testimony in reaching our Decision here, we dismiss Patent Owner's motion to exclude this evidence as moot.

IV. CONCLUSION

We conclude that Petitioner has not shown by a preponderance of the evidence that claims 1, 8–10, 13–15, 43, 45, and 46 of the '280 patent are unpatentable under 35 US.C. § 103.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1, 8–10, 13–15, 43, 45, and 46 of the '280 patent are not held unpatentable;

FURTHER ORDERED that Petitioner's Motion to Exclude Evidence is *denied in part and otherwise dismissed*;

FURTHER ORDERED that Patent Owner's Motion to Exclude Evidence is *denied in part and otherwise dismissed*; and

FURTHER ORDERED that, because this is a Final Written Decision, the parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

PETITIONER:

Gasper J. LaRosa
gjlarosa@jonesday.com

Kelsey I. Nix
knix@jonesday.com

Lynda Q. Nguyen
lqnguyen@jonesday.com

PATENT OWNER:

Judy M. Mohr
JMohr@MWE.com

Paul Andre
PAndre@kramerlevin.com

Geoffrey G. Hu
GHu@kramerlevin.com