No. _____

IN THE

Supreme Court of the United States

PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., AND RHODES TECHNOLOGIES,

Petitioners,

v.

EPIC PHARMA, LLC, MYLAN PHARMACEUTICALS INC., MYLAN INC., AMNEAL PHARMACEUTICALS, LLC, AND TEVA PHARMACEUTICALS USA, INC.,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

The Patent Act states that, in determining whether a claimed invention, though novel, is impermissibly obvious, the touchstone is whether the "differences" between that invention and the prior art are such that the invention "*as a whole*" would have been obvious to a person having ordinary skill in the art. 35 U.S.C. § 103 (emphasis added); *see also* 35 U.S.C. § 103(a) (2006). As this Court has instructed, that inquiry is holistic and flexible, *see KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), and, at least since Chief Justice Taft authored the Court's decision in *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45 (1923), it has taken into account a patentee's discovery of a nonobvious source of the problem that the patent overcomes.

Here, the inventors discovered that, in the manufacture of the prescription pharmaceutical oxycodone, a previously unknown molecule was being created and causing unwanted amounts of a potential toxin to appear in the final drug product. The inventors' discovery of this previously unknown molecule allowed them to create the patented invention, the first-ever oxycodone substantially free of the potential toxin.

The question presented is:

Whether the inventors' discovery is relevant to the obviousness inquiry (as section 103 and *Eibel Process* command), or whether that discovery and other indicia of invention may be ignored as a matter of law, as the Federal Circuit did here.

PARTIES TO THE PROCEEDING AND RULE 29.6 STATEMENT

Petitioners, who were Plaintiffs-Appellants below, are Purdue Pharma L.P.; The P.F. Laboratories, Inc.; and Purdue Pharmaceuticals L.P. (collectively, Purdue); and Rhodes Technologies. None of these entities has a parent company, and no publicly traded corporation owns 10% or more of any of their stock. Grünenthal GmbH was also a Plaintiff-Appellant in the consolidated proceedings below, with respect to a different, unrelated patent that it owns.

Respondents, who were Defendants or Appellees below, are Epic Pharma, LLC; Mylan Pharmaceuticals Inc.; Mylan Inc.; Amneal Pharmaceuticals, LLC; and Teva Pharmaceuticals USA, Inc.

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INTRODUCTION

This Court recently underscored that "[t]he diversity of inventive pursuits and of modern technology counsels against limiting the [obviousness] analysis [in patent cases]" "by a formalistic conception." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 419 (2007). Sometimes, patentable invention arises where the scientific principles underlying the invention are obvious, but their real-world implementation is not. *See id.* at 418-19 (recognizing that invention can arise even where it involves "the combination of two known devices according to their established functions"). Other times, the principles themselves are not obvious but, once those principles are discovered and recognized, a solution becomes simple. This Court's decision in *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 63 (1923), involved the latter type of invention; Eibel "made a very useful discovery" about the source of a recognized problem in existing machines and, enlightened by his discovery, devised a simple solution to that problem.

As then-Judge Kennedy described these converse scenarios, sometimes the "operating requirement may be readily apprehended, but its mechanical implementation difficult for an inventor to achieve," while other times "the operating principle is obscure, but once perceived, its design becomes relatively simple." *Saf-Gard Prods., Inc. v. Serv. Parts, Inc.*, 532 F.2d 1266, 1272 (9th Cir. 1976). In either case, the patentee has made a "real innovation" worthy of the limited protection of a patent. *KSR*, 550 U.S. at 419. The "expansive and flexible approach" to obviousness required by this Court's decisions takes

all the relevant evidence into account, and ensures that "real innovation" will be protected. *Id.* at 415. "Application of the bar [on patents claiming obvious subject matter] must not be confined within a test or formulation too constrained to serve its purpose." *Id.* at 427.

Here, however, the Federal Circuit failed to protect Purdue and Rhodes's work as a classic act of invention by ignoring critical indicia of invention, in direct conflict with section 103, *KSR*, and *Eibel Process*, and with the Ninth Circuit's *Saf-Gard* decision, among other circuit precedent. It is undisputed that Purdue and Rhodes "discover[ed] … the source" of a problem and then "appli[ed] … the remedy," which *Eibel Process* recognized as nonobvious invention. 261 U.S. at 68. Purdue and Rhodes discovered the unexpected source of a suspected toxin in oxycodone. That discovery gave them the necessary knowledge to modify the traditional production process and create a non-trivial, inventive advancemendt: the first oxycodone substantially free of that suspected toxin.

The appellate court's contrary determination turned a blind eye to this evidence by curtailing—improperly—the obviousness inquiry. *First*, the court held that *Eibel Process*'s protection for inventions based on true discoveries applies only to patent claims directed to "machines," not "end products." *Second*, it held that "process" language in so-called product-by-process claims should be ignored in determining obviousness. And in operation together, these limiting rules are as nonsensical as they are wrong: an inventor's acknowledged discovery will be overlooked entirely unless the patent claims a

machine or a process, and even if the claims include process language, that language still will not matter.

Before *KSR*, the Federal Circuit had adopted a rigid rule restricting the ways in which alleged infringers could demonstrate obviousness. This Court corrected that error, but now the Federal Circuit has swung the pendulum in the opposite direction, with a rigid anti-patent approach to obviousness. That approach finds no support in the Patent Act or this Court's precedents, and is just as narrowing and unjustified as the patent-friendly test rejected in *KSR*.

The Federal Circuit's categorical approach is not only in conflict with *KSR* and *Eibel Process*; it will also cause serious harm to inventors in a host of disciplines whose contribution to the sum of useful knowledge involves the implementation of a new discovery. This is particularly important with pharmaceuticals, such as the safer oxycodone at issue here, for the need to encourage investment is at its zenith when the development of new and safer drugs is at stake. The Court should grant certiorari to restore the Patent Act's broad, flexible approach to nonobviousness, as recognized by *KSR*, and to ensure that this Court's *Eibel Process* decision continues to be honored.

OPINIONS BELOW

The district court's opinion (App.32a-176a) is reported at 994 F. Supp. 2d 367 (S.D.N.Y. 2014). The Federal Circuit's opinion (App.1a-31a) is reported at 811 F.3d 1345 (Fed. Cir. 2016). Its order denying rehearing en banc is reproduced at App.189a-90a.

JURISDICTION

The Federal Circuit denied rehearing en banc on May 4, 2016. On June 30, 2016, the Chief Justice extended Purdue and Rhodes's time to petition for certiorari to and including September 1, 2016. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Patent Clause provides:

> The Congress shall have Power … To promote the Progress of Science and useful Arts, by securing for limited Times to … Inventors the exclusive Right to their … Discoveries.

35 U.S.C. § 103(a) (2006) provided:

> A patent may not be obtained though the invention is not identically disclosed or described … if the differences between the subject matter sought to be patented 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. Patentability shall not be negatived by the manner in which the invention was made.

35 U.S.C. § 103 now provides:

> A patent … may not be obtained, notwithstanding that the claimed invention is not identically disclosed … , 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. Patentability shall not be negated by the manner in which the invention was made.[1]

STATEMENT

1. Before 1995, millions of Americans suffered from moderate to severe pain that could not be effectively managed; over-the-counter analgesics were not strong enough, and stronger prescription drugs generally had undesirable side effects or could not safely be given in doses that would guarantee long-lasting coverage. Late that year, however, FDA approved OxyContin®, Purdue's extended-release oxycodone hydrochloride pharmaceutical, which gave many of these patients the relief they needed.

Purdue's original formulation of OxyContin®, however, had room for improvement: it contained high levels of 14-hydroxy, the common name for 14-hydroxycodeinone, on the order of 1500 parts per million (ppm). App.6a. 14-hydroxy "belongs to a class of potentially dangerous compounds known as alpha, beta unsaturated ketones," or "ABUKs." *Id.* ABUKs have long been suspected as potentially genotoxic—that is, they may damage human DNA. App.89a. The "medical need" for oxycodone products compelled FDA to keep high-ABUK oxycodone on the market anyway. C.A.App.A1226. Nonetheless, in light of 14-hydroxy's potential dangers, lower

[1] The prior version of section 103 applies to this case, *see* Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, § 3(n)(1), 125 Stat. 284, 293 (Sept. 16, 2011), but there are no material differences between the two for present purposes. *See infra* n.4.

amounts of 14-hydroxy were desirable, and scientists at Rhodes (a company associated with Purdue) began looking for ways to reduce its quantity in finished oxycodone. App.7a. That task became even more urgent when FDA forbade Rhodes from manufacturing oxycodone for use in OxyContin® until Rhodes could reduce the amount of 14-hydroxy to less than 10 ppm—a reduction from existing levels by more than 99%—or demonstrate that the existing, higher levels were safe. App.6a-7a. The task also became more urgent for other manufacturers, including generic manufacturers, who saw the writing on the wall for high-ABUK oxycodone but worried that reducing or eliminating these toxins from oxycodone posed a "technical and scientific challenge." App.88a.

At the time, oxycodone production proceeded in three steps: first, an opium derivative was oxidized to form 14-hydroxy; second, that 14-hydroxy was hydrogenated to form oxycodone free base; and third, that free base was "salted" by reacting it with acid to form a stable, soluble oxycodone salt. App.6a. As noted, this process left considerable 14-hydroxy in the end product.

Everyone knew that hydrogenation converted 14-hydroxy into oxycodone base. In keeping with that conventional wisdom, Rhodes's scientists attempted to reduce the 14-hydroxy remaining in the end product by increasing the duration of hydrogenation, making sure that all of the 14-hydroxy had been eliminated by the hydrogenation occurring in the second step. App.7a. Had conventional wisdom been correct, that should have been enough: the 14-hydroxy should have been eliminated during the

second step. Initially, that approach seemed successful. As Rhodes's leading scientist excitedly reported on the results of extended hydrogenation, "[t]he numbers [of minimal 14-hydroxy] speak for themselves!" C.A.App.A830-33; A45502-06. But inexplicably, as the manufacturing process continued, high amounts of 14-hydroxy reappeared in the final oxycodone salt.

2. Flummoxed, Purdue and Rhodes started a research program to find a solution. C.A.App.A835. They considered whether a known byproduct of the initial oxidation step called 8β (pronounced "eight-Beta") was transforming into 14-hydroxy, but their testing ruled out that theory. C.A.App.A845-46; A906-07. The researchers then developed a new hypothesis: perhaps some unknown molecule was involved.

The odds were long. Since no such other molecule was "reported in the literature," the researchers surmised that "it probably didn't exist." C.A.App.A843. Indeed, though every oxycodone producer had long had reason to remove the potentially genotoxic 14-hydroxy from its products, no one had ever even speculated that some unknown molecule might be responsible for the problem, let alone found evidence to suggest as much.

Nonetheless, the diligence and ingenuity of Rhodes's researchers paid off. They discovered 8α (pronounced "eight-Alpha"), a new molecule similar to the known byproduct 8β but with different chemical properties, including significant reactivity with acid. And they "determined that 8α was indeed being produced at step one and, in fact, was

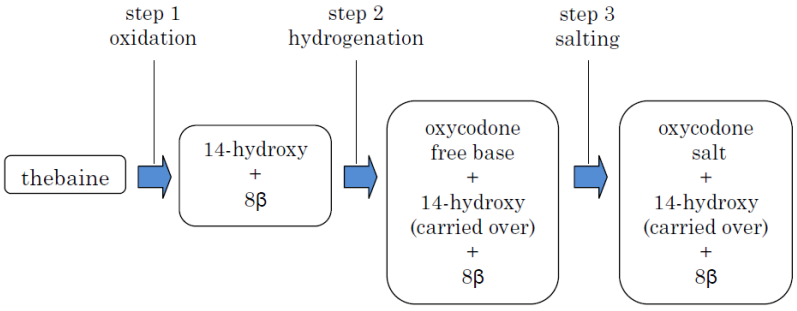
transforming into 14-hydroxy during the acid-catalyzed dehydration at step three." App.7a.[2]

Discovering 8α was the key to producing the world's first low-ABUK oxycodone. Purdue and Rhodes figured out why the single hydrogenation step of the existing method could not eliminate 14-hydroxy from the end product: although hydrogenation eliminated virtually all of the 14-hydroxy generated during the first step, it had no effect on the *new* 14-hydroxy created by the reaction of 8α with acid during the final salting step. Armed with this insight, Purdue and Rhodes researchers revised the process, adding another, different hydrogenation step. As described in the patent specifications, this additional hydrogenation takes place after oxycodone free base is formed in step two, uses additional acid, and employs other conditions likewise tailored to 8α to ensure that the vast majority of new, 8α-derived 14-hydroxy is converted into 14-hydroxy and then immediately into oxycodone salt. App.7a-8a; C.A.App.A923-24; Supp. Patent App.23. The difference between the original approach and the final high-ABUK product, which

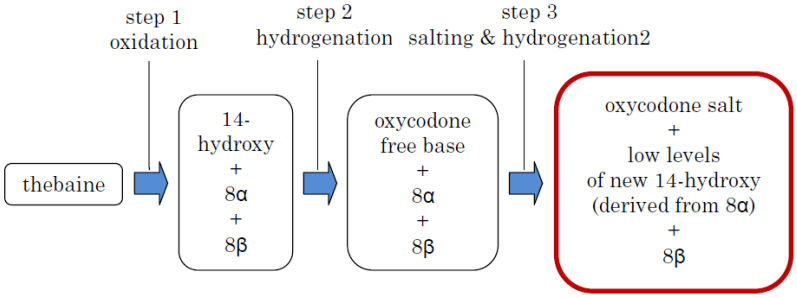
[2] In technical terms, 8α and 8β are diastereomers: each has the same chemical formula (14-dihydroxy-7,8-dihydrocodeinone) and the same chemical bonds, but in space the two molecules are mirror images of each other. If you drew both on a piece of paper, the hydroxyl group in each would be in the so-called 8 position (hence the "8" in "8α" and "8β"), but that group would point *away* from you (that is, extend below the plane) in 8α and *toward* you (above the plane) in 8β. The different orientation of their atoms causes diastereomers to have different properties, notwithstanding their facial similarity. The existence of one diastereomer does not presume the existence of the other. App.56a-57a.

assumed (incorrectly) that the 14-hydroxy in the end product was carried over from earlier steps in the production process, and the new, 8α-inspired approach and low-ABUK product can be seen in the following figures:

Original Assumption and Product



Purdue and Rhodes's New, 8α-Inspired Manufacture and Product



The unexpected discovery of 8α thus allowed the researchers to create a greatly desired product unknown in the prior art, oxycodone salt with very low levels of 14-hydroxy. 8α was critical to Purdue and Rhodes's new invention; prior to their discovery, no one understood the source of the remaining 14-hydroxy, nor did anyone understand why hydrogenation—the traditional method of removing

14-hydroxy—was ineffective. By discovering 8α and its chemical properties—and *only* by doing so—Purdue and Rhodes's researchers made a major pharmaceutical advancement: substantially toxin-free oxycodone.

3. Rhodes soon began practicing the invention by producing low-ABUK oxycodone. No one else was able to produce oxycodone with similarly low amounts of 14-hydroxy until at least three years later, *after* Purdue and Rhodes's discovery of 8α and their new low-ABUK products were made public. C.A.App.20a. And the competitors generally succeeded only by trading on Purdue and Rhodes's efforts. When one competitor later sought a patent related to low-ABUK oxycodone, its application was based on, and specifically credited, Purdue and Rhodes's discovery of 8α and its role as the source of the new 14-hydroxy in the oxycodone salt. App.91a; C.A.App.A40851.

In 2004, Purdue and Rhodes filed patent applications claiming low-ABUK oxycodone, the invention embodying their discovery of 8α. In 2010, they were granted the three patents at issue here—U.S. Patent Nos. 7,674,799 (Mar. 9, 2010), 7,674,800 (Mar. 9, 2010), 7,683,072 (Mar. 23, 2010) (the '799 patent, '800 patent, and '072 patent, respectively). Supp. Patent App.1-85. Each is directed to a new oxycodone salt containing very low levels of 14-hydroxy derived from 8α.

Claim 1 of the '072 patent recites: "An oxycodone hydrochloride active pharmaceutical ingredient having less than 25 ppm 14-hydroxy[], wherein at least a portion of the 14-hydroxy[] is derived from 8α,"

while dependent claims 4 and 5 of that patent recite even lower levels of 14-hydroxy—less than 15 and 10 ppm, respectively. Supp. Patent App.84-85. The relevant claims of the '799 patent recite similar products in "[a]n oral dosage form," while the relevant claims of the '800 patent claims recite "[o]xycodone salt prepared according to" the specific process laid out in other claims of the '800 patent.[3] Supp. Patent App.27-28, 56.

4. In March 2011, Teva Pharmaceuticals filed an Abbreviated New Drug Application (ANDA) seeking FDA approval to sell generic versions of Purdue's low-ABUK OxyContin®. App.11a. Because that filing triggered the infringement provisions of the Hatch-Waxman Act, Purdue and Rhodes sued Teva. *See* 35 U.S.C. § 271(e)(2)(A); *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670 (2012). They filed similar lawsuits against Epic, Mylan, and Amneal after they too filed similar ANDAs. App.11a. The cases were consolidated in multi-district litigation before the U.S. District Court for the Southern District of New York. App.11a, 35a.

At a bench trial in the lead case, the district court found that each of Teva's products infringed Purdue and Rhodes's asserted patent claims. App.36a. As to patent validity, Teva did not dispute the novelty of Purdue and Rhodes's new, low-toxin invention, only its obviousness. The court found that Purdue and Rhodes had "discovered 8α as the source of the 14-hydroxy problem"; indeed, it found that before then, "8α was unknown in the prior art" and "its very

[3] Purdue and Rhodes's low-ABUK OxyContin® also includes patented, abuse-deterrent features that make it more difficult to inject or snort the drug.

existence was unexpected." App.58a, 90a. Moreover, it found that, prior to the discovery of 8α, no one had successfully made oxycodone "substantially free of 14-hydroxy." App.83a. As Purdue and Rhodes pointed out, C.A.App.A7483-84, these factual findings put their invention squarely within the rule of *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45 (1923): where an inventor "discover[s] … the source not before known [of a recognized problem] and … appli[es] … the remedy" that follows from that discovery, he is "entitled to be rewarded in his patent," even if the remedy itself was simple, once the discovery became known. 261 U.S. at 68.

Nonetheless, without mentioning *Eibel Process* or its principles, the district court held these patents invalid as obvious. App.105a-108a; App.184a-86a (applying issue preclusion based on Teva's case). It reasoned that those skilled in the art generally knew how to remove 14-hydroxy through hydrogenation and thus would have known how to eliminate the 14-hydroxy that 8α generated. App.99a-102a. It further concluded that the portions of Purdue and Rhodes's patent claims specifically related to 8α—the language in the '799 and '072 patent claims requiring the final product to contain some 14-hydroxy "derived from" 8α, and the processes recited in the '800 patent claims that referenced 8α—were "process" limitations that, although necessary to find infringement, should be ignored in determining obviousness. App.100a-01a. In short, the district court's obviousness analysis focused solely upon the laboratory technique (hydrogenation used to remove the 14-hydroxy); it gave no weight to the inventors' discovery of the 8α

molecule or the role of that discovery in tailoring the removal of excess 14-hydroxy.

The Federal Circuit affirmed. App.31a. It, too, recognized the district court's unchallenged factual findings that Purdue and Rhodes had discovered 8α, and how that discovery played a crucial role in the production of the first low-toxin oxycodone. App.7a-8a. But, like the district court, it legally erred by giving that discovery no weight. Per the panel, *Eibel Process*'s rule did not apply because Purdue and Rhodes claimed an "end product," not a "machine that remedied the problem" or a "particular method for creating" low-toxin oxycodone. App.15a-16a. Along similar lines, the panel erroneously held that the district court properly ignored the 8α claim language in its obviousness analysis because 8α was recited in "process" limitations. In support, it cited the "longstanding rule that an old product is not patentable even if it is made by a new process," App.18a, even though Purdue and Rhodes's low-toxin product was undisputedly "new" (*i.e.*, novel) under 35 U.S.C. § 102.

The Federal Circuit denied Purdue and Rhodes's petition for rehearing en banc. App.189a-90a.

REASONS FOR GRANTING THE WRIT

I. THE FEDERAL CIRCUIT'S CATEGORICAL RESTRICTIONS ON THE OBVIOUSNESS INQUIRY CONFLICT WITH LONGSTANDING PATENT LAW AND THIS COURT'S DECISIONS

Purdue and Rhodes created a new drug, with sought-after low levels of a suspected genetic toxin, by discovering the existence and role of a never-

before-known molecule that was causing the presence of that toxin. In holding that inventive advancement "obvious," the Federal Circuit applied a rigid approach to ascertaining the presence of invention that conflicts with section 103 and this Court's decisions in *KSR* and *Eibel Process*, as well as with numerous decisions of the courts of appeals. Certiorari should be granted to bring the law of nonobviousness back into line with the statute and the longstanding goals of the patent laws.

A. Patent Law Requires a Holistic Inquiry into Nonobviousness

The Patent Act's three "conditions of patentability"—"novelty and utility as articulated and defined in § 101 and § 102, and nonobviousness … as set out in § 103"—ensure that only genuine advancement receives the reward of a patent. *Graham v. John Deere Co.*, 383 U.S. 1, 12 (1966). They undertake that task through complementary but distinct inquiries.

Section 101's list—unchanged in essentials since then-Secretary Jefferson drafted it in 1793—defines the categories of "[i]nventions patentable" under the Act. It declares: "Whoever invents or discovers any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101; *see* Patent Act of 1793, ch. 11, § 1, 1 Stat. 318 (1793).

Section 102's novelty requirement, for its part, denies patent protection to what was already known. If a claimed invention was previously "patented,

described in a printed publication" or "available to the public," no patent may be granted. 35 U.S.C. § 102(a)(1).

The portion of the Patent Act most relevant here—section 103's nonobviousness requirement—is the third leg of the stool. Long before Congress put an explicit nonobviousness requirement into the statute in 1952, this Court's decisions undertook a "functional approach," *Graham*, 383 U.S. at 12, to distinguish between the technically novel but unpatentable work of the mere "mechanic" and "that degree of skill and ingenuity which constitute essential elements of every [patentable] invention." *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 248, 267 (1850). Thus, in *Hotchkiss*, the Court rejected a patent claiming clay knobs based expressly on pre-existing wood and metal knobs, because any "ordinary mechanic" could have made that substitution. *Id.* at 268. In *Smith v. Goodyear Dental Vulcanite Co.*, 93 U.S. (3 Otto) 486, 495 (1876), by contrast, the Court upheld a patent for rubber dentures because the creation of those dentures using new materials was "more than the exercise of mechanical judgment and taste"; "it was, in truth, invention." Likewise, in *Webster Loom Co. v. Higgins*, 105 U.S. (15 Otto) 580, 591 (1881), the Court upheld a patent to an apparently "simple" but highly effective improvement on a loom because the inventor "was the first to see [the new combination], to understand its value, to give it shape and form, to bring it into notice and to urge its adoption." (emphasis omitted). And in *Eibel Process*, the Court upheld a patent for a modest but critical modification to a well-known printing machine after answering

the "first and most important question" of whether the inventor's discovery of the source of the problem with existing machines "was a real discovery of merit." 261 U.S. at 52.

In each of these cases, the Court's inquiry was holistic. Because the product was new, the Court conducted a totality-of-the-circumstances analysis of the facts surrounding the patent holder's claimed invention—a "thorough examination of the whole voluminous record," *id.* at 53—to see whether the inventor had added meaningfully to human knowledge via "invention." *See Hotchkiss*, 52 U.S. at 265-67; *Smith*, 93 U.S. at 492-97; *Webster Loom*, 105 U.S. at 589-92; *Eibel Process*, 261 U.S. at 52-63.

That holistic approach makes perfect sense. Then, as now, other conditions of patentability screen out "inventions" directed to improper subject matter such as natural phenomena, as well as "inventions" whose essentials were already disclosed in the prior art in the manner claimed by the patent. *Compare* Patent Act of 1793, § 1 (patents may issue on eligible subject matter so long as the invention was "not known or used before"), *with* 35 U.S.C. § 101 (subject matter); 35 U.S.C. § 102 (novelty). By definition, then, any case about obviousness turns on a broader inquiry: whether the patent's (admittedly novel) claim (to patent-eligible subject matter) represents a true, patentable advance over prior art, or is instead mere tinkering. Necessarily, because inventions arise in a vast array of technologies and circumstances, a host of factors speak to that question—the state of the prior art, the general knowledge of practitioners in that art, the means by which the inventor created his product, the difficulty others had in creating similar

ones, and so on. *See, e.g.*, *Webster Loom*, 105 U.S. at 591-92 (shortcomings in prior art); *Eibel Process*, 261 U.S. at 55-56 (rapid adoption by others).

Section 103 carried forward the "expansive and flexible approach" of this Court's early patent precedents for "identifying new and useful innovations that were capable of sustaining a patent." *Graham*, 383 U.S. at 11-12; *see also KSR*, 550 U.S. at 415 (reiterating section 103's "expansive," "flexible," "functional" approach). It considers any relevant information in determining whether the claimed invention represents a true discovery, *KSR*, 550 U.S. at 416; after all, it expressly instructs courts to consider, not just the claim language, but the subject matter "as a whole":

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious to a person having ordinary skill in the art to which said subject matter pertains.

Patent Act of 1952, Pub. L. No. 593, § 103, 66 Stat. 798 (July 19, 1952); *see also* 35 U.S.C. § 103(a) (2006) (same in relevant respects); 35 U.S.C. § 103 (same in relevant respects).[4] Thus, only where a claimed

[4] The AIA changed section 103(a)'s reference to "the subject matter as a whole" to "the claimed invention as a whole." *Compare* 35 U.S.C. § 103(a) (2006), *with* 35 U.S.C. § 103 (2012). The older version of the statute controls this case, *see supra* n.1, but the change is not substantive. The revised Patent Act defines "claimed invention" as "the subject matter defined by a claim in a patent or an application for a patent."

invention "could readily be deduced from publicly available material by a person of ordinary skill in the pertinent field of endeavor" is it held obvious. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150 (1989).

Congress further dismissed rigid contours to the inquiry when it specifically added that "[p]atentability shall not be negated by the manner in which the invention was made." 35 U.S.C. § 103; *see also* Patent Act of 1952, § 103 (same in relevant respects). In this way, Congress made clear that even inventions that did not require what this Court once called a "flash of creative genius" qualify for patenting so long as they genuinely advanced the art. *Graham*, 383 U.S. at 15 & n.7 (quoting *Cuno Eng'g Corp. v. Automatic Devices Corp.*, 314 U.S. 84, 91 (1941)).

B. Invention Can Flow from a New Discovery, as *Eibel Process* Holds

Chief Justice Taft's unanimous opinion for the Court in *Eibel Process* illustrates how the approach to obviousness works in practice. As *Eibel Process* shows, invention can arise from a new discovery that leads the patentee to design a simple solution just as much as it can arise from known principles that the patentee puts to innovative use.

(continued…)

35 U.S.C. § 100(j). Further, both focus on the "whole" invention. *Id.* § 103; *see also* Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 Fed. Cir. Bar J. 435, 490 (noting that the AIA "ma[de] some stylistic changes to subsection (a) of pre-AIA § 103" and gathering relevant legislative history).

Eibel operated a Fourdrinier machine, an industry-standard device for making paper. At one end, a "flow box" or "pond" held papermaking stock comprised of wood pulp fibers mixed with water. 261 U.S. at 47. That stock traveled through an opening in the flow box onto one end (the "breast roll") of the "wire," an "endless wire cloth sieve passed over a series of rolls at constant speed." *Id.* Once on the wire, much of the water drained out of the stock, aided by constant shaking of the wire and by suction boxes. *Id.* at 48. After passing the suction boxes, the remaining mixture went through the "couch rolls," which pressed the mixture for uniform distribution. *Id.* at 47. The sheet then left the wire and was pressed and dried to make finished paper. *Id.*

Before Eibel's efforts, no one could run Fourdrinier machines at a pace "much beyond 500 feet a minute" without the produced paper being unacceptably uneven. *Id.* at 52. Eibel surmised that this speed constraint related to the different speeds at which the stock and the wire ran: because the wire was traveling much faster than the stock where the stock met the wire, the stock pooled and rippled between the breast roll and the first suction box, making it impossible to form even paper over the length of the wire. *Id.* Armed with this insight, Eibel deployed one of the oldest tools around: gravity. He equalized the speeds by "substantially tilting up the wire and giving the stock the added force of the down hill flow." *Id.* His modified machines produced wrinkle-free paper at speeds up to 1,000 feet per minute. *Id.* at 55.

Eibel's competitors (and the circuit court in that case) rightly pointed out that the way in which Eibel

altered existing machines was not exactly brain surgery; after all, he just tilted the breast roll, in recognition of the (rather obvious) fact that "water will run down hill." *Id.* at 52. For them, the obviousness inquiry turned on that and nothing more.

This Court took a broader view. It framed "[t]he first and most important question" as "whether [Eibel's] was a real discovery of merit." *Id.* In answering that question, the Court emphasized that it could not "lose sight of the fact that one essential part of Eibel's discovery" was his recognition that the difference in speed between the stock and the wire caused the problems with high-speed operation. *Id.* at 67. Accordingly, Eibel's "invention was not the mere use of a high or substantial pitch to remedy a known source of trouble." *Id.* at 68. Rather, "[i]t was the *discovery of the source not before known*, and the application of the remedy" based on that discovery. *Id.* (emphasis added). For that, Eibel was "entitled to be rewarded in his patent." *Id.* To borrow terms that then-Judge Kennedy would later use, patentable invention is not limited to situations in which, though the idea behind an improvement could "be readily apprehended," its "mechanical implementation" is "difficult for an inventor to achieve." *Saf-Gard Prods.*, 532 F.2d at 1271. As Eibel's patentable invention shows, invention also arises where the "primary creative value … inheres in the principle for its operation," not the "readily obtain[able]" "mechanical means for achieving it." *Id.* at 1272.

C. Through Categorical Limits, The Federal Circuit Deprives Patentability for True Invention

This Court's cases thus establish fundamental propositions governing the obviousness inquiry: all true inventions deserve patent protection, including where ingenuity begins with the discovery of the unknown source of an existing problem, and to meaningfully assess whether true invention has occurred, the inquiry into innovation is broad and holistic. The Federal Circuit's parochial limitations have no place in that inquiry. Real advancements based on genuine discoveries deserve patent protection, even if those discoveries lead to new end products rather than new processes, and even if those discoveries find expression in process limitations rather than structural limitations.

1. The Federal Circuit's approach disregards an inventor's discovery if it does not lead to a claimed machine or process.

The Federal Circuit held that those who discover the source of a problem do not merit a patent where they claim "the end product" rather than a process or "a machine" that remedied the problem they identified. App.15a; *see also* App.16a (Eibel Process does not apply unless the patent claims "a particular method"). Section 103, however, expressly instructs courts to consider the claimed invention "as a whole." 35 U.S.C. § 103(a). As explained, *see supra* 17-18, that purposefully broad language instructs courts to consider *every* fact relevant to the claimed invention's ingenuity in *every* case, not just some of the facts in

some category of cases. That is, after all, the "functional approach" adopted by this Court and then codified by Congress. *Graham*, 383 U.S. at 12; *see id.* at 12-14 (discussing the relationship between section 103 and prior cases); *Teva Pharm. USA v. Sandoz, Inc.*, 135 S. Ct. 831, 850 (2015) (Thomas, J., dissenting) ("[O]bviousness turns on historical facts about the circumstances of the invention."). In the same vein, *Eibel Process* demonstrates that an inventor's discovery need not be contained within the four corners of the patent claim for evaluating obviousness, let alone that the claim must be directed to a machine or process. *See* 261 U.S. at 63, 67-68.

There is no meaningful difference—aside from result—between the decision below and *Eibel Process*. Eibel's discovery—that the unequal speed between stock and wire led to rippling at higher operating speeds—was mentioned only in his patent's specification, not his claims. *See id.* at 49-51. And he did not claim a process of making paper based on that insight. Rather, he claimed a modified Fourdrinier machine itself, one with an elevated breast roll that would increase the speed of the stock to match the speed of the wire. *See id.* at 50-51. That retooled machine was an "end product" just as much as a pharmaceutical compound is, and yet this Court still framed "[t]he first and most important question" as whether Eibel's entire inventive act—discovering the source of the problem and then making the requisite adjustment to Fourdrinier machines—was one of "real merit." *Id.* at 52. The Court then drove home the importance of this inquiry when it answered that question: it focused at length on the nature and importance of Eibel's insight into the problem with

existing Fourdrinier machines when upholding his claim to a modified one. *See id.* at 67-68.

That basic factual pattern—identification of a problem, discovery of the source of that problem, and a new invention incorporating modifications that account for that source—occurs across all kinds of disciplines. Indeed, as the following chart demonstrates, it is exactly what happened here.

Old Paper Machine	**Old Oxycodone**
The Problem: Uneven paper when run at high speed (>500 ft./min.)	*The Problem*: Too much potentially genotoxic 14-hydroxy (>1,500 ppm)
The Discovery: The difference in speed between the stock and the wire led to rippling.	*The Discovery*: A new, unknown molecule, 8α, created 14-hydroxy during the salting step.
Account for the Discovery: Increase the stock's speed by tilting the wire.	*Account for the Discovery*: Hydrogenate again tailored to 8α's unique properties.
The Invention: **Faster Paper Machine (~1,000 ft./min.)**	*The Invention*: **Safer Oxycodone (<25 ppm ABUKs)**

It is little surprise, then, that no court has previously limited *Eibel Process* to patents claiming processes or to machines rather than end products. The Patent Act contains a set of principles of patentability common to all classes of invention; "process[es], machine[s], manufacture[s] or

composition[s] of matter, or any new and useful improvement[s] thereof" are all equally eligible for patenting. 35 U.S.C. § 101. Thus, courts have long applied *Eibel Process* to inventions of all kinds. In *In re Linnert*, 309 F.2d 498, 499 (C.C.P.A. 1962), for example, the existing alloys used to build airplanes would develop "minute pockets" when welded, pockets that led to "local stress concentration and ultimate deterioration." The patentees uncovered the source of the problem: during arc welding, chemicals present in the base metal partially decomposed and vaporized into gas, leaving nitrogen gas bubbles trapped in pockets in the weld. *See id.* To solve this problem, the patentees added a small amount of titanium, zirconium, or uranium, each of which has a high affinity for nitrogen, to the base metal. *See id.* The patentees claimed their metal alloy (a "composition of matter" under § 101). The Patent Office Board of Appeals disallowed the patent, reasoning (like the Federal Circuit here) that the patent did not claim the "physical means by which the problem was solved" and did not mention porosity or welding. *Id.* at 503. The Court of Customs and Patent Appeals, however, rejected those purported distinctions.

Citing *Eibel Process*, the appellate court in *Linnert* explained that the "solution to [a] problem is only a *part* of the invention" under section 103; the "*essence* of [the patentees'] invention, *i.e.*, the determination of the cause of weld porosity" was also "an inseparable part of the 'invention as a whole.'" *Id.* (emphasis added). Since that discovery was not obvious, the patentees deserved a patent for the end product, the metal alloy itself. *See id.*

The list of cases respecting *Eibel Process* goes on and on. To name just a few, in *In re Sponnoble*, 405 F.2d 578 (C.C.P.A. 1969), the court upheld a claim to a silicone-coated rubber plug separating the liquid and dry components stored in a single pharmaceutical vial (a "manufacture" under § 101) because the inventor discovered that moisture traveled *through* existing plugs, not just around them. In *In re Nomiya*, 509 F.2d 566, 568 (C.C.P.A. 1975), the court upheld a claim to a new kind of insulated semiconductor (another "manufacture") because the inventors discovered that existing semiconductors experienced "parasitic transistor action," action that the inventors then eliminated by adding a second protective diode. And in *Watson v. Heil*, 192 F.2d 982 (4th Cir. 1951), the court remanded for the district court to properly take into account evidence that the inventor's nesting grocery cart (yet another "manufacture"), though analogous to storage containers in other fields, embodied the inventor's novel approach to the longstanding but then-unmet demand for strong but space-saving shopping carts. *See also* 2 Donald S. Chisum, Chisum on Patents § 5.04B (collecting cases).

Leo Pharmaceutical Products v. Rea, 726 F.3d 1346 (Fed. Cir. 2015), decided almost 100 years after *Eibel Process*, demonstrates that the principle of *Eibel Process* was so embedded in the law that it no longer required citation to that precedent. Everyone knew that vitamin D and corticosteroids could be used together to treat psoriasis, but Leo discovered that existing products that combined the two into one compound were not storage stable. *See id.* at 1348-49.

After a few false starts, Leo discovered a solution, the use of a new solvent. *See id.*

The Federal Circuit upheld Leo's claim to the compound substance itself—a pharmaceutical composition, just like Purdue's new low-toxin oxycodone—not just the process used to make it. *See id.* at 1353-59. Without even mentioning *Eibel Process* by name, the court invoked its central teaching: "invention can often be the recognition of [the] problem itself," so Leo deserved a patent for discovering and then solving the stability problems associated with other compound treatments. *Id.* at 1353; *see also id.* at 1356-57 (upholding the patent because "[t]he problem was not known, the possible approaches to solving the problem were not known or finite, and the solution was not predictable").

Here, however, the Federal Circuit took the opposite approach: it acknowledged *Eibel Process*, but cabined its principles to a vanishing point. *Eibel Process*'s central insight—that often the "primary creative value" of a new, patentable invention will "inhere[] in the [discovery of the] principle for its operation" rather than in the "mechanical means for achieving" that principle, *Saf-Gard Prods.*, 532 F.2d at 1272—applies to inventions embodying all kinds of discoveries, not just ones that lead to new processes or new machines. The Federal Circuit gave no reason for suddenly concluding otherwise.

2. The Federal Circuit's approach disregards process-based limitations.

In addition to gutting *Eibel Process*'s protection for *all* genuine inventions based on true discoveries, the Federal Circuit held that, in every case, courts should

ignore process-related limitations when determining obviousness of product claims. That rule makes little sense. First of all, it, too, is a categorical rule barred by the plain terms of section 103 and this Court's precedents demanding a flexible and broad approach. *See supra* 14-18. Moreover, that rule will have serious repercussions on the longstanding availability of product-by-process claiming. "[I]n some instances a claim may validly describe a new product," not by reference to its ultimate composition, but by "reference to the method of production." *Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 373 (1938); *see also Bonito Boats*, 489 U.S. at 158 n.* (in product-by-process claims, the claimed product is defined "at least in part in terms of the method or process by which it is made"). The ingenuity in such claims typically resides in the process limitations; that is, after all, how the new, often difficult-to-describe product is made. *See* 3-8 Chisum on Patents § 8.05. But those limitations are *irrelevant* under the Federal Circuit's approach, posing unnecessary and extra-statutory barriers to the patentability of new, nonobvious products created through new processes.

The Federal Circuit's approach also conflicts with the "fundamental tenet of patent law" that claims "must be interpreted consistently for purposes of infringement and validity." 1-18A Chisum on Patents § 18.01; *see also, e.g.*, *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 230 (1964) (The "prerequisites to obtaining a patent are strictly observed," and "when the patent has issued the limitations on its exercise are equally strictly enforced."); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003) ("It is

axiomatic that claims are construed the same way for both invalidity and infringement."). For purposes of infringement, the process language in a process-by-product claim is critical: unless the patent "identif[ies]" the product "so that it can be recognized *aside from* the description of the process for making it,… nothing can be held to infringe the patent which is not made by that process." *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293, 310 (1884) (emphasis added); *see also Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1293 (Fed. Cir. 2009) (en banc) ("[P]rocess terms in product-by-process claims serve as limitations in determining infringement."). Contrary to the Federal Circuit's new rule, then, that language ought to also be considered when determining whether the claimed product-by-process is impermissibly obvious.

Indeed, in categorically disregarding process limitations when determining obviousness of product claims, the Federal Circuit cast aside its own established precedent. Those cases demonstrate that process limitations deserve at least some consideration in the analysis. In *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1369 (Fed. Cir. 2009), for example, the court recognized that, while process limitations are not the "focus" of the invalidity analysis for product-by-process claims, they still can play a role, particularly where the claimed product is a new one. So too in *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834, 845 (Fed. Cir. 1992), where the court acknowledged that, while the "emphasis" of the inquiry remains on the product, "the process language in the claim" remains one of its "defining" aspects and should be considered.

As chief support for its contrary position, the Federal Circuit relied on the "longstanding rule that an old product is not patentable even if it is made by a new process." App.18a. Purdue and Rhodes do not take issue with that rule; it has a venerable origin. *See Cochrane*, 111 U.S. at 464. But their product was not "an old product" and was not invalidated (or even challenged) for lack of novelty under section 102. Rather, their innovation was the first-ever low-toxin oxycodone drug. Accordingly, the court's categorical ban on considering process limitations as part of the obviousness inquiry in every case makes no sense. There is no reason to ignore process limitations reflecting the inventor's discovery when considering whether a *new* product, previously unknown, represents a true advance beyond the prior art, as was the case here.

3. The Federal Circuit's approach to obviousness is as erroneously narrow as its prior one.

By categorically refusing to consider an inventor's discovery unless that discovery led to a machine or a process and likewise refusing to consider process limitations in product claims, the Federal Circuit improperly restricted the obviousness inquiry. Of course, this is not the first time that court has established an inflexible and narrow obviousness approach in the face of Congress's and this Court's call for a flexible and broad one. Prior to *KSR*, the Federal Circuit's "teaching, suggestion, or motivation" (TSM) test provided that "a patent claim is only proved obvious if … 'some motivation or suggestion to combine the prior art teachings' can be found in the prior art, the nature of the problem, or the knowledge

of a person having ordinary skill in the art." *KSR*, 550 U.S. at 407. As a result of the TSM test, those claiming a patent was obvious had to fight with one hand tied behind their backs: they could rely only on prior art that addressed "the precise problem that the patentee was trying to solve" and could not argue that it would have been "obvious to try" the claimed invention's new combination of existing elements. *Id.* at 414.

In *KSR*, this Court emphatically rejected this "rigid approach." *Id.* at 415. In its place, the Court reiterated *Graham*'s "expansive," "flexible," and "broad" inquiry into all of the facts surrounding the claimed invention. *Id.* As the Court explained, that holistic inquiry is more consistent with both the role of section 103 and the real world of invention: given "[t]he diversity of inventive pursuits," the nature of "modern technology," and the teachings of "common sense," *id.* at 419, 421, courts must examine *all* of the relevant facts, not a "constrained" subset of them, to determine whether a claimed invention represents a true advance over the prior art, *see id.* at 415-22, 427.[5]

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[5] In several other areas of patent law, the Court has likewise rejected the Federal Circuit's apparently unyielding preference for unyielding rules. *See, e.g.*, *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923 (2016) (appropriate test for treble damages under 35 U.S.C. § 284); *Octane Fitness, LLC v. Icon Health & Fitness, Inc.*, 134 S. Ct. 1749 (2014) (appropriate test for attorney's fees under 35 U.S.C. § 285); *Bilski v. Kappos*, 561 U.S. 593 (2010) (appropriate test for patentable processes); *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007) (appropriate test for Article III standing in declaratory-judgment actions); *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006) (appropriate test for preliminary injunctions in infringement suits); *Festo Corp. v. Shoketsu Kinzoku Kogyo*

KSR invalidates the Federal Circuit's new categorical approach to obviousness just as much as it invalidated that court's old TSM test. To be sure, unlike the TSM test (and many of the Federal Circuit's other now-discarded rules), that court's decision here makes life harder for patent holders rather than alleged infringers. But that was not *KSR*'s point. Neither the Patent Act nor this Court's cases take sides in the perennial fights between patent holder and alleged infringer. Instead, each gives effect to the bargain at the heart of patent law—limited exclusionary rights for genuine inventions, free competition for everything else—by demanding that, for claimed inventions not in the prior art, the court consider *all* of the evidence that speaks to the invention's creativity. Just as this Court has intervened to level the playing field when the Federal Circuit had tilted it against patent challengers, it should intervene here to prevent the Federal Circuit from slanting it in the opposite direction now with equally impermissible and unjustified narrowing rules.

II. THIS CASE IS AN EXCELLENT VEHICLE FOR PREVENTING THE SIGNIFICANT DAMAGE OF THE FEDERAL CIRCUIT'S NEW OBVIOUSNESS TEST

In addition to being wrong and in conflict with this Court's precedents, the Federal Circuit's newfound approach to obviousness is dangerous. Because the

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(continued…)

Kabushiki Co., 535 U.S. 722 (2002) (appropriate test for prosecution-history estoppel).

Federal Circuit is the national arbiter of patent law unless and until this Court intervenes, its errors threaten innovation across a host of disciplines nationwide.

1. This case itself demonstrates the importance of following the Patent Act's and this Court's flexible, totality-of-the-circumstances approach to obviousness. Everyone acknowledges that Purdue and Rhodes discovered the 8α molecule, as well as the fact that it was the cause of the high levels of potential toxin in oxycodone. App.7a (Federal Circuit); App.54a-59a (district court). Everyone also acknowledges that, prior to the discovery of 8α, existing manufacturing methods produced *more* 14-hydroxy when researchers tried to remove it through the traditional hydrogenation approach. App.7a (Federal Circuit); App.55a (district court). Purdue and Rhodes then applied their discovery, in an exercise of inventive innovation, by created a significant, long-desired pharmaceutical advancement—the the first-ever low-toxin oxycodone. Under the Patent Act and this Court's precedents, these facts—not just undisputed but affirmatively found by the district court under Federal Rule of Civil Procedure 52(a)—should have carried the day. When properly viewed as a whole, Purdue and Rhodes's claimed invention embodies true innovation. Only by crafting new legal restrictions on the obviousness inquiry was the Federal Circuit able to conclude otherwise.

2. The Federal Circuit's new legal restrictions will have drastic consequences far beyond this case. To begin with, they will dramatically affect the pharmaceutical industry. As this case demonstrates, much pharmaceutical innovation does not involve

discovering new, basic chemical reactions; everyone knew, for instance, that one could generally remove 14-hydroxy through hydrogenation. Instead, advancements in this field often look exactly like what happened here: the industry recognizes the existence of an intractable problem with an existing compound, researchers struggle to discover the underlying source of that problem, and then, if they succeed, they use their knowledge of established chemical principles to create a new compound. *Cf. Leo Pharm. Prods.*, 726 F.3d at 1353-57 (tracing a similar inventive pathway for a pharmaceutical). If developers cannot recoup the expenses inherent in developing and then bringing to market new prescription drugs, everyone loses. *See* J. DiMasi *et al.*, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20 (2016) (estimating $1.4 billion per approved new compound for out-of-pocket costs alone); *FTC v. Actavis*, 133 S. Ct. 2223, 2228 (2013) (noting the "long, comprehensive, and costly testing process" of developing a new pharmaceutical).

Moreover, these harms will fall across disciplines because innovation across disciplines often proceeds through the discovery of the source of a problem. *See, e.g.*, Jeanne C. Fromer, *A Psychology of Intellectual Property*, 104 Nw. U. L. Rev. 1441, 1459-71 (2010) (tracing the literature on technological advance). The cases discussed above, *see supra* 23-26, prove as much. Faster paper-making machines, safer aircraft, better packaging, safer and more effective new drugs—each of these new, valuable, patentable products demonstrates that invention often depends as much on those who creatively solve problems with

existing products or processes as it does upon those who come up with new ones from scratch. The Federal Circuit's newfound limitations thus threaten innovation everywhere, not just in the pharmaceutical industry.

That potential damage, moreover, will fall particularly hard on those whose discoveries lead to product-by-process claims. Under the Federal Circuit's reading of *Eibel Process*, inventors can't win for trying. If they do not claim a machine or process resulting from their discovery, that discovery will be considered irrelevant in determining obviousness. But if they *do* incorporate that process as part of a product-by-process claim, that process will *still* be discarded when evaluating obviousness. Faced with this "heads you win, tails I lose" mode of analysis, a would-be product-by-process innovator will likely not make the effort. *See Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974) (The "right of exclusion for a limited period" provides an incentive to inventors to "risk the often enormous costs in terms of time, research, and development").

3. Fortunately, however, this Court can stop all of these harms from coming to pass: this case is an excellent vehicle through which to review and reject the Federal Circuit's new approach to obviousness. To begin with, the issue is properly before this Court. At every stage of the proceedings below, Purdue and Rhodes pressed the importance of their discovery and the need to consider it when evaluating the obviousness of their claimed inventions, whether or not their patent claims were directed to an end product or a process and whether or not the 8α-related limitations in the claims were process

limitations or structural limitations. *See, e.g.*, C.A. Opening Br. 34-50; C.A. Reply Br. 4-20; C.A.App.A7315; A7483-84. And though the district court did not, the Federal Circuit squarely addressed Purdue and Rhodes's arguments. It unequivocally held that *Eibel Process* does not apply where the patentee claims an "end product" rather than a "particular method of creating" a product, App.16a, and it unequivocally held that process limitations should be "disregard[ed]" when determining obviousness, App.18a.

This case is also an excellent vehicle because the essential facts are not just undisputed, but affirmatively found by the district court. As mentioned above, the district court found, and the Federal Circuit acknowledged, the only facts necessary for Purdue and Rhodes to prevail under the right approach to obviousness: no one had ever made oxycodone substantially free of 14-hydroxy, the existing approach to removing 14-hydroxy could not solve the problem, and the discovery of previously unknown 8α allowed Purdue and Rhodes to remove substantially all of the 14-hydroxy from the finished product. *See supra* 6-10.

To be sure, the Federal Circuit stated that, "[e]ven if determining the source of 14-hydroxy in the end product was not obvious, that problem did not need to be solved to arrive at the claimed invention." App.15a. In a similar vein, it elsewhere stated that one did not need to know the source of 14-hydroxy to determine "whether it would be obvious … to use hydrogenation to remove the excess 14-hydroxy in the oxycodone." App.16a-17a.

These statements are not, and could not be, independent appellate fact-findings. Rather, they illustrate the Federal Circuit's legal errors. In each, the court was considering only whether the final step of the solution was obvious, without evaluating any of the inventors' prior steps or the invention as a whole. For instance, the court defended its disregard of the "problem" of the source of 14-hydroxy on the basis that Purdue and Rhodes "did not claim" a second hydrogenation step, but rather "the end product." App.16a. So too with the court's statement that "[o]ne need not know" the source of 14-hydroxy to know "whether it would be obvious … to use hydrogenation to remove the excess 14-hydroxy." App.16a-17a. As the court viewed it, the discovery of 8α was irrelevant because Purdue and Rhodes "claimed the end product" and did not claim the different reaction conditions necessary to properly handle 8α. App.16a. These statements thus provide no "factual" shield from this Court's review; they are legal error unto themselves. They are entirely premised on the erroneous approach of assuming away the discovery of 8α and its particular properties in assessing nonobviousness.[6]

CONCLUSION

The petition should be granted.

[6] Analogous statements perpetuated the district court's similar legal errors, which relied on the obviousness of "hydrogenation" as the solution once the problem had been identified. *E.g.*, App.101a ("*[T]he inventors' knowledge* of 8α defined a universe of possible 8α-specific processes to achieve low-ABUK oxycodone." (emphasis added)); App.102a (relying on an inventor's statement that "*[o]nce the mechanism of formation was known*,… hydrogenation was the first thing that popped into [his] mind" (emphasis added)).

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APPENDIX

APPENDIX A

United States Court of Appeals
for the Federal Circuit

PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., RHODES TECHNOLOGIES,
Plaintiffs-Appellants

v.

EPIC PHARMA, LLC,
Defendant

2014-1294

Appeal from the United States District Court for the Southern District of New York in No. 1:13-cv-00683-SHS, Senior Judge Sidney H. Stein.

PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., RHODES TECHNOLOGIES,
Plaintiffs-Appellants

v.

MYLAN PHARMACEUTICALS INC., MYLAN INC.,
Defendants-Appellees

2014-1296

Appeal from the United States District Court for the Southern District of New York in No. 1:12-cv-02959-SHS, Senior Judge Sidney H. Stein.

PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., RHODES TECHNOLOGIES, GRUNENTHAL GMBH,
Plaintiffs-Appellants

v.

AMNEAL PHARMACEUTICALS, LLC,
Defendant-Appellee

2014-1306, -1307

Appeals from the United States District Court for the Southern District of New York in No. 1:11-cv-08153-SHS, Senior Judge Sidney H. Stein.

GRUNENTHAL GMBH, PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., RHODES

TECHNOLOGIES,
Plaintiffs-Appellants

v.

TEVA PHARMACEUTICALS USA, INC.,
Defendant-Appellee

2014-1311, -1312, -1313, -1314

Appeals from the United States District Court for the Southern District of New York in Nos. 1:11-cv-02037SHS, 1:12-cv-05083-SHS, Senior Judge Sidney H. Stein.

Decided: February 1, 2016

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Before PROST, *Chief Judge*, REYNA, *Circuit Judge*, and STARK, *Chief District Judge*.[*]

PROST, *Chief Judge*.

This appeal arises from consolidated Hatch-Waxman proceedings involving the reformulated version of the pain reliever OxyContin®. The Appellants, Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., and Rhodes Technologies (collectively, "Purdue") and Grunenthal GmbH ("Grunenthal") asserted a number of claims from multiple different patents against the Appellees, Amneal Pharmaceuticals, LLC ("Amneal"), Epic Pharma, LLC ("Epic"), Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, "Mylan"), and Teva Pharmaceuticals USA, Inc. ("Teva"), all of whom have filed Abbreviated New Drug Applications ("ANDAs") seeking to sell generic versions of OxyContin®. The United States District Court for the Southern District of New York held a three-week bench trial in the case against Teva, following which it held all of the asserted patent claims invalid. *In re OxyContin Antitrust Litig.*, 994 F. Supp. 2d 367, 377 (S.D.N.Y. 2014) ("*District Court Decision*"). The court then entered orders of dismissal in the three remaining cases against Amneal, Epic, and Mylan based on collateral estoppel. Purdue and Grunenthal appeal the final judgment in the Teva action, and Purdue also appeals the orders of dismissal in the three other cases. For the reasons stated below, we affirm the district court's rulings.

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[*] Honorable Leonard P. Stark, Chief District Judge, United States District Court for the District of Delaware, sitting by designation.

BACKGROUND

Oxycodone hydrochloride—the active pharmaceutical ingredient ("API") in OxyContin®—is an opioid analgesic used to treat moderate to severe pain. This consolidated appeal concerns four patents associated with the reformulated version of OxyContin®: U.S. Patent No. 7,674,799 ("'799 patent"), U.S. Patent No. 7,674,800 ("'800 patent"), Patent No. 7,683,072 ("'072 patent") (collectively, "the low-ABUK patents"), and U.S. Patent No. 8,114,383 patent ("'383 patent").

I. The Low-ABUK Patents

The low-ABUK patents recite an improved formulation of oxycodone hydrochloride. Those patents describe an oxycodone salt with extremely low levels of a particular impurity, 14-hydroxycodeinone ("14-hydroxy"), which belongs to a class of potentially dangerous compounds known as alpha, beta unsaturated ketones ("ABUKs"). The prior art method of synthesizing oxycodone hydrochloride involved three steps: first, thebaine, a derivative of the opium poppy, was oxidized to form 14-hydroxy; second, the 14-hydroxy was converted to oxycodone free base through hydrogenation; and third, the oxycodone free base was reacted with hydrochloric acid to form oxycodone hydrochloride. The end product created by that process, however, contained high levels of 14-hydroxy, on the order of 1500 parts per million ("ppm").

In January 2004, the U.S. Food and Drug Administration ("FDA") became concerned that 14-hydroxy was potentially toxic and thus mandated that oxycodone hydrochloride manufacturers either

provide evidence that the 14-hydroxy levels in their formulations were safe or reduce the amount of 14-hydroxy to less than 10 ppm. Even before the FDA's mandate, however, Rhodes Technologies—a subsidiary of Purdue—had begun researching methods to reduce 14-hydroxy levels in its oxycodone API. The scientists initially hypothesized that the 14-hydroxy present in the final salt was leftover 14-hydroxy that had not been hydrogenated in the second step. Thus, they extended the hydrogenation reaction to completion, confirming that every molecule of 14-hydroxy converted to oxycodone free base at step two. But the scientists found that after step three—transforming the oxycodone free base into oxycodone hydrochloride—the 14-hydroxy had returned.

The scientists thus shifted their focus to step three. It was well known in the art that an impurity, 8,14-dihydroxy-7,8-dihydrocodeinone ("8,14-dihydroxy") was produced as a byproduct of the oxidation of thebaine (step one). More specifically, it was known that a particular isomer of 8,14-dihydroxy was formed: 8ß, 14-dihydroxy-7,8-dihydrocodeinone ("8ß"). Scientists did not know with certainty, however, whether 8α, 14–dihydroxy–7,8– dihydrocodeinone ("8α")—a diastereomer of 8ß—was also produced during the oxidation step. Purdue scientists had previously noted the potential existence of 8α, but no scientific literature discussed that particular isomer. Through experimentation, the scientists determined that 8α was indeed being produced at step one and, in fact, was transforming into 14-hydroxy during the acid-catalyzed dehydration at step three. To remove the 14-hydroxy from the oxycodone API, the

scientists added another hydrogenation step at the end of step three to convert the remaining 14-hydroxy into oxycodone free base. By June 2003, Rhodes's laboratory could routinely produce oxycodone API with 14-hydroxy levels less than 10 ppm using the double-hydrogenation process. Purdue and Rhodes thus sought approval from the FDA and patent protection for their low-ABUK oxycodone product.

The low-ABUK patents continue from application No. 11/391,897, known as the "Chapman Application." The claims of the Chapman Application have previously been before us; we authored a non-precedential decision affirming the Board of Patent Appeals and Interferences' determination that the Chapman claims were obvious. *Chapman v. Casner*, 315 F. App'x 294, 295 (Fed. Cir. 2009) (Rader, CJ., dissenting). In that case, the Board declared an interference between the Chapman Application and U.S. Patent No. 7,153,966 ("Casner"). The relevant claims in the Chapman Application related to a method for making oxycodone API using a hydrogenation step to remove 14-hydroxy, but they did not require that some of the remaining 14-hydroxy be derived from the 8α isomer. *Id.* The Board compared Chapman's claims to the prior art and concluded that they were obvious. Chapman appealed directly to us, and we agreed with the Board. We reasoned that, because the claims did not specify the source of the 14-hydroxy, any prior art reference that disclosed conditions under which either 8α or 8β converted to 14-hydroxy would render the claim obvious. *Id.* at 297. We further noted that the prior art references did just that—they disclosed the conversion of 8β to 14-hydroxy under certain

conditions. *Id.* Thus we affirmed the Board's decision to reject the Chapman claims as obvious. *Id.* at 297–98.

Purdue eventually amended the Chapman claims to include the claims now on appeal. Unlike the claims in the Chapman Application, the claims at issue here are product claims instead of process claims, and they explicitly recite 8α as the source of at least a portion of the minimal amounts of 14-hydroxy remaining in the oxycodone API. In 2010, the U.S. Patent and Trademark Office allowed the claims and issued the low-ABUK patents.

II. The '383 Patent

The '383 patent covers abuse-resistant formulations. Original OxyContin® was a popular opioid analgesic which delivered a large dose of oxycodone over a twelve-hour period. In the early 2000s, however, reports of widespread abuse of Original OxyContin® emerged, and the problem began to garner significant public attention. Original OxyContin® was susceptible to tampering because abusers could crush the tablets easily into powder, which could then be swallowed, snorted, or injected for an instant opioid "high." In 2001, Purdue and the FDA changed the label of Original OxyContin® to warn doctors about the potential for abusers to tamper with the dosage form.

Purdue thus investigated ways to reformulate OxyContin® to deter abuse. Purdue initially considered, among other ideas, creating a tablet that would be difficult to crush and difficult to inject, but those efforts were unsuccessful. In 2003, Purdue became aware of technology developed by Grunenthal

that made tablets extremely hard (in order to prevent crushing) and formed a gel upon dissolution in water (in order to prevent injecting).

Grunenthal first began to research abuse resistant properties for its opioid product, tapentadol. In October 2002, Johnson & Johnson proposed a joint venture with Grunenthal, using Johnson & Johnson's osmotically controlled-release oral delivery system ("OROS") to deter abuse. The OROS technology consists of a tablet with an outer shell that limits the flow of the API from an inner core through the use of a "push compartment" in the tablet. The hard outer shell is composed of high molecular weight polyethylene oxide ("PEO"), and the "push compartment" expands to force the API through a hole in the outer shell. But the tablet could still be easily crushed with a mortar and pestle, so it was not a workable solution. Dr. Johannes Bartholomaeus, who was the head of pharmaceutical development for Grunenthal at the time, tried to strengthen tapentadol's dosage form by making the entire tablet, instead of just the outer shell, resistant to crushing. Dr. Bartholomaeus thus designed a formulation that contained a matrix of API and PEO throughout the tablet. Moreover, Dr. Bartholomaeus's experimentation with PEO demonstrated that using both heat and pressure to form the tablet resulted in a stronger solid that resisted breaking by a hammer or by a mortar and pestle, and withstood a breaking strength test that exerted 500 N of force.

After a series of negotiations, Purdue obtained a license from Grunenthal to use the abuse deterrent technology of the '383 patent in its Reformulated OxyContin® product. Purdue submitted a New Drug

Application to the FDA in November 2007, proposing a Reformulated OxyContin®, which the FDA approved in April 2010. By July 2012, Purdue noted reductions in the abuse of OxyContin® and provided that information to the FDA. On April 16, 2013, the FDA withdrew its approval for Original OxyContin® and stopped accepting ANDAs that proposed generic versions of it, reasoning that Reformulated OxyContin® was available to provide the same benefits with lower risks of abuse and misuse. On the same day, the FDA approved a new label that allowed Purdue to market Reformulated OxyContin® on the basis of its abuse deterrent properties.

III. Procedural History

In March 2011, Purdue sued Teva for infringement of the low-ABUK patents in response to Teva's filing of an ANDA seeking FDA approval to market generic versions of Reformulated OxyContin®. Between November 2011 and January 2013, Purdue filed similar lawsuits against Epic, Mylan, and Amneal. In addition, in June 2012, Grunenthal and Purdue jointly sued Teva for infringement of the '383 patent. The two Teva cases were consolidated and joined with the Epic, Mylan, and Amneal cases, along with six actions involving other defendants, in multi-district litigation for pretrial purposes.

In September 2013, the district court held a three-week bench trial in the Teva cases.[1] The district court found that the asserted claims were infringed

[1] Before the district court, Purdue accused Teva of infringing claims 3 and 19 of the '799 patent, claims 30–34 and 76–79 of the '800 patent, claims 1, 4, and 5 of the '072 patent, and claims 1, 2, 5, 7, and 8 of the '383 patent.

by Teva's proposed generic product, but it also held that all of the claims were invalid as anticipated by or obvious over the prior art. *District Court Decision*, 994 F. Supp. 2d at 377. Based on that decision, the district court issued an order for Purdue to show cause as to why the actions against Epic, Mylan, and Amneal should not be dismissed under the doctrine of collateral estoppel. Purdue stated that it intended to appeal the Teva decision but it agreed that the district court's decision regarding the invalidity of the low-ABUK patents precluded Purdue's claims for relief against the other defendants. Accordingly, the district court dismissed the three remaining actions based on collateral estoppel.

Purdue and Grunenthal appeal the final judgment in the Teva actions and Purdue also appeals the orders of dismissal in the three other cases. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

A patent is invalid for anticipation under 35 U.S.C. § 102 if a single prior art reference discloses each and every limitation of the claimed invention. *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003). A single prior art reference may anticipate without disclosing a feature of the claimed invention if such feature is necessarily present, or inherent, in that reference. *Id.* Anticipation is a question of fact, which we review for clear error. *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1346 (Fed. Cir. 1999).

A patent is invalid for obviousness "if the differences between the subject matter sought to be patented 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." 35 U.S.C. § 103(a). Obviousness is a legal conclusion based on underlying facts. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). We review the underlying findings of fact for clear error, and we review de novo the court's ultimate legal conclusion of whether the claimed invention would have been obvious. *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 719 F.3d 1346, 1354 (Fed. Cir. 2013). Underlying factual inquiries include (i) the scope and content of the prior art; (ii) the differences between the prior art and the claims at issue; (iii) the level of ordinary skill in the field of the invention; and (iv) relevant secondary considerations. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 406 (2007); *Graham*, 383 at 17–18.

I. Invalidity of the Low-ABUK Patents

Purdue challenges the district court's conclusion that the asserted claims of the low-ABUK patents are invalid as obvious. Those claims recite an oxycodone API product with low ABUK levels.[2] The district court found that the prior art taught that oxidation of

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[2] All of the asserted claims are product claims. The asserted claims of the '072 patent are directed to "an oxycodone hydrochloride active pharmaceutical ingredient" with low ABUK levels, *see, e.g.*, '072 patent col. 34 ll. 57–60, while the asserted claims of the '799 patent are directed to an "oral dosage form" of low-ABUK oxycodone hydrochloride, *see, e.g.*, '799 patent col. 35 ll. 8–15. The asserted claims of the '800 patent are product-by-process claims; they are directed to "[o]xycodone salt prepared according to [a] process" that yields low ABUK levels. *See, e.g.*, '800 patent col. 35 ll. 49–50.

thebaine produced 14-hydroxy and that it was well known in the art that 14-hydroxy could be removed using hydrogenation. *District Court Decision*, 994 F. Supp. 2d at 395–96. The court further determined that the discovery of 8α was not necessary to the claimed invention: a skilled artisan would recognize that hydrogenation could be used to remove the remaining 14-hydroxy, regardless of the source of the 14-hydroxy. *Id.* at 405–06. Moreover, the court concluded that the claim limitation requiring that the remaining 14-hydroxy is at least in part "derived from 8α[]" is a product-by-process limitation and thus immaterial in the obviousness determination. *Id.* at 405. Finally, the district court found that the secondary considerations did not demonstrate nonobviousness. *Id.* at 407. Purdue alleges clear error in a number of the court's findings, but none of its arguments are meritorious.

A. Discovery of 8α

First, Purdue contends that the court failed to properly credit the discovery of 8α as the core of the claimed inventions. It relies heavily on *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 68 (1923), for the proposition that "where an inventor discovers a non-obvious source of a problem and then applies a remedy in response, the invention is nonobvious and worthy of a patent—even if the remedy, standing alone, would generally appear to be known in the art." Purdue Br. 40. In *Eibel Process*, the invention was a machine that could make quality paper at high speeds. 261 U.S. at 54. At the time, paper-making machines could not operate at high speeds without producing wrinkled paper. *Id.* Eibel discovered that the unequal speeds of paper stock

and a wire in the machine produced the wrinkled paper. Thus, he made a minor modification in the existing papermaking machines: he increased the pitch (angle) of the wire so that, through gravity, the paper stock would travel at substantially the same speed as the wire, and the paper would not wrinkle. *Id.* at 57–58, 64–65. The Supreme Court upheld the validity of Eibel's patent, reasoning that the discovery of the problem—unequal speeds of paper stock and the wire—was nonobvious, and thus the solution was as well. *Id.* at 68. Purdue contends that, similarly here, the discovery of the source of 14-hydroxy was not obvious, so the solution of hydrogenating the oxycodone salt must also be nonobvious.

Purdue's reliance on *Eibel Process* is misplaced. Even if determining the source of 14-hydroxy in the end product was not obvious, that problem did not need to be solved to arrive at the claimed invention; thus, *Eibel Process* does not apply. As discussed above, the claimed invention in *Eibel Process* was a machine that remedied the problem of wrinkled paper at high-speed printing. But, here, Purdue did not claim the remedy of the problem of remaining 14-hydroxy in the oxycodone API—performing a second hydrogenation step. Instead, it claimed the end product—an oxycodone API with low ABUK levels. And, as the district court found, identification of the source of the remaining 14-hydroxy as being 8α had no effect on the structure or nature of the low-ABUK oxycodone product. Because "[o]ne molecule of 14-hydroxy is the same as the next, whether derived from 8α or 8β," knowledge of 8α "did not make hydrogenation more or less effective as a technique

for converting 14-hydroxy to oxycodone." *District Court Decision*, 994 F. Supp. 2d at 405.

Purdue also argues that, without knowing that the 14-hydroxy was derived from 8α, a person of ordinary skill in the art would not know when to conduct the hydrogenation step or under what conditions to run the hydrogenation to create low-ABUK oxycodone. Purdue notes that the prior art references were directed to lowering 14-hydroxy levels in the oxycodone free base, not the API or salt. For example, U.S. Patent No. 6,177,567 ("Chiu reference") disclosed a method for preparing low-ABUK free base, but it did not teach how to convert the low-ABUK free base into low-ABUK salt. In fact, as Purdue and the district court noted, Chiu completed his method by adding acetic acid to the free base. In so doing, Chiu likely converted the latent 8α into 14-hydroxy in the final product because 8α reacts with the acid to form 14-hydroxy. But, again, Purdue claimed the end product; it did not claim a particular method for creating that product, such as the use of hydrogenation after the salting step. In fact, Teva's generic product would not infringe if that were the case because the Teva product is not made by hydrogenating the salt—instead the free base is purified through two hydrogenation cycles and then is treated with acid to create the oxycodone salt. Similarly, nothing in the asserted patents indicates that the hydrogenation process to remove 14-hydroxy derived from 8α must be conducted under different conditions from the process used to remove 14-hydroxy that is derived from 8β. The issue again comes down to whether it would be obvious to a person having ordinary skill in the art to use

hydrogenation to remove the excess 14-hydroxy in the oxycodone API. One need not know that the 14-hydroxy was derived from 8α as opposed to 8β to answer that question.

B. "Derived from 8α[]" Limitation

Purdue next argues that, because the asserted claims require that the remaining 14-hydroxy in the oxycodone API is derived from 8α and because 8α was not previously known in the art as being the source of 14-hydroxy, the claims must be nonobvious. Indeed, Purdue points out that the reason it added that limitation was because of our decision in *Chapman* where we said the claims were obvious *because* the claims did not differentiate between the 8α and 8β. 315 F. App'x at 297. The district court rejected that argument because it found that the "derived from 8α[]" limitation was a process limitation and thus immaterial to the obviousness analysis.

Purdue says, first, the limitation is not a process limitation, and, second, even if it is, it should not be wholly disregarded. Again, Purdue's arguments fail.

The relevant claim language provides:

> An oral dosage form comprising . . . oxycodone hydrochloride active pharmaceutical ingredient having less than 25 ppm 14-hydroxy[], *wherein at least a portion of the 14-hydroxy[] is derived from 8α[]* during conversion of oxycodone free base to oxycodone hydrochloride[.]

See, e.g., '799 patent col. 34 l. 65 to col. 35 l. 4 (emphasis added). We agree with the district court that "derived from 8α[]" does not describe the structure of 14-hydroxy and thus is a process limitation. The patent specification describes

methods for detecting and removing 14-hydroxy without regard to the source. For example, the written description defines 8,14-dihydroxy as 8α, 8ß, or a mixture of the two and does not indicate any difference in the resulting 14-hydrodxy depending on the particular isomer from which it is derived. More specifically, there is no suggestion in the patents that the hydrogenation process changes depending on whether the 14-hydroxy is created by 8α or 8ß. Indeed, even Purdue's expert testified that "[t]he structure of the 14-hydroxy that is generated from 8α is the same structure that is generated from 8ß." J.A. 4428. Because the source of the 14-hydroxy has no effect on its structure or its removal through hydrogenation, the limitation that it be "derived from 8α[]" cannot be a structural limitation.

We also conclude that, because "derived from 8α[]" is a process limitation, the district court did not err in disregarding the limitation in its obviousness analysis. We have clearly stated that "'[i]n determining validity of a product-by-process claim, the focus is on the product and not the process of making it.'" *Greenliant Sys., Inc. v. Xicor LLC*, 692 F.3d 1261, 1268 (Fed. Cir. 2012) (quoting *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1369 (Fed. Cir. 2009)). "That is because of the . . . longstanding rule that an old product is not patentable even if it is made by a new process." *Id.*; *see also SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1317 (Fed. Cir. 2006) ("It has long been established that one cannot avoid anticipation by an earlier product disclosure by claiming . . . the product as produced by a particular process."); *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985) ("If the

product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.").

Purdue looks to the exception we carved out in *Amgen*: "if the process by which a product is made imparts 'structural and functional differences' distinguishing the claimed product from the prior art, then those differences 'are relevant as evidence of no anticipation' although they 'are not explicitly part of the claim.'" *Greenliant*, 692 F.3d at 1268 (quoting *Amgen*, 580 F.3d at 1340). As previously discussed, however, the fact that the 14-hydroxy is derived from 8α imparts no structural or functional differences in the low-ABUK hydrocodone API as compared to the prior art products. Thus, the court did not err in disregarding the process limitation in its obviousness determination.

C. Secondary Considerations

Finally, Purdue contends that the court erroneously discounted the secondary considerations which it argues demonstrate nonobviousness. Purdue first points to Rhodes's commercial success; it says that Rhodes became Purdue's oxycodone API supplier by marketing the low-ABUK features of its product to Purdue, which resulted in almost $71 million in sales in 2010. As the district court found, however, Rhodes was not successful at marketing its low-ABUK oxycodone API to any significant customer other than Purdue, which is its corporate affiliate. The district court further found that Purdue invested in Rhodes not because of the low-ABUK features, but because it could get oxycodone API at a lower cost

from its subsidiary than it could from an unaffiliated manufacturer during times of high demand. Purdue does not persuasively rebut these findings on appeal. Thus, the district court did not clearly err in concluding that there was no nexus between the low-ABUK product of the patents and the commercial success of Purdue or Rhodes.

Purdue next argues that the failure of others is shown by the experience of Teva's oxycodone API supplier, Noramco, Inc. ("Noramco"). Purdue claims Noramco was unable to obtain low ABUK levels until 2007, years after Purdue discovered 8α, and only then by infringing the low-ABUK patents. But, as the district court found, there is no evidence that Noramco tried but failed to create low-ABUK oxycodone API. Instead, the record showed that Noramco and the FDA agreed to a timetable for producing low-ABUK oxycodone API, that Noramco adhered to that timetable, and that Noramco continued to manufacture the higher ABUK products during that time. Purdue also argues that long-felt need was shown because, although the FDA only made low-ABUK oxycodone API a regulatory requirement in 2003—less than a year before Purdue commercialized its low-ABUK product—the need for low-ABUK products was present long before. That does not, however, change the fact that there was no pressing need for companies to create a low-ABUK product before the FDA's mandate, as they were able to continue to sell their higher-ABUK products. Thus, the district court did not clearly err in finding that Purdue failed to prove the failure of others or long-felt but unaddressed need.

Finally, Purdue points to the fact that Noramco credited Purdue and Rhodes with the discovery of 8α and contends that such recognition shows praise from competitors. But recognition that Rhodes discovered that 8α is a byproduct of thebaine oxidation does not equal praise for the invention—the low-ABUK oxycodone API. Purdue also argues that industry praise is shown because Noramco copied its process for creating low-ABUK oxycodone, but provides no support whatsoever for that argument. Finally, Purdue contends that the court wholly ignored evidence showing that Purdue and Rhodes were surprised over their discovery and solution. But, again, there was no surprise as to the patented product. Even if it was unexpected that thebaine oxidation would create 8α, it was not surprising that, after the FDA mandate, manufacturers would create a low-ABUK oxycodone API or that they would do so using the known technique of hydrogenation.

We find Purdue's remaining arguments unpersuasive and conclude that the asserted claims of the low-ABUK patents are obvious. We thus affirm the district court's finding of invalidity as to those claims.

II. Invalidity of the '383 Patent

Purdue and Grunenthal also challenge the district court's conclusion that the asserted claims of the '383 patent are invalid as anticipated, or, in the alternative, obvious.[3] The district court concluded

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[3] Claim 1 is the only independent claim of the '383 patent and recites:

A thermoformed dosage form comprising:

that the asserted claims are anticipated by WO 97/49384, known as the McGinity reference, which later became U.S. Patent No. 6,488,963. *District Court Decision*, 994 F. Supp. 2d at 421–26. The McGinity reference discloses the use of hot-melt extrusion of high molecular weight PEO to create a controlled-release dosage form for pharmaceuticals. The district court found that McGinity disclosed opioid formulations and that it inherently disclosed tablets with a breaking strength in excess of 500 N, as required by the asserted claims. Alternatively, the district court concluded that even if the McGinity reference did not anticipate the '383 patent, "a person of ordinary skill in the art would have had sufficient knowledge and motivation to make the invention claimed by the '383 patent." *Id.* at 426.

On appeal, Grunenthal contends that the district court clearly erred in finding that McGinity discloses all of the limitations of the asserted claims and that the district court impermissibly combined discrete disclosures in McGinity to arrive at its anticipation determination. Grunenthal also asserts a number of

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i) one or more active ingredients with abuse potential (A) selected from the group consisting of opiates and opioids,

ii) optionally physiologically acceptable auxiliary substances (B),

iii) at least 60% by weight of polyalkylene oxide (C) having a molecular weight of 1–15 million according to rheological measurements, and

iv) optionally at least one wax (D)

wherein said dosage form has a breaking strength of at least 500 N and wherein the active ingredient with abuse potential (A) is present in a controlled release matrix of component (C).

grounds of error in the district court's obviousness determination.

A. McGinity's Disclosure of Opioid Formulations and Breaking Strength

McGinity discloses a variety of therapeutic compounds to be used in its formulations, including "analgesics such as aspirin, acetaminophen, d[i]flunisal and the like." J.A. 135074. Grunenthal argues that, because the only specifically mentioned drugs are non-opioids, McGinity does not describe formulations that contain opioids such as oxycodone. It invokes the canon of construction *ejusdem generis*—which provides that general terms are construed as referring to things of the same kind as those specifically mentioned—to argue that the terms "such as" and "and the like" should be understood as also referring to other non-opioids. But, as the district court found, the McGinity reference cannot be read so narrowly. The McGinity reference explicitly notes the use of its process with analgesics to treat pain, and the words "such as" and the residual clause "and the like" demonstrate that the application discloses a broader group of analgesics than just those listed. Moreover, the record showed that opioids are a major class of analgesics and that oxycodone was one of the most widely prescribed analgesics at the time. The district court also noted that the McGinity reference is directed to sustained-release dosage forms and credited expert testimony that the only analgesics on the market in a sustained-release form at the time were opioids.[4]

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[4] Grunenthal says that the record evidence expressly contradicts this testimony, as it shows that there were, in fact,

The district court's assessment is persuasive and not clearly erroneous.[5]

Grunenthal next argues that McGinity does not inherently disclose the limitation that the dosage forms have a breaking strength of at least 500 N. According to the district court,

> The pivotal evidence [with respect to the breaking strength limitation] is a series of breaking strength tests that Dr. Fernando Muzzio performed in preparation for this litigation. Muzzio thermoformed thousands of tablets according to the McGinity Application disclosures. He used a variety of chemical compositions, extruder temperatures, screw speeds, and die diameters. He tested a vast number of the resulting tablets, and without exception they withstood forces greater than

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three analgesics on the market in a sustained-release form at the time and only two of them were opioids. But Grunenthal never made that argument before the district court—it did not cross-examine the expert on this point or otherwise take issue with the accuracy of the expert testimony. In any event, the fact that two of the three sustained-release drugs on that market at the time were opioids is persuasive evidence that a skilled artisan would understand McGinity as describing formulations that use opioids.

[5] Grunenthal also contends that McGinity does not disclose the limitation that the active ingredient has "abuse potential." '383 patent col. 22 l. 3. Because we find that the district court did not err in concluding that McGinity discloses the use of an opioid as an active ingredient, and because the record clearly demonstrates that opioids have abuse potential, we similarly find that the district court did not err in concluding that McGinity discloses formulations where the active ingredient has abuse potential.

> 500N. In fact, Muzzio often exerted forces in the thousands of Newtons and never had a tablet break.

District Court Decision, 994 F. Supp. 2d at 423. The district court credited Dr. Muzzio's testing and noted that, "[i]n contrast with [Dr. Muzzio's] persuasive experimental evidence, plaintiffs have not put forward any evidence that any tablet produced according to the McGinity Application can ever break when a force of 500N is applied to the tablet." *Id.* The district court thus concluded that the McGinity reference "inherently discloses a breaking strength greater than 500N, because the experimental results indicate unanimously, reliably, clearly, and convincingly that any tablet made according to the McGinity Application would exhibit this characteristic." *Id.* at 424.

Grunenthal asserts a number of grounds of error, many of which focus on the adequacy and reliability of Dr. Muzzio's testing. For example, Grunenthal argues that Dr. Muzzio did not provide API release data, photographs after breaking strength testing, or laboratory notebooks for his reproductions of the McGinity disclosures. But the district court rejected that argument, finding that "Muzzio has supplemented his own credibility with abundant documentary support in the form of raw data, photographs, and force curves" and concluded that Grunenthal's attacks "do not seriously lessen the weight the Court assigns to Muzzio's vast empirical results and credible opinion on the inherency of a 500N breaking strength." *Id.* Similarly, Grunenthal says that Dr. Muzzio did not perform a torque test on its reproductions, which would have shown if the

extrusion was being accurately repeated. Again, however, the district court found that argument unpersuasive, concluding that "because torque is not an input or setting in the extrusion process, the lack of torque data does not affect the reliability of Muzzio's process as a replication of the McGinity Application's process." *Id.* The district court credited Dr. Muzzio with having "recreated the McGinity Application's process fairly, accurately, and with no material variation," and Grunenthal has shown no clear error in that finding.

Grunenthal also points to specific disclosures in McGinity which it argues show that the McGinity formulations do not necessarily have the required breaking strength. First, it notes that McGinity discloses tablets that can be scored—making them easy to break in half—or ground, which it contends is the antithesis of high breaking strength tablets. Next, Grunenthal argues that McGinity contemplates the use of heat or pressure to create the disclosed tablets, but notes that tablets with 500 N breaking strength can only be formed using both heat and pressure. Neither of those disclosures, however, changes the fact that every tablet made according to McGinity's disclosures and tested by Dr. Muzzio had a breaking strength of over 500 N. And, again, Grunenthal has not shown clear error in the district court's crediting of Dr. Muzzio's testing results, nor has it provided any independent testing to rebut Dr. Muzzio's findings.[6]

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[6] Moreover, Grunenthal incorrectly characterizes the McGinity disclosures. Grunenthal relies on one isolated sentence to support its argument that McGinity contemplates the use of

Grunenthal's last two arguments relate to testing that Dr. Muzzio did not perform. Grunenthal notes that Dr. Muzzio only tested formulations with the active ingredient disclosed in McGinity, chlorpheniramine maleate ("CPM"), which is an antihistamine, not an opioid. Thus, Grunenthal says that Dr. Muzzio's tests only proved that CPM formulations would have a breaking strength of 500 N or more, not that opioid formulations, as claimed in the '383 patent, would have such a breaking strength. But, Dr. Muzzio testified that *any* tablet made using at least fifty weight percent PEO and heated above the melting point of PEO would have a breaking strength above 500 N, regardless of the active ingredient used. J.A. 3462. The district court did not clearly err in crediting that testimony.

Next, Grunenthal argues that Dr. Muzzio did not perform any testing to confirm that the tablets he made according to the McGinity disclosures were controlled-release formulations. Grunenthal contends that without this testing, "there is no clear proof that Teva actually carried out the same

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heat *or* pressure in its process: "[A] hot-melt extrudable polymer is one that is . . . capable of deformation . . . under elevated heat or pressure." J.A. 135076. But that sentence merely defines the type of polymer used; it does not say that the extrusion process requires only heat or pressure and not both. In fact, in describing the actual hot-melt process, McGinity says it should be "conducted at an elevated temperature" and explains that the pharmaceutical mixture should be "passed through the heated area of the extruder at a temperature which will melt or soften the PEO." J.A. 135077. Indeed, Grunenthal's own expert testified that hot-melt extrusion requires achieving the "melt flow" temperature of ninety-eight degrees Celsius for high molecular weight PEO. J.A. 3845–46.

process—and made the same tablets—disclosed in McGinity." Grunenthal Br. 38. That is incorrect. As stated above, the district court credited Dr. Muzzio with recreating the McGinity process "fairly, accurately, and with no material variation." *District Court Decision*, 994 F. Supp. 2d at 424. Grunenthal has not shown clear error in the district court's finding and cannot do so by claiming that Dr. Muzzio did not conduct an additional test to confirm what the district court already found—that he properly replicated the McGinity process. Grunenthal also says that, without testing the controlled-release properties of the tablets, Teva cannot prove that the limitation requiring "a controlled release matrix of [the PEO]" is disclosed by McGinity. That is also incorrect. Teva did not need to conduct any controlled-release testing because McGinity clearly discloses PEO formulations with controlled-release properties. For example, in the "Field of the Invention" section, McGinity says, "The invention relates more specifically to formulations which have been prepared by hot melt extrusion of mixtures containing high molecular weight PEO and a therapeutic compound for use in controlled-release drug delivery." J.A. 135067. Thus, the district court did not clearly err in concluding that the controlled-release limitation was disclosed in McGinity.

B. Combination of McGinity Disclosures

Finally, Grunenthal argues that the district court erred by using distinct sections of McGinity and reassembling them into an embodiment to find that all of the limitations were present. *See Application of Arkley*, 455 F.2d 586, 587 (C.C.P.A. 1972) (noting that an anticipating reference "must clearly and

unequivocally disclose the claimed compound or direct those skilled in the art to the compound without *any* need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference"). For example, Grunenthal points out that the court selected only "analgesics" from the long list of pharmaceutical categories that could be used as the active ingredient, and then further picked oxycodone, which was not even disclosed, to find anticipation. Moreover, Grunenthal notes that McGinity teaches that the amount of PEO will vary depending on various factors and does not consistently disclose formulations with at least sixty weight percent PEO, as required by the claims. Thus, Grunenthal argues that the court impermissibly chose only those examples that included the claimed amount of PEO to find anticipation.

These arguments are without merit. The disclosures pointed to by the district court are all "directly related" and thus there is no impermissible picking and choosing. *Arkley*, 455 F.2d at 587. For example, in the section providing a detailed description of the preferred embodiment, McGinity says:

> [T]he invention provides a hot-melt extrudable controlled release pharmaceutical formulation comprising an effective amount of a therapeutic compound, high molecular weight [PEO] . . . , the [PEO]:therapeutic compound ratio being in the range from about 99.99:0.01 to about 80:20 % wt.

J.A. 135802. In that single disclosure, McGinity describes the controlled-release formulation and the use of over sixty weight percent PEO. It does not specifically say what therapeutic compound is used, but it provides a list of the types of therapeutic compounds contemplated. That list of compounds, although in a distinct section of the reference, is directly related to the disclosure reproduced above. Thus, the district court did not impermissibly combine distinct disclosures in McGinity to arrive at the claimed invention.

We conclude that the district court did not clearly err in finding that the McGinity reference discloses each and every limitation in the asserted claims of the '383 patent. We thus affirm the district court's anticipation determination and do not reach the question of obviousness.

III. Collateral Estoppel

In addition to appealing the judgments of invalidity, Purdue also appeals the dismissal of the Epic, Mylan, and Amneal actions with respect to the low-ABUK patents. On appeal from orders of dismissal due to collateral estoppel, "our role is limited to reviewing the district court's application of collateral estoppel, not the correctness of the [underlying] verdict[]." *Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.*, 170 F.3d 1373, 1380 (Fed. Cir. 1999). Before the district court, Purdue conceded that collateral estoppel applied to the judgment of invalidity as to the low-ABUK patents in the Teva case, which precluded it from obtaining the relief sought in the remaining actions. Purdue also does not present any persuasive argument on appeal as to

why collateral estoppel should not apply. Thus, we affirm the district court's dismissal of the remaining actions as barred by collateral estoppel.

CONCLUSION

For the foregoing reasons, we affirm the district court's invalidity determinations as to the low-ABUK patents and the '383 patent and the district court's dismissal of the Epic, Mylan, and Amneal actions.

AFFIRMED

APPENDIX B

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re: OXYCONTIN ANTITRUST LITIGATION	04 Md. 1603 (SHS)
PURDUE PHARMA L.P., et al., Plaintiffs, -against- TEVA PHARMACEUTICALS, USA, INC., Defendant.	*This document relates to:* 11 Civ. 2037 (SHS) 12 Civ. 5083 (SHS)

FINDINGS OF FACT AND CONCLUSIONS OF LAW

* * *

TABLE OF ABBREVIATIONS

'072 Patent	U.S. Patent No. 7,683,072
'314 Patent	U.S. Patent No. 7,776,314
'383 Patent	U.S. Patent No. 8,114,383
'799 Patent	U.S. Patent No. 7,674,799
'800 Patent	U.S. Patent No. 7,674,800
'963 Patent	U.S. Patent No. 6,488,963
14-hydroxy	14-hydroxycodeinone
2013 Stip.	Stipulations or Agreed Statements of Fact or Law, Joint Pretrial Order,

	Case No. 04 Md. 1603, Dkt. No. 572, filed Aug. 28, 2013
2012 Stip.	Stipulations or Agreed Statements of Fact or Law, Joint Pretrial Order, Case No. 10 Civ. 3734, Dkt. No. 168, filed Oct. 12, 2012
8,14-dihydroxy	8,14-dihydroxy-7,8-dihydrocodeinone
8α	8α, 14-dihydroxy-7,8-dihydrocodeinone
8ß	8ß, 14-dihydroxy-7,8-dihydrocodeinone
8-acetoxy	8-acetoxy-14-hydroxydihydrothebaine
ABUK	α, ß-unsaturated ketone
ANDA	Abbreviated New Drug Application
API	active pharmaceutical ingredient
Bastin	International Application No. WO 95/20947
Casner	U.S. Patent No. 7,153,966
Chiu	U.S. Patent No. 6,177,567
COB	crude oxycodone base
Da	Daltons
DMF	Drug Master File
FDA	U.S. Food and Drug Administration
HCl	hydrochloride
Hoffmeister	U.S. Patent No. 4,070,494
HPLC	high-performance liquid chromatography
N	Newtons
NDA	New Drug Application
OROS	osmotically controlled-release oral delivery system

ppm	parts per million
PEO	polyethylene oxide
POB	purified oxycodone base
PTO	U.S. Patent and Trademark Office
Teva Mem.	Defs.' Post-Trial Mem. dated Nov. 6, 2013
Wright-Oshlack	U.S. Provisional Patent Application No. 60/310,534

SIDNEY H. STEIN, U.S. District Judge.

PART 1. INTRODUCTION

This consolidated trial concerns six patents associated with the pain reliever OxyContin. Plaintiffs, led by the OxyContin manufacturer Purdue, allege that Teva, which manufactures generic pharmaceutical products, has infringed these patents by seeking approval from the U.S. Food and Drug Administration ("FDA") to sell bioequivalents of OxyContin. In response, Teva argues that its proposed products do not infringe plaintiffs' patents and that, in any event, the asserted patents are invalid. These arguments played out over the course of extensive litigation, culminating in a twenty-day-long bench trial before this Court. These findings of fact and conclusions of law are the results of that litigation.

Three patents-in-suit—United States Patent Nos. 7,674,799 ("the '799 Patent"), 7,647,800 ("the '800 Patent"), and 7,683,072 ("the '072 Patent") (collectively, "the low-ABUK patents")—recite an improved formulation of oxycodone, the active pharmaceutical ingredient in OxyContin. Those patents describe an oxycodone salt with extremely low levels of a particular impurity, 14-hydroxycodeinone ("14-hydroxy"), which belongs to a class of potentially dangerous compounds known as α, ß-unsaturated ketones ("ABUKs"). Purdue was the first to succeed in developing a low-ABUK oxycodone salt as an active pharmaceutical ingredient ("API"). Its low-ABUK patents reflect that work.

Also in suit are two patents—United States Patent Nos. 7,776,314 ("the '314 Patent") and 8,114,383

("the '383 Patent") (collectively, "the abuse-proof patents")—that claim technology making tablets resistant to abuse. The technology disclosed in these patents is intended to hinder would-be abusers from crushing tablets into powder, converting the powder into a liquid, and then injecting the solution intravenously in order to experience an opioid "high."

The parties in these actions play various roles in the scientific and pharmaceutical communities. Universities provide the infrastructure for the advancement of human knowledge; pharmaceutical manufacturers seeking patents and marketing branded drugs discover new frontiers of medication and health; and generic pharmaceutical companies make those frontiers available to the public. This circle of invention, medicine, health, and profit depends on principles of intellectual property—the law's allocation of restrictions and liberties.

Applying those principles and the evidence presented at trial, the Court concludes that Teva has not infringed any valid patent asserted by plaintiffs. As explained below, plaintiffs have not carried their burden of proving infringement of the '314 Patent. Although plaintiffs have proved by a preponderance of the evidence that Teva's proposed products infringe the '799 , '800, '072, and '383 Patents, Teva has proved by clear and convincing evidence that the asserted claims of those patents are invalid.

I. The Record and Relevant Proceedings

A. The Asserted Patent Claims

Purdue[1] alleges that Teva's proposed formulations infringe several claims of the patents-in-suit. In the low-ABUK portion of the trial, Purdue accuses Teva of infringing claims 3 and 19 from the '799 Patent, claims 30–34 and 76–79 from the '800 Patent, and claims 1, 4, and 5 from the '072 Patent. These claims are directed to an oxycodone salt API that contains 14-hydroxy at extremely low levels, and some of the claims specifically refer to an oral dosage form of that API.

In the abuse-proof portion of the litigation, Purdue accuses Teva of infringing claims 1, 2, 5, 7, and 8 from the '383 Patent. These claims describe a thermoformed pharmaceutical dosage form that is so physically hard that it can withstand forces as strong as 500 Newtons (500N) without breaking. Finally, Purdue accuses Teva of infringing claims 1, 2, 6, and 9 from the '314 Patent. These claims relate to a pharmaceutical dosage form that deters abuse by becoming viscous when dissolved in a liquid.

This consolidated litigation also included Purdue's claims against Impax Laboratories, Inc., and Sandoz Inc., two other generic manufacturers. Impax and Sandoz appeared at trial alongside Teva but have since settled their actions. (*See* Case No. 11 Civ. 2400, Dkt. No. 147; Case No. 11 Civ. 4694, Dkt. No. 124; Case No. 12 Civ. 5082, Dkt. No. 43.) Purdue asserted claims from one patent—United States Patent No. 6,488,963 ("the '963 Patent")—against

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[1] This Opinion refers to plaintiffs collectively as "Purdue."

Impax and Sandoz but not against Teva. This Opinion therefore does not address arguments related to the infringement or invalidity of the '963 Patent.

B. The 2012 Ranbaxy Trial

In November and December of 2012, the Court held an eight-day bench trial in *Purdue Pharma, L.P., et al. v. Ranbaxy, Inc., et al.*, No. 10 Civ. 3734 (SHS). There, Purdue and its affiliates asserted claims of infringement against Actavis Elizabeth LLC with respect to the low-ABUK patents. Actavis, in turn, presented evidence that the low-ABUK patents were invalid. The parties to the 2012 trial filed a consent judgment on May 1, 2013. That consent judgment provided, inter alia, that "[t]he Low ABUK Patents are valid and enforceable with respect to the Actavis [Abbreviated New Drug Applications] and any products described therein" and "[t]he products described in the Actavis [Abbreviated New Drug Applications] infringe the Low ABUK Patents." (Case No. 04 Md. 1603, Dkt. No. 546 ¶ 2.) Consequently, no findings of fact or conclusions of law ever emerged from that trial.

The same claims and defenses presented in the 2012 trial are again at issue in this trial, and the parties have agreed to adopt the entire record of the 2012 trial as part of the factual record in this trial. (Supp. to the Joint Pretrial Order Relating to *Ranbaxy et al*. Trial Record, Case No. 04 Md. 1603, Dkt. No. 582, filed Sept. 13, 2013, at 1 ¶ 1.)

C. Claim Construction

After extensive briefing and a claim construction hearing, this Court issued a Claim Construction

Opinion and Order in this matter. *See In re OxyContin Antitrust Litigation*, No. 04 Md. 1603 (SHS), 2013 WL 4509633 (S.D.N.Y. Aug. 23, 2013) ("*OxyContin Claim Construction*"). There, the Court construed the patent claims at issue in these actions to the extent the parties disputed the meanings of claim terms. All parties to this trial participated in litigating the claim constructions, so for purposes of this trial that Opinion and Order "define[s] the invention[s] to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quotation marks omitted).

D. The 2013 Trial

The bench trial in the above-captioned matters began on September 23, 2013. The Court heard testimony from 22 witnesses and admitted hundreds of exhibits over the course of more than three weeks. Because of the adoption of the 2012 trial record as part of this trial's record, the parties focused their presentations on the abuse-proof patents. That said, because Teva was not a party to the 2012 trial, it had (and took advantage of) the opportunity to present additional evidence on the low-ABUK patents.

E. This Opinion

On the basis of the record established by the parties and the applicable law, the Court enters these findings of fact and conclusions of law pursuant to Rule 52(a) of the Federal Rules of Civil Procedure. To the extent that any findings of fact may be deemed conclusions of law, they shall also be considered conclusions of law; to the extent that any conclusions of law may be deemed findings of fact,

they shall also be considered findings of fact. *See Miller v. Fenton*, 474 U.S. 104, 113–14 (1985).

II. Legal Standards

A. Procedural Context and the Hatch-Waxman Act

This litigation arises under the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 301 *et seq*.) ("Hatch-Waxman Act"). The Hatch-Waxman Act provides a streamlined regulatory pathway for generic pharmaceutical companies to seek approval of their drugs, while giving branded pharmaceutical companies an opportunity to sue to defeat approval of the generic drugs.

Under the Hatch-Waxman Act, a pharmaceutical company can seek FDA approval for a generic drug based on an already-approved branded drug by filing an Abbreviated New Drug Application ("ANDA"). 21 U.S.C. § 355(j)(2)(A), (8)(B). As the name suggests, an ANDA does not require the detailed showings necessary for the pioneer New Drug Application ("NDA"), such as proof of safety and effectiveness. *See id*. Where a branded manufacturer's patent has not yet expired but a generic manufacturer nonetheless wants to enter the market, the generic must file a pre-expiration challenge (known colloquially as a "Paragraph IV" certification, after the relevant paragraph number in the legislation). *Id*. § 355(j)(2)(A)(vii)(IV). A generic firm's Paragraph IV certification must establish bioequivalence of the proposed generic version with the approved branded version of the drug. *See* 21 C.F.R. § 314.94(a)(9).

The Paragraph IV certification must also state and explain at least one of the following claims: that the generic product would not infringe the branded firm's patent, or that the branded firm's patent is invalid. *See* 21 U.S.C. § 355(j)(2)(B)(iv)(II).

As the U.S. Court of Appeals for the Second Circuit has explained, the mere filing of "[a]n ANDA-IV certification . . . constitutes an act of infringement, triggering the branded manufacturer's right to sue." *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 101 (2d Cir. 2010) (citing 35 U.S.C. § 271(e)(2)(A)). When a branded manufacturer files suit pursuant to that right within 45 days of receiving notice of the Paragraph IV certification, the litigation automatically stays the generic's entry to the market. 21 U.S.C. § 355(j)(5)(B)(iii). At its core, then, the Hatch-Waxman Act shifts risks between the patent holder and the generic manufacturer, allowing the generics to challenge the validity of the brands' patents without incurring either high market entry costs or the risk of damages from infringement. *See Ark. Carpenters Health & Welfare Fund*, 604 F.3d at 101. More significantly for purposes of this trial, this structure allows the parties to try the dueling issues of patent infringement and patent invalidity at once.

B. Claims of Patent Infringement

"Patent infringement, whether literal or by equivalence, is an issue of fact, which the patentee must prove by a preponderance of the evidence." *Siemens Med. Solutions USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.*, 637 F.3d 1269, 1279 (Fed. Cir. 2011). "In order to prove infringement, a patentee must show that every limitation of the

claims asserted to be infringed is found in the accused device." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1565 (Fed. Cir. 1997).

The infringement inquiry has two steps: (1) "the claim must be properly construed to determine its scope and meaning" and (2) "the claim as properly construed must be compared to the accused device or process." *Absolute Software, Inc. v. Stealth Signal, Inc.*, 659 F.3d 1121, 1129 (Fed. Cir. 2011) (quotation marks omitted). The Court's Claim Construction Opinion and Order of August 23, 2013 represents the first step. The second step—assessing infringement by way of a comparison—remains. Because the allegedly infringing product in a Hatch-Waxman Act case is not yet on the commercial market, the infringement inquiry focuses on what is likely to be sold following FDA approval. *See Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002).

"The second step in [this two-step] analysis is to apply the claims to the accused device." *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1345 (Fed. Cir. 2002). The accused device literally infringes a claim "when each of the claim limitations 'reads on,' or in other words is found in, the accused device." *Id*.

Where the accused product does not literally infringe a claim limitation, the patentee may nonetheless prove infringement under the doctrine of equivalents. *See generally Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997). To prove infringement of a claim through the doctrine of equivalents the patentee must prove that the difference between a missing claim element and what is found in the accused product is only "insubstantial."

Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 610 (1950); *TIP Sys. LLC v. Phillips & Brooks/Galdwin, Inc.*, 529 F.3d 1364, 1376–77 (Fed. Cir. 2008). More specifically, the finder of fact inquires "whether a substitute element matches the function, way, and result of the claimed element, or whether the substitute element plays a role substantially different from the claimed element." *Warner-Jenkinson Co.*, 520 U.S. at 40. This analysis is known as "the function, way, and result" test.

The doctrine of equivalents has important limits. "There can be no denying that the doctrine of equivalents, when applied broadly, conflicts with the definitional and public-notice functions of the statutory claiming requirement." *Id.* at 29. The Court therefore scrupulously applies the function-way-result test, remaining "specially vigilant against allowing the concept of equivalence to eliminate any claim limitations completely." *Allen Eng'g Corp.*, 299 F.3d at 1345.

C. The Affirmative Defense of Patent Invalidity

A defendant "in any action involving . . . infringement of a patent" may plead as an affirmative defense that the asserted patent is invalid. 35 U.S.C. § 282 (b)(2)–(3); *see also Microsoft Corp. v. i4i Ltd.*, 131 S. Ct. 2238, 2242 (2011). Because "[a] patent shall be presumed valid," "[t]he burden of establishing invalidity . . . rest[s] on the party asserting such invalidity." 35 U.S.C. § 282(a). A defendant asserting patent invalidity must demonstrate invalidity by clear and convincing evidence. *Microsoft Corp.*, 131 S. Ct. at 2242.

1. Novelty and Anticipation

An invention must be novel in order to receive a valid patent. 35 U.S.C. § 102. "Invalidity based on lack of novelty (often called 'anticipation') requires that the same invention, including each element and limitation of the claims, was known or used by others before it was invented by the patentee." *Hoover Grp., Inc. v. Custom Metalcraft, Inc.*, 66 F.3d 299, 302 (Fed. Cir. 1995). A patent is therefore invalid due to anticipation when "a single prior art reference . . . expressly or inherently disclose[s] each claim limitation." *Finisair Corp. v. DirectTV Group, Inc.*, 523 F.3d 1323, 1334 (Fed. Cir. 2008). The doctrine's application is encapsulated in the old chestnut: "[t]hat which infringes, if later, would anticipate, if earlier." *Upsher-Smith Labs., Inc. v. Pamlab, LLC*, 412 F.3d 1319, 1322 (Fed. Cir. 2005) (quoting *Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (1889) (quotation marks omitted)).

The anticipating reference need not explicitly spell out each element of the anticipated patent claim, but rather can teach a claim limitation if the "teaching is inherent in [the] prior art reference." *Corning Glass Works v. Sumitomo Elec. USA, Inc.*, 868 F.2d 1251, 1262 (Fed. Cir. 1989). To show inherent anticipation, a defendant must demonstrate clearly and convincingly that a claim limitation not disclosed in the anticipating reference will always be present when the prior art is practiced as taught in that reference. *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047–48 (Fed. Cir. 1995). "Inherent anticipation requires that the missing descriptive material is 'necessarily present,' not merely probably or possibly present" in the anticipating reference.

Trintec Indus., Inc. v. Top-USA Corp., 295 F.3d 1292, 1295 (Fed. Cir. 2002) (quoting *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999)).

In considering whether a prior art reference anticipates a claim, courts do not consider whether that reference includes optional elements of the claim. After all, "optional elements do not narrow the claim because they can always be omitted." *In re Johnston*, 435 F.3d 1381, 1384 (Fed. Cir. 2006). Whether a device includes or excludes the optional element does not determine whether it is an embodiment of the claimed invention, *see id.*, so optional elements do not affect an anticipation analysis. *Cf. Upsher-Smith Labs., Inc.*, 412 F.3d at 1322.

Anticipation and its subsidiary issues are questions of fact. *Amkor Tech., Inc. v. Int'l Trade Comm'n*, 692 F.3d 1250, 1254 (2012) (anticipation); *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1328 (2001) (inherency).

2. Obviousness and Nonobviousness

"Generally, a party seeking to invalidate a patent as obvious must demonstrate by clear and convincing evidence that a skilled artisan would have been motivated 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 in doing so." *OSRAM Sylvania, Inc. v. Am. Induction Techs., Inc.*, 701 F.3d 698, 706–07 (Fed. Cir. 2012) (quotation marks omitted). "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 707 (citing *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 415, 419 (2007)).

A claim must have been nonobvious "at the time the invention was made." 35 U.S.C. § 103(a). Accordingly, courts must avoid the improper use of hindsight in this analysis and ought not "simply retrace[ ] the path of the inventor." *See Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008). Therefore, unlike in an analysis of novelty, an inherent property of a prior art reference contributes to obviousness only to the extent that the inherent property was known at the time of the invention. *See In re Newell*, 891 F.2d 899, 901 (Fed. Cir. 1989); *In re Adams*, 356 F.2d 998, 1001–02 (C.C.P.A. 1966).

"The ultimate judgment of obviousness is a legal determination." *KSR Int'l Co.*, 550 U.S. at 427. That legal determination rests on "underlying factual inquiries including: (1) the scope and content of the prior art, (2) the differences between the claimed invention and the prior art, (3) the level of ordinary skill in the art, and (4) objective indicia of nonobviousness." *Pregis Corp. v. Kappos*, 700 F.3d 1348, 1354 (Fed. Cir. 2012); *see also Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966).

The analysis of obviousness must therefore include consideration of secondary, objective indicia. *See*, *e.g.*, *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 711 F.3d 1348, 1368 (Fed. Cir. 2013). "Objective evidence of nonobviousness can include copying, long felt but unsolved need, failure of others, commercial success, unexpected results created by the claimed invention, unexpected properties of the

claimed invention, licenses showing industry respect for the invention, and skepticism of skilled artisans before the invention." *Id.* In order for commercial success to provide a secondary indication of nonobviousness, the success of the commercial product must arise from the patent claims at issue. *See*, *e.g.*, *King Pharms., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1281 (Fed. Cir. 2010); *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000) ("A nexus between commercial success and the claimed features is required."). And in considering whether there was "a long-felt, unmet need" that the invention satisfied—another secondary indication of nonobviousness, *see Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1332 (Fed. Cir. 2009)—the starting point is "the date of an articulated identified problem and evidence of efforts to solve that problem." *Tex. Instruments v. U.S. Int'l Trade Comm'n*, 998 F.2d 1165, 1178 (Fed. Cir. 1993).

3. Written Description and Enablement

A patent is invalid if it violates the "written description" or "enablement" clauses of 35 U.S.C. § 112. Section 112 demands both (1) that a patentee adequately disclose his or her invention to the public, and (2) that the patent enable others to replicate it. *Id.* § 112(a). The written description requirement and the enablement requirement are distinct, and the patent must satisfy both. *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1344 (Fed. Cir. 2010) (en banc).

a) Written Description

A patent's "description must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed." *Ariad Pharm.*, 598 F.3d at 1351. To analyze a patent's written description, a court considers "whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Id.* (quotation marks, alterations, and citations omitted). Thus, a court must conduct "an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Id.* The invention that must be adequately described is measured by the asserted claims. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1565 (Fed. Cir. 1991). The issue of written description is one of fact. *Id.*

b) Enablement

A valid patent must disclose enough detail to enable a person of ordinary skill in the art to practice the invention "without undue experimentation at the time of filing." *Alza Corp. v. Andrx Pharms., LLC*, 603 F.3d 935, 939 (Fed. Cir. 2010). "The key word is 'undue,' not 'experimentation.'" *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Accordingly, patents are not required to be blueprints for commercial production of a product. *See CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1339 (Fed. Cir. 2003). Furthermore, "a patent need not teach, and preferably omits, what is well known in the art." *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1365

(Fed. Cir. 2006) (quotation marks and alteration omitted).

"Although the ultimate determination of whether one skilled in the art could make and use the claimed invention without undue experimentation is a legal one, it is based on underlying findings of fact." *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1355 (Fed. Cir. 2012) (quotation marks omitted). Factors to consider include: (1) quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability of the art; and (8) the breadth of the claims. *See In re Wands*, 858 F.2d at 737. While "a specification need not disclose what is well known in the art," the requirement of an enabling disclosure is not satisfied by complete reliance on a skilled artisan's knowledge. *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997).

4. Definiteness

A valid patent "particularly point[s] out and distinctly claim[s] the invention." 35 U.S.C. § 112(b). "Because claims delineate the patentee's right to exclude, the patent statute requires that the scope of the claims be sufficiently definite to inform the public of the bounds of the protected invention." *Halliburton Energy Svcs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249 (Fed. Cir. 2008). A patent that does not satisfy this requirement fails to put the public on notice of what would infringe and what would not

infringe. *See id.*; *Athletic Alternatives, Inc. v. Prince Mfg., Inc.*, 73 F.3d 1573, 1581 (Fed. Cir. 1996). Thus, to meet the definiteness requirement a patent must "clearly circumscribe what is foreclosed from future enterprise." *United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 236 (1942), *quoted in Halliburton Energy Svcs., Inc.*, 514 F.3d at 1249.

The definiteness analysis boils down to whether a claim limitation is "insolubly ambiguous," such that a court could not construe the claim. *See Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1347 (Fed. Cir. 2005). For example, in *Halliburton Energy Services, Inc.*, a claim limitation requiring that a certain material be a "fragile gel" without further detail was found to be insolubly ambiguous because "neither [the patentee's] proposed definition nor any other possible construction resolves the ambiguity of the scope of the term." 514 F.3d at 1250. Other indefinite claims include those that "recite[ ] means-plus-function elements without disclosing corresponding structure in the specification, . . . include[ ] a numeric limitation without disclosing which of multiple methods of measuring that number should be used, . . . and contain[ ] a term that is completely dependent on a person's subjective opinion." *Id.* (internal citations and quotation marks omitted)

D. Product-by-Process Claims

A patent claim may describe a product "'at least in part in terms of the method or process by which [the product] is made.'" (*Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 158 n.* (1989) (quoting 3 Chisum on Patents § 8.05, p. 8–67 (1988)).

A patentee can state a claim in product-by-process form by reciting a product and a series of steps by which that product is obtainable. *E.g.*, *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1295 (Fed. Cir. 2009). For instance, when "the claimed physical properties of [a product] are attributable to the process that is used to make [it]," the claims are to a product made by a process. *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1372 (Fed. Cir. 2007). An accused product infringes a product-by-process claim only if it is made by a substantially identical process. *See Atl. Thermoplastics Co., Inc. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992).

A court determines the obviousness of a product-by-process claim without reference to its process limitations. *Greenliant Sys., Inc. v. Xicor LLC*, 692 F.3d 1261, 1268 (Fed. Cir. 2012); *Amgen Inc. v. F. Hoffmann-La Roche Ltd.*, 580 F.3d 1340, 1366-67 (Fed. Cir. 2009). The same is true for determinations of novelty or anticipation. *See SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1318 (Fed. Cir. 2006), *reh'g and reh'g en banc denied*, 453 F.3d 1346 (Fed. Cir. 2006). Conversely, for the purposes of written description and enablement, unlike obviousness and novelty, the Court gives meaning to the process terms of the patent because the specification must describe and enable the full scope of the claims. *See* 35 U.S.C. § 112; *cf. Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991).

E. Attorneys Fees

In a lawsuit for patent infringement, "[t]he court in exceptional cases may award reasonable attorney

fees to the prevailing party." 35 U.S.C. § 285. The U.S. Court of Appeals for the Federal Circuit has explained Section 285's limitation to "exceptional cases" in this way:

> A case may be deemed exceptional where there has been some material inappropriate conduct related to the matter in litigation, such as willful infringement, fraud or inequitable conduct in procuring the patent, misconduct during litigation, vexatious or unjustified litigation, conduct that violated Fed. R. Civ. P. 11, or like infractions.

Brooks Furniture Mfg., Inc. v. Dutailier Int'l, Inc., 393 F.3d 1378, 1381 (Fed. Cir. 2005) (citing cases). In order for a court to award fees to the prevailing party, that party must demonstrate by clear and convincing evidence that the case is exceptional. *See id*. at 1384.

PART 2. THE LOW-ABUK PATENTS

I. Findings of Fact

A. Purdue's development of low-ABUK oxycodone

The FDA approved Original OxyContin in 1995. (Stipulations or Agreed Statements of Fact or Law, Joint Pretrial Order, Case No. 04 Md. 1603, Dkt. No. 572, filed Aug. 28, 2013, at 24 [hereinafter 2013 Stip.] ¶ 42.) Purdue brought Original OxyContin to market, heralding its design as a controlled-release tablet. (*See* Gasdia 2012 Tr. 477.[2]) In other words,

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[2] Because several trial witnesses testified at both the 2012 trial and the 2013 trial, the Court refers to trial transcripts with both the witness name and the relevant trial, as in "([Witness] 2012

OxyContin's significant advantage over other opioid pain relievers was its ability to sustain the release of its API over a twelve-hour period. (*See id.*; Sellers 2013 Tr. 81–82.) The API in OxyContin is oxycodone hydrochloride ("oxycodone HCl"). (Wuest 2012 Tr. 610.)

In 2000, Rhodes Technologies, then Purdue's wholly owned subsidiary, began to construct a facility to manufacture oxycodone hydrochloride. (Shamblen 2012 Tr. 76.) Purdue aimed to use the oxycodone API produced by that facility in its OxyContin products. Rhodes synthesized the API in three steps: first, it oxidized thebaine, a derivative of the opium poppy, to form 14-hydroxy; second, Rhodes hydrogenated the 14-hydroxy to form oxycodone free base; and third, it added hydrochloric acid to form oxycodone hydrochloride salt. (*Id.* at 80; Kupper 2012 Tr. 124–25; PTX 304 at P2378483.)

In February 2003, Purdue submitted a supplemental NDA to the FDA, seeking approval for Rhodes to manufacture its oxycodone API. (Stipulations or Agreed Statements of Fact or Law, Joint Pretrial Order, Case No. 10 Civ. 3734, Dkt. No. 168, filed Oct. 12, 2012, at 14 [hereinafter 2012 Stip.] ¶ 38; PTX 304.) The FDA responded in January 2004, setting forth several conditions for its approval of the drug master file. (PTX 266.) Among those conditions, the FDA directed Rhodes to either provide evidence that the level of 14-hydroxy in its oxycodone API was safe or else lower the level of 14-hydroxy in the API to less than ten parts per million (10 ppm). (*Id.*)

Tr.)" for a witness's 2012 trial testimony or "([Witness] 2013 Tr.)" for a witness's 2013 trial testimony.

Purdue proposed that the FDA temporarily allow Rhodes to produce oxycodone API with up to 500 ppm 14-hydroxy, while the company worked toward the 10 ppm limit. (PTX 305 at P2378417-18; Shamblen 2012 Tr. 88–89; Kelly 2012 Tr. 514.) The FDA accepted the proposal. (Kelly 2012 Tr. 514–15; PTX 267.) To achieve the 500 ppm purity level, the Rhodes facility practiced "better washing and better drying" of its product using a high-capacity, high-efficiency spherical dryer and a centrifuge. (Shamblen 2012 Tr. 89–90.) In March 2004, Rhodes submitted an amended drug master file that summarized this intermediate production process. (PTX 268.)

By the fall of 2004, Rhodes had developed a permanent solution to the 14-hydroxy levels. On November 12, 2004, Rhodes submitted to the FDA a second amendment to its drug master file. (PTX 269; PTX 308; Kelly 2012 Tr. 517–18.) Rhodes described a revised manufacturing process that used a "new low ABUK step" designed to "convert any residual [14-hydroxy] that reappeared after the normal processing into the final product of oxycodone hydrochloride." (Shamblen 2012 Tr. 93.) Rhodes reported that this process achieved less than 5 ppm of 14-hydroxy in each of three validation lots. (PTX 269 at P2376224; PTX 308 at P2379581.) The FDA approved Rhodes as a commercial supplier of oxycodone API on March 15, 2005. (PTX 382; Kelly 2012 Tr. 519–20.)

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Rhodes had begun experimenting with ways to reduce 14-hydroxy levels in its oxycodone hydrochloride years before the FDA's 2004 mandate.

(*See* Kupper 2012 Tr. 129–32.) In 2001 and 2002, Rhodes focused on the second synthesis step—the step of hydrogenating 14-hydroxy into oxycodone—for a quick fix. More specifically, Rhodes hypothesized that the unwanted 14-hydroxy in the end product was merely left-over 14-hydroxy that had not been hydrogenated in this second step. So its scientists attempted to control the 14-hydroxy in the final API by ensuring that "the hydrogenation reaction from [14-hydroxy] [to] oxycodone free base was run to completion." (*Id*. at 129.) Rhodes's scientists thought they had succeeded: they ran this extended hydrogenation step, analyzed samples of the oxycodone free base using high-performance liquid chromatography ("HPLC"), and found no 14-hydroxy. (*Id*. at 133–34; PTX 374). The HPLC analysis had a lower limit of detection of 100 ppm (PTX 374), giving Rhodes great confidence that it had found its answer.

As the Rhodes scientists soon discovered, however, their answer was incomplete at best. When they finished the third and final synthesis step—creating a salt from the oxycodone free base by adding hydrochloric acid—they tested the final API and found that the 14-hydroxy had returned in vast quantities. (Kupper 2012 Tr. 135, 137–38.) Although there had been no sign of 14-hydroxy in the oxycodone free base after step two, it rebounded to "a level of around 1,500 [ppm]" in the final API of oxycodone hydrochloride after step three. (*Id*.)

Scratching their heads at the reappearance of 14-hydroxy after the final synthesis step, Rhodes scientists resumed their research into the sources of the 14-hydroxy and how to remove it. (*Id*. at 137.) That research program quickly bore fruit. In a

November 27, 2002, report, Rhodes research scientist Lonn Rider hypothesized that the 14-hydroxy present in the API formed due to the dehydration of two impurities, 8α, 14-dihydroxy-7,8-dihydrocodeinone ("8α") and 8β, 14-dihydroxy-7,8-dihydrocodeinone ("8β"). (*Id*. at 139–41.)

8α and 8β are diastereomers of 8,14-dihydroxy-7,8-dihydrocodeinone ("8,14-dihydroxy"). (2012 Stip. ¶ 77.) In other words, 8α and 8β are two forms of the same compound, namely 8,14-dihydroxy. 8α and 8β "have the same atoms connected to other atoms but they differ in the[ ] three-dimensional arrangement of the atoms." (Heathcock 2012 Tr. 1144; *see also Chapman v. Casner*, 315 F. App'x 294, 295–96 (Fed. Cir. 2009) (discussing 8,14-dihydroxy's stereoisomers).) That difference in three-dimensional arrangement relates to the orientation of a hydroxyl group. The difference is clear in a molecular diagram. In such a diagram:

> Carbons and carbon-carbon bonds that lie close to the average plane of the molecule are represented by simple lines. Groups that are oriented toward the viewer are represented through bonds that use a solid wedge symbol. And groups that are oriented away from the viewer, beneath the molecular plane, are represented by [ ] hashed wedges.

(Wuest 2012 Tr. 554–55.) An ordinarily skilled chemist can tell 8α from 8β by those graphical representations. (*See* Heathcock 2012 Tr. 1211; Molander 2013 Tr. 2198–2200; *cf*. Wolf 2012 Tr. 1006–07.)

Rider's focus on 8,14-dihydroxy flowed intuitively from two known principles: First, as Rhodes and Rider knew, 8,14-dihydroxy formed as a byproduct of the first synthesis step. That step, the oxidation of thebaine to yield 14-hydroxy, also produces "several overoxidation products . . . in small amounts," including 8,14-dihydroxy. (Kupper 2012 Tr. 140.) Second, as Rhodes and Rider knew, 8,14-dihydroxy could undergo acid-catalyzed dehydration to form 14-hydroxy. (DTX 727; Heathcock 2012 Tr. 1141–42.) Rhodes suspected that the addition of acid at the salt-formation step was converting the 8,14-dihydroxy to 14-hydroxy. (Kupper 2012 Tr. 138.)

What Rhodes's scientists still did not know was whether the reappearance of 14-hydroxy resulted from the dehydration of 8ß, 8α, or some combination of the two. In fact, Rhodes's scientists were uncertain whether 8α even existed. Rhodes's scientists were familiar with the 8ß isomer of 8,14-dihydroxy. They "had a reference standard for it," and there were "easily detectable amounts" present in Rhodes's oxycodone product. (*Id*. at 142.) By comparison, Rhodes knew little about the 8α isomer. Purdue's scientists had previously noted its potential existence in oxycodone products, but no scientific literature discussed 8α. (*Id*.) Purdue and Rhodes investigated. Purdue scientist Frank Cheng conducted mass spectral analysis of the suspected 8α isomer. That analysis returned a molecular weight consistent with the hypothesis that 8α was formed during thebaine oxidation. (*Id*. at 145; PTX 303.) The suspected 8α compound also had a "fragmentation pattern" from the mass spectrum similar to the 8ß isomer. (Kupper 2012 Tr. 145; PTX 303.) Moreover, the compound's

HPLC chromatogram resembled 8ß's chromatogram. (Kupper 2012 Tr. 145; PTX 303.) This evidence suggested that the oxidation step produced both 8ß and 8α.

Knowing that both isomers were present after the second synthesis step (oxidation), Rhodes's scientists set to work studying which isomer dehydrated to 14-hydroxy in the third synthesis step (salt formation). (*See* Rider 2012 Tr. 211.) In January 2003, Rider "conducted an experiment to examine the stability of oxycodone hydrochloride solution in isopropanol and water under the conditions" of the Rhodes spherical dryer used in the salt-formation step. (*Id.*; PTX 312.) Rider sampled the resulting solution. (Rider 2012 Tr. 215.) He discovered that the amount of 14-hydroxy had increased compared to the free base, the amount of 8α had decreased compared to the free base, and the amount of 8ß had roughly stayed the same. (*Id.* at 211, 216–17.) In other words, while 8ß stayed constant, levels of 8α and 14-hydroxy changed in a complementary manner. To Rider and the other Rhodes scientists, the experiment confirmed that 8α was the "culprit." (*Id.* at 217–18; Kupper 2012 Tr. 147–48.) 8α was transforming into 14-hydroxy.

Having discovered 8α as the source of the 14-hydroxy problem, Rhodes scientists set out to solve that problem. Rhodes and Purdue entertained several potential solutions, but the one that stood out immediately was the addition of a further hydrogenation step, at the end of the three-step oxycodone hydrochloride synthesis, to convert the remaining 14-hydroxy into oxycodone. (Rider 2012 Tr. 219–21; Kupper 2012 Tr. 151.) This solution occurred to Dr. Robert Kupper, a Rhodes scientist,

immediately: "[o]nce the mechanism of formation was known, the hydrogenation was the first thing that popped into my mind." (Kupper 2012 Tr. 197.) And besides having support in scientific principles, this solution was productive both because Rhodes "had excess equipment" for the task and because it had "several million dollars worth of oxycodone hydrochloride" in its inventory that would become usable product if the second hydrogenation step succeeded in converting the remaining 14-hydroxy into oxycodone. (*Id*. at 151.)

This new hydrogenation step did not, however, exactly replicate the hydrogenation of 14-hydroxy in oxycodone free base, as Rhodes had done in its original synthesis steps. That original hydrogenation step used water and formic acid to produce a formate salt, which Rhodes then "converted to the free base by an addition of a base of sodium hydroxide." (Rider 2012 Tr. 298; *see* Kupper 2012 Tr. 151–52.) The newly-added hydrogenation step, by contrast, happened after the free base had been converted to oxycodone hydrochloride. (Rider 2012 Tr. 299.) This hydrogenation converted 14-hydroxy into oxycodone but did not react with previously formed oxycodone hydrochloride. (*Id*. at 300–01.)

By June 2003, Rhodes's laboratory could routinely produce oxycodone API with 14-hydroxy levels less than 10 ppm using the two-hydrogenation process. (Kupper 2012 Tr. 152; PTX 343 at P2217855.) Method in hand, Rhodes scientists worked to fit the method into the factory manufacturing process. They set up the factory process by July 2004 and submitted the amended drug master file to the FDA in November 2004. (Kupper 2012 Tr. 153.)

B. Purdue obtains the '799 , '800, and '072 Patents

Purdue and Rhodes's work on low-ABUK oxycodone yielded three further patents in March 2010: the '799 , '800, and '072 Patents. (2012 Stip. ¶ 23.) Broadly speaking, the '800 Patent claims "a process for preparing an oxycodone salt substantially free of 14-[hydroxy]." (*E.g.*, PTX 3 at 34:21–22.) The '072 Patent claims low-ABUK "oxycodone hydrochloride active pharmaceutical ingredient." (*E.g.*, PTX 4 at 34:56–59.) The '799 Patent claims an "oral dosage form" of low-ABUK oxycodone hydrochloride. (*E.g.*, PTX 2 at 34:54–64.)

Purdue's patents did not come easily. They required years of advocacy before the U.S. Patent and Trademark Office ("PTO"), the Board of Patent Appeals and Interferences, and the U.S. Court of Appeals for the Federal Circuit. Because the parties dispute the significance of the history of the patents, the Court highlights aspects of that history here.

1. The Chapman Application

The '799 , '800, and '072 Patents continue from application No. 11/391,897, known as the "Chapman Application." (*See* 2013 Stip. ¶ 27(a)–(c).) The Chapman Application, in turn, continues from the March 30, 2005 application No. 11/093,626, which issued as U.S. Patent No. 7,129,248. (*See id.*) As with the patents-in-suit, the Chapman Application recited a "process for preparing oxycodone hydrochloride having less than 25 ppm [14-hydroxy]." Purdue was the real party in interest behind the Chapman Application. (DTX 715; Bjorge 2012 Tr. 1048–49, 1070.)

On April 19, 2007, the Board of Patent Appeals and Interferences declared an interference between the Chapman Application and U.S. Patent No. 7,153,966 (known as "Casner"). (2012 Stip. ¶ 26.) That action, Patent Interference 105,553, concerned a claim from the Chapman Application and one from the Casner patent. (DTX 715.)

The relevant claims, claim 1 of the Casner patent and claim 96 of the Chapman Application, "relate[d] to a method for making oxycodone using a hydrogenation step" for the purpose of "the formation of oxycodone having low levels" of ABUKs. (*Id*. at P1057606; Bjorge 2012 Tr. 1052.) Chapman's claim 96 disclosed a process for making oxycodone similar to claim 1 of the '800 Patent, but without any limitation that a portion of the 14-hydroxy must have derived from the 8α isomer. (PTX 10 at P1056017.) The Board further stated that Chapman claims 96-118 "correspond" to the subject matter of the interference. (DTX 715 at P1057605.) Chapman claims 115-118 called for "the process according to claim 96, wherein the resultant oxycodone contains [14-hydroxy] in an amount less than" various purity limits ranging from 25 ppm to 5 ppm. (DTX 678 at P1055888.)

Casner, the junior party in the interference,[3] asked the Board to rule that the Chapman Application was invalid as obvious. (DTX 715 at P1057640; Bjorge

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[3] In an interference proceeding at the PTO, the earliest-filing applicant (with presumptive priority) is the senior party and a later-filing applicant (with the burden to show priority) is a junior party. *See generally Brown v. Barbacid*, 276 F.3d 1327, 1332–33 (Fed. Cir. 2002).

2012 Tr. 1070.) On March 13, 2008, the Board declared the subject matter of the interference to be obvious. (*See* 2012 Stip. ¶ 31.) The Board characterized the purported invention as "a method for making oxycodone using a hydrogenation step" for the purpose of forming "oxycodone having low levels . . . of [ABUK] impurities." (DTX 715 at P1057606.) The Board compared Chapman's claims to the prior art and concluded that "the principal difference[ ]" between them was that "no one reference describes all of the claimed process steps." (*Id*. at P1057625.) The Board concluded that "[b]ased on the record before us, we hold that the subject matter of Chapman claim 96 and . . . Casner claim 1 would have been obvious within the meaning of 35 U.S.C. § 103." (*Id*. at P1057640.)

Purdue appealed directly to the Federal Circuit. *See Chapman*, 315 F. App'x at 294. The Federal Circuit agreed with the Board and affirmed the Board's conclusion that claim 96 of the Chapman Application was obvious and therefore unpatentable. *See id*. at 297–98. The Federal Circuit reasoned that "claim 96 would have been obvious if properly-combinable references disclosed conditions suitable to promote reaction of 8,14-dihydroxy to 14-hydroxy. The prior art references here do just that: they indicate that [8ß], at least, will under certain reaction conditions form 14-hydroxy." *Id*. at 297.

2. Further proceedings before the PTO

Purdue filed several continuations of the Chapman Application. The '799 Patent continued as Serial No. 11/653,531 and issued on March 9, 2010. The '800

Patent continued as Serial No. 11/729,741 and issued on March 9, 2010. The '072 Patent continued as Serial No. 11/653,529 and issued on March 23, 2010. (2012 Stip. ¶ 23.)

The PTO initially rejected as obvious a number of asserted claims of the patents as they were then drafted. The Examiner paid particular attention to one prior art reference, U.S. Patent No. 6,177,567 (the "Chiu" patent), which disclosed a process for preparing a low-ABUK oxycodone crude base. (PTX 10 at P1052803–04; PTX 11 at P1034148–49; PTX 12 at P1045523–24; PTX 741.) The Examiner observed:

> Chiu teaches that in order to determine the completeness of the reaction, the disappearance of [14-hydroxy] was determined by HPLC . . . and further teaches that if the reaction was discerned to be incomplete, the batch was stirred for an additional 2h period. Therefore, it would have been obvious to one skilled in the art to prepare the instant Oxycodone hydrochloride composition having less impurities with different levels of [14-hydroxy] since Chiu teaches determining levels of [14-hydroxy] by HPLC during preparation of Oxycodone or its salt.

(PTX 12 at P1045524.)

The Examiner also questioned the nonobviousness of the patents on the grounds that prior art regarding 8β might render obvious those claims relating to 8α. As the Examiner wrote, "unless applicants provide some unexpected results of [8α] as compared to [8β], it would have been obvious to one skilled in the art to prepare Oxycodone salt with reduced amount of 14-

hydroxy[ ] with reasonable expectation of success." (PTX 11 at P1035381–82; Heathcock 2012 Tr. 1142–43.)

Purdue's response distinguished the prior art based on stereochemistry (the spatial arrangement of atoms) and based on the process steps involved in the Chiu reference. As to the stereochemistry, Purdue submitted the declaration of Dr. Steven Baldwin to demonstrate the "unexpected results" of 8α to the Patent Office. Baldwin stated that 8α and 8ß are "different compounds and have surprisingly different properties (*e.g.* reactivities)." (PTX 11 at P1035678; Heathcock 2012 Tr. 1143.) As to the Chiu reference, Purdue explained that the prior art reference concerned 14-hydroxy in oxycodone free base, not 14-hydroxy that "would reappear during hydrochloride salt formation." (PTX 10 at P1052961–62; *see* Crimmins 2012 Tr. 799–800.)

Purdue prevailed. The Examiner approved the patents, in part "due to [Purdue's] persuasive arguments and declaration by Dr. Baldwin." (PTX 10 at P1059552.)

3. The low-ABUK patents-in-suit

Purdue has asserted that Teva's ANDA infringes claims 3 and 19 of the '799 Patent; claims 30–34 and 76–79 of the '800 Patent; and claims 1, 4, and 5 of the '072 Patent. The '799 , '800, and '072 Patents have substantially identical specifications but differ in the nature of the claims.

Each of the three patents has an identical "Figure 1," which depicts the synthesis of oxycodone hydrochloride from thebaine. First, thebaine undergoes oxidization, yielding 14-hydroxy. Second,

the 14-hydroxy is hydrogenated to produce oxycodone free base. Third, a hydrochloride solution acidifies that oxycodone free base, resulting in oxycodone hydrochloride. In addition, another reaction appears alongside the first synthesis step: over-oxidation of the thebaine, forming 8α. In depicting this reaction, Figure 1 identifies 8α both by name and by graphical representation. (PTX 2 at 6; PTX 3 at 6; PTX 4 at 6; Wuest 2012 Tr. 554–55, 1253–54.)

Figure 2, identical in each of the three low-ABUK patents, provides further context regarding 8α. It depicts the conversion of 8α into 14-hydroxy as a result of dehydration in the presence of acid. (PTX 2 at 7; PTX 3 at 7; PTX 4 at 7; Wuest 2012 Tr. 1254.) Here, as in Figure 1, the 8α isomer is labeled as such and is further identified by graphical representation. Even the caption of Figure 2 recites the isomer's name, for a belt-and-suspenders identification: "Dehydration of 8α,14-hihydroxy-7,8,-dihydrocodeinone." (PTX 2 at sheet 2, fig. 2.)

By way of a taxonomy of the isomers, the patents' specifications all state that "[t]he term 8,14-dihydroxy-7,8-dihydrocodeinone includes either 8α,14-dihydroxy-7,8-dihydr ocodeinone; or 8β,14-dihydroxy-7,8-dihydrocodeinone or can include a mixture of both compounds." (*E.g.*, PTX 3 at 5:54–57.)

The common specification includes no method for detecting 8α. (Kupper 2012 Tr. 191; Wuest 2012 Tr. 1324–25.) However, the description goes on to recite the chemical structure of 8α and the nature of the reaction that produces it. For example, the specification states that 8,14-dihydroxy converts to 14-hydroxy "during salt formation reactions known in

the art." (PTX 3 at 8:4–11.) The patents' written description does not explicitly identify conditions that transform 8α, but not 8β, into 14-hydroxy. (*See*, *e.g.*, Rider 2012 Tr. 278.) The specification also does not disclose a pH range at which 8α will not form. (*Id.* at 278-79; Wuest 2012 Tr. 1330–31.) But Example 3 of the specification demonstrates conditions that suffice to convert 8α into 14-hydroxy. (Wuest 2012 Tr. 1258.) Furthermore, as Dr. James Wuest explained at trial, a skilled artisan "would understand that the 8β compound is essentially inert under [the] conditions [of Example 3] and would not undergo this acid-induced transformation." (*Id.* at 1258.)

The reactivity or inertness of 8β under the conditions of Example 3 represent a fulcrum in the arguments over how much the common specification discloses about 8α. After all, in arguing that an ordinary skilled artisan would understand the patents' reference to 8α, Purdue relies on the premise that the patent's reader understands Example 3 as *not* referring to 8β. Example 3 uses hot 0.2N hydrochloride, with 0.2N representing the normality, or the equivalent concentration of the acid. (*Id.* at 1258–59.) In that acid, according to Example 3, the 8,14-dihydroxy reacts, decreasing from 0.29% to 0.04%. (PTX 3 at 26:8–11.) Wuest credibly opines that an ordinary skilled artisan would know that the 8,14-dihydroxy reacting in those conditions *must* be 8α and not 8β, because the Weiss reference shows that 8β is inert in such conditions. (Wuest 2012 Tr. 1258; Wuest 2013 Tr. 2364–65; *see* Ulrich Weiss, *Derivatives of Morphine II Demethylation of 14-Hydroxycodeinone 14-Hydroxymorphinone and 8,14-Dihydroxydihydromorphinone*, 22 J. Org. Chem.

1505–078 (1957) ("Weiss") (DTX 727).) As Wuest explains, Weiss shows 8β reacting in 6N hydrochloride ("HCl") and not reacting in 2N HCl. (Wuest 2013 Tr. 2305–06.) An ordinarily skilled chemist would understand that 6N HCl is more concentrated than 2N HCl, which in turn is more concentrated than 0.2N HCl, and that an acid-catalyzed reaction that occurs in 6N HCl but not in 2N HCl will not occur in 0.2N HCl. (*See* Wuest 2012 Tr. 1255–61, 128790; Heathcock 2012 Tr. 1187–90; Wuest 2013 Tr. 2303–13.)

Teva has attempted to show just the opposite, that 8β *reacts* and is not inert under the conditions of Example 3. They put forth Dr. Brian Smith's experimental results that replicate Weiss's work to show the reactivity of 8β in 6N HCl (Smith 2013 Tr. 2044–47) and that attempt to extrapolate through limited testing how 8β behaves in 2N HCl (*id*. at 2037–52). The Court cannot credit this extrapolation as reliable evidence of reactivity: Smith did not measure the purity of the 8β base at the start of his experiment in 2N HCl (in contrast to his experiment in 6N HCl, which began with a measurement of the 8β base's purity), thereby eliminating any substantial meaning from the purity he measured at the end of his experiment. (*See id*. at 2047; Wuest 2013 Tr. 2307–09.) Moreover, even assuming *arguendo* that Smith's 2N HCl experiment began with the purity of 8β base that Teva assumes, the large extent of the reaction into 14-hydroxy could not be explained by 8β alone; at least some 8α must have contributed to the reaction. (*See* Wuest 2013 Tr. 231113, 2441–42.) On balance, Wuest's credible explanation of the Weiss reference, balanced against Teva's attacks on that

explanation, persuades the Court that a person of ordinary skill in the art would have read Example 3 as describing 8α.

C. The Noramco process

Teva proposes to use oxycodone API manufactured by Noramco, Inc. (2013 Stip. ¶ 110.) Noramco is an FDA-approved supplier of oxycodone API. (Kelly 2012 Tr. 510–11.) At trial, the parties intensely disputed whether 8α forms during Noramco's manufacturing process and, if it does, whether some of that 8α converts to 14-hydroxy during the final salt formation step of the Noramco process.

1. Teva plans to sell tablets containing oxycodone hydrochloride API and a sustained release carrier.

Teva has sought FDA approval for generic tablets by filing ANDA No. 202455. (*See* 2013 Stip. ¶ 97.) The proposed product is an oral dosage tablet that contains oxycodone hydrochloride and a pharmaceutically acceptable excipient.[4] (*See id*. y[¶¶ 104–208.) The proposed tablets are extended release tablets (*see id*. ¶¶ 105, 113) that use oxycodone hydrochloride API substantially free of 14-hydroxy (*see* PTX 3803; Wuest 2013 Tr. 1896–99). Teva intends to use oxycodone hydrochloride API manufactured by Noramco pursuant to Drug Master File ("DMF") No. 20975, rather than manufacture its own oxycodone hydrochloride API. (2013 Stip. ¶ 110.)

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[4] Excipients are "[t]he inactive ingredient[s] of a pharmaceutical product." (Mannion 2013 Tr. 180.)

2. Teva's tablets contain a non-zero amount of 14-hydroxy.

Teva reported in its ANDA that its proposed products contain 14-hydroxy in an amount less than 10 ppm. (PTX 2027 at 3–4; Wuest 2013 Tr. 1897–98; *see* 2013 Stip. ¶ 111.) The testimony of Karen James, Director of Regulatory Affairs at Noramco, confirms the point. James testified that Noramco's API contained "trace levels" of 14-hydroxy. (James 11/4/2011 Dep. 43:08–18.) Further, Noramco reported to the FDA in its drug master file that its API contained 14-hydroxy, but at less than 10 ppm. (PTX 207; *see also* Wuest 2012 Tr. 588–89.) The Court gives significant weight to these results, which were obtained in advance of litigation and reported to a government agency.

In further support of this finding, Kevin Gauger, Lead Scientist in the Organic Spectroscopic Group at Catalent Pharma Solutions, LLC, testified that the Noramco API (the oxycodone hydrochloride used both by Actavis and by Teva) included a non-zero amount of 14-hydroxy based on testing conducted by Catalent on behalf of Purdue. (*See* Gauger 2012 Tr. 352–54, 374–81; *see* PTX 468; PTX 471; PTX 480; PTX 481; PTX 494; PTX 495.) At the 2012 trial, Actavis attacked Gauger's results on the ground that the results differ depending on whether Catalent integrated the test data by computer or by hand. (*See* Gauger 2012 Tr. 380–84.) Gauger's computer-integrated analysis of the API returned "non-detect" for six of six injections of one lot and "non-detect" for five of six of the second lot of injections. (*Id*. at 399–403; DTX 994 at 133, 136; DTX 951 at 6.) The sixth sample of the second lot returned a result of 14-

hydroxy at 1.39 ppm. (DTX 994 at 133.) By contrast, when Gauger manually integrated the raw data, he returned consistent "detect" results of between 3.76 ppm and 5.51 ppm 14-hydroxy. (Gauger 2012 Tr. 380–87, PTX 468; PTX 480; PTX 481; PTX 494; PTX 495.) Actavis also criticized the quality and reliability of Gauger's manual integration. (*See*, *e.g.*, Dolan 2012 Tr. 717–20 (improperly identified "peaks"); *id*. 723–25 (improper use of "perpendicular drop" method).)

Although Actavis emphasized at the 2012 trial that Gauger manually integrated the data only after his initial results failed to detect 14-hydroxy, the Court does not find the sequence to be especially suspicious. Indeed, the trial evidence proved that manual integration is a best-practice of HPLC analysis. (*Id.* at 716, 763–64.) The Court does, however, agree that the methodological flaws of Gauger's procedure weaken the strength of his results.

The Court finds the presence of 14-hydroxy in Teva's API by a preponderance of the evidence. The most persuasive—and unchallenged— proof comes in the form of Teva's own reports. (*See* 2013 Stip. ¶ 111; PTX 2027 at 4; Wuest 2013 Tr. 1897–98.) The finding is bolstered by evidence that Noramco's API, which Teva uses in its tablets, has "trace amounts" of 14-hydroxy. (James 11/4/2011 Dep. 43:08–18; PTX 207.) Additionally, although the Court gives little weight to Gauger's HPLC analysis, the Court finds that the balance of the Catalent evidence tilts in Purdue's favor and that Teva's tablets contain a non-zero amount of 14-hydroxy.

3. 8α forms during the Noramco process.

The Court finds that 8α is present in the Noramco process. Noramco uses the five-step process disclosed in its DMF (PTX 205 at NORA5) to synthesize oxycodone from thebaine as follows:

- Noramco's first step synthesizes thebaine into a crude oxycodone base ("COB"). Noramco begins this step by oxidizing thebaine in water, acetic acid, and peracetic acid to form 14-hydroxy. To complete step one, Noramco hydrogenates the 14-hydroxy to form an oxycodone base, acidifies the mixture with sulfuric acid, and neutralizes the mixture with sodium hydroxide to form COB. (*Id*. at 2, 4–5.)
- In steps two and three, Noramco further hydrogenates the oxycodone base to purify it. Step two yields a first purified oxycodone base ("POB-1"). Step three yields a second purified oxycodone base ("POB-2"). (*Id*. at 2, 6–9.)
- In step four, Noramco treats POB-2 with hydrochloric acid to create oxycodone hydrochloride. (*Id*. at 2, 10.)
- In step five, Noramco mills the oxycodone hydrochloride "to achieve the desired particle size." (*Id*. at 2, 12.)

The Court credits Wuest that the reaction conditions used by Noramco to oxidize thebaine will also yield 8α. (Wuest 2012 Tr. 574–75, 614.) Wuest's opinion is consistent with a patent owned by Noramco, U.S. Patent No. 7,906,647. Although that

patent does not set out the Noramco commercial process, it discloses that 8α forms when thebaine is oxidized using peracetic acid, acetic acid, and water. (Crimmins 2012 Tr. 928–29; PTX 221 at Scheme 1.) Noramco uses the same reagents to oxidize thebaine in its commercial process. (Wuest 2012 Tr. 573, 583; Crimmins 2012 Tr. 929–30; PTX 205; PTX 221.)

Wuest's opinion finds further support in Catalent's testing. (*See* Gauger 2012 Tr. 378–80; PTX 466; PTX 474; PTX 477.) Gauger analyzed samples from Noramco by HPLC and detected the presence of 8α in the samples. His tests focused on samples from intermediate stages of the Noramco process, including COB and POB-2. (Wuest 2012 Tr. 578, 595; PTX 205.)

Teva did not offer any proof that 8α does not form during the oxidation of thebaine. Rather, Teva once more attacked the reliability of Catalent's work. It effectively identified the risk of a false positive in some of the 8α that Gauger found. Specifically, Gauger's tests might possibly have generated 8α as an artifact of the testing process: in his search for 8α, Gauger used acid that could generate the very 8α he later detected. (Molander 2013 Tr. 2069–70.) But Gauger found vastly greater amounts of 8α than could have been generated as an artifact. (Wuest 2013 Tr. 2276–85.) As Wuest explained, even if the Teva was correct about the possibility of a false positive, "the amount of [8α] that could be generated from the 14-hydroxy would be trivially small." (*Id.* 2278.)

Wuest credibly opined that Gauger's work was "well carried out" (Wuest 2012 Tr. 596), and this

opinion dampens the blow of Teva's attacks. More importantly, the evidence besides Gauger's confirmatory testing—namely, Wuest's well-reasoned opinion about 8α's presence in the Noramco process and Noramco's documents disclosing 8α's formation in the presence of its thebaine-oxidizing reagents—persuades the Court that 8α is present in Noramco's COB, POB-2, and final API.

4. 8α converts to 14-hydroxy during the Noramco process.

The Court finds that 8α converts to 14-hydroxy during the Noramco process. The Court credits Wuest's testimony that the 8α formed before hydrogenation (*i.e.*, in step one) will be carried through the remainder of step one unaffected. (Wuest 2012 Tr. 578–79; *see also* Crimmins 2012 Tr. 913.) The Court further credits Wuest's testimony that the addition of sulfuric acid to the oxycodone base will dehydrate 8α and thereby form 14-hydroxy. (Wuest 2012 Tr. 579–83.) In particular, the Court accepts Wuest's testimony that, though Rhodes's experimental conditions and the "salt formation steps" in the Noramco process are not identical, "in essence the conditions are the same." (*Id.* at 581.) Based on this evidence, the Court finds that 8α converts to 14-hydroxy when sulfuric acid is added to form the crude oxycodone base. (*Id.* at 580-81, 621–24.) Further, the addition of acetic acid to form each of the two purification bases will convert a portion of the remaining 8α into 14-hydroxy. (*Id.* at 584–85.)

Far less persuasive is Teva's evidence that none of the 14-hydroxy present in Noramco's product derives from 8α. Teva does not dispute that 8α will react to

form 14-hydroxy under certain oxidation conditions. (*See*, *e.g.*, Molander 2013 Tr. 2173–75.) Rather, Teva raises the possibility that all of the 14-hydroxy present in its tablets derives from some other source, such as 8β or 8-acetoxy-14-hydroxydihydrothebaine ("8-acetoxy"), or is carried-over 14-hydroxy. (*E.g.*, Crimmins 2012 Tr. 811–12.) Teva suggests that 8-acetoxy can be a source of the 14-hydroxy in the Noramco process, but there is no evidence that any 8-acetoxy is ever present in the Noramco process in the first place. (*See* Molander Tr. 2189–90; Wuest 2013 Tr. 198788.) Teva alternatively attempts to show that 8β may be the culprit, with 8β and not 8α converting to 14-hydroxy. (*See* Molander 2013 Tr. 2067, 2094–99.) Specifically, Teva compares a sample of Noramco's POB-2 with a sample of Noramco's API: the API sample contains dramatically less 8β than does the POB-2 sample; it contains slightly less 14-hydroxy than does the POB-2 sample; and it contains the same level of 8α as does the POB-2 sample. (*See* Wuest 2013 Tr. 1983–84.) But this data does not come from a single solution, measured over time; rather, it comes from separate samples, weakening the integrity of the analysis and results. (*See id.* at 2299.) It does not, therefore, lessen the credibility of Wuest's testimony that "[t]he [8β] compound is essentially inert under these conditions [of the Noramco process] that are used to promote the conversion of 8α into 14-hydroxy." (Wuest 2012 Tr. 622.) At any rate, even if Teva's analysis tended to show a reaction from 8β to 14-hydroxy, that evidence would not show that no 8α whatsoever reacts to 14-hydroxy.

The Court is left with the evidence from Purdue, on the one hand, that 8α forms in the Noramco process and converts to 14-hydroxy before the final salt, and evidence from Teva, on the other hand, that hypothetically all of the 14-hydroxy of the Noramco process derives from some other source. Purdue's evidence shows by a preponderance that 14-hydroxy present in Teva's products derives, at least in part, from 8α.

The Court further finds by a preponderance that some portion of the 8α present in Noramco's purified free base POB-2 converts to 14-hydroxy in the final salt formation step. The evidence that proves this fact is inferential, as Gauger admitted that he did not test how a particular molecule of 14-hydroxy made its way into the API. (Gauger 2012 Tr. 393.) First, Gauger established the existence of 8α in POB-2. (*See* PTX 466, 474, 477.) Second, Wuest testified that the conditions of the final salt formation step suffice to convert at least some 8α present in POB-2 to 14-hydroxy. (Wuest 2012 Tr. 586.) At the 2012 trial, Actavis attempted to show that the pH of the final salt formation step was not suitable to convert 8α to 14-hydroxy. (*See* Crimmins 2012 Tr. 826–28.) But Noramco's own documentation confirms Wuest's testimony that some 8α will convert to 14-hydroxy at those pH levels. (PTX 260; Wuest 2012 Tr. 1246–50.) The Court therefore finds it more likely that 8α converts to 14-hydroxy during the final salt formation step than that no 8α converts at that stage.

D. Facts pertinent to obviousness

1. The ordinary skill in the art is impressive.

For the purposes of the asserted low-ABUK claims, a person of ordinary skill in the art is an organic chemist with experience in synthetic and analytical chemistry. (*See OxyContin Claim Construction*, 2013 WL 4509633, at *19 n.8.) This person would have knowledge of the chemical reactions relevant to the field, how to search the relevant literature, and how to accomplish complicated organic chemistry reactions. (Wuest 2012 Tr. 564, 1269; Heathcock 2012 Tr. 1118; *see also* DTX 715.)

2. The prior art disclosed the fact that 8β converted to 14-hydroxy and it disclosed methods of using hydrogenation to reduce 14-hydroxy levels in free base and salt compositions.

As of March 2004, when Purdue filed the provisional application that would result in the patents-in-suit, the prior art taught those of skill how to synthesize oxycodone from thebaine. The art taught how to oxidize thebaine to form 14-hydroxy and how to hydrogenate 14-hydroxy to form oxycodone. The art also disclosed that by-products form during the oxidation of thebaine, including an isomer of 8,14-dihydroxy, and that the 8,14-dihydroxy molecule can be dehydrated to form 14-hydroxy.

a) The prior art taught that oxidation of thebaine produces 14-hydroxy and byproducts.

A skilled artisan would have known in the beginning of 2004 that oxidation of thebaine forms 14-hydroxy and certain by-products. "[O]xidation is a reaction that leads to an increased oxygenation of a compound." (Wuest 2012 Tr. 551.) During the oxidation of thebaine, "two carbon atoms become more highly oxygenated as indicated by the formation of carbon oxygen bonds at those positions." (*Id.* at 551–52.) The result is principally 14-hydroxy.

Two prior art references to the patents-in-suit illustrate the oxidation reaction and its products:

One reference discloses a method for obtaining oxycodone from thebaine. (*See* Roland Krassnig et al., *Optimization of the Synthesis of Oxycodone and 5-Methyloxycodone*, Arch. Pharm. Pharm. Med. Chem. 329, 325–26 (1996) ("Krassnig") (DTX 737).) Krassnig discloses how to oxidize thebaine with performic acid to produce 14-hydroxy. Krassnig teaches that oxidation of thebaine yields mostly 14-hydroxy but can also create by-products. (*Id.*; *see also* Heathcock 2012 Tr. 1119, 1138–39.) Though Krassnig did not recognize it, 8α formed as a by-product of the disclosed oxidation reaction. (Heathcock 2012 Tr. 1140; *see also* Wuest 2012 Tr. 1333 (identifying 8α as a by-product of thebaine oxidation).) Krassnig does not discuss 8α or any 8,14-dihydroxy isomer. (DTX 737; Heathcock 2012 Tr. 1176.) Krassnig does not discuss oxycodone salts, the dehydration of 8,14-dihydroxy in a salt formation reaction, or the purity levels of oxycodone. (DTX 737;

Heathcock 2012 Tr. 1176–77, 1180; Wuest 2012 Tr. 1277.)

The Proksa reference also teaches that oxidation of thebaine produces 14-hydroxy and by-products. (Bohumil Proska, *10-Hydroxythebaine*, Arch. Pharm. Pharm. Med. Chem. 332, 369–370 (1999) (DTX 728).) Proksa teaches that oxycodone and at least two by-products form during the oxidation of thebaine, one of which is 8β. (*Id.* at tbls. 1–2) Proksa does not, however, teach the existence of 8α. (*See id.*; Heathcock 2012 Tr. 1185–86.)

b) The prior art taught that hydrogenation of 14-hydroxy converted it to oxycodone.

An ordinarily skilled artisan would be familiar with a hydrogenation reaction and its effect on 14-hydroxy. "Hydrogenation is a reaction in which hydrogen atoms are added to a carbon-carbon double bond or . . . a similar double bond." (Wuest 2012 Tr. 552.) "In the presence of a catalyst and suitable conditions," atoms of hydrogen append to that carbon-carbon double bond "form[ing] new carbon hydrogen bonds and convert[ing] the carbon-carbon double bond into a carbon-carbon single bond." (*Id.*) This technique converts 14-hydroxy, because when 14-hydroxy is "treated with hydrogen in the presence of a catalyst, the carbon-carbon double bond is subjected to the addition of two atoms of hydrogen to produce oxycodone." (*Id.* at 553; Heathcock 2012 Tr. 1161–62.)

Multiple prior art references illustrate that hydrogenation of 14-hydroxy produces oxycodone. Proksa, for example, taught how to hydrogenate 14-

hydroxy to form oxycodone. (Heathcock 2012 Tr. 1119, 1138–39.) Krassnig also taught hydrogenation, specifically that hydrogenating a mixture of 14-hydroxy and other by-products provides a higher yield of oxycodone than attempting to hydrogenate 14-hydroxy molecules alone. (*Id*. at 1138–39; *see also* DTX 715 at P1057637.)

The Chiu reference would further have taught a skilled artisan seeking to purify an oxycodone salt mixture that he could do so by hydrogenating 14-hydroxy. (U.S. Patent No. 6,177,567 (DTX 741).) Although primarily concerned with obtaining 14-hydroxy from codeine, rather than from thebaine, Chiu disclosed methods of making crude oxycodone base by hydrogenating a solution of 14-hydroxy and acetic acid. (*See* DTX 741.) In particular, Chiu taught to hydrogenate the oxycodone acetate mixture until substantially free of 14-hydroxy, to check the completeness of the reaction by HPLC analysis, and to re-hydrogenate if necessary to achieve the desired purity level. (Heathcock 2012 Tr. 1129–38; Wuest 2012 Tr. 1279–81, 1355–56.)

Chiu's hydrogenation method functioned both as a synthetic step—that is, converting the starting 14-hydroxy material into oxycodone—and as a purification step—that is, preferentially removing from the oxycodone base residual 14-hydroxy impurities. (Heathcock 2012 Tr. 1127–30.) But the end product achieved by Chiu—the impurity-controlled oxycodone—is "crude oxycodone," meaning oxycodone free base. (*Id*. at 1182, 1184; Wuest 2012 Tr. 1279.) Chiu did not teach anything about the reappearance of 14-hydroxy in a salt produced from a previously purified oxycodone free base. (Heathcock

2012 Tr. 1184; Wuest 2012 Tr. 1279.) If the free base of Chiu were filtered as Chiu described and left in acetic acid, 14-hydroxy would form from 8α. (Wuest 2012 Tr. 1309–10.)

The Ramanathan reference, published in 1964 (*see* 2013 Stip. ¶ 153), further discloses the hydrogenation of 14-hydroxy's hydrochloride salt (DTX 3020; Molander 2013 Tr. 2137). More specifically, Ramanathan discloses conditions that allow for the oxidation of thebaine into 14-hydroxy (Wuest 2013 Tr. 2386), for the conversion of 14-hydroxy into its hydrochloride salt (Molander 2013 Tr. 2137; Wuest 2013 Tr. 2386), and for the hydrogenation of 14-hydroxy hydrochloride into oxycodone hydrochloride (Molander 2013 Tr. 2138; Wuest 2013 Tr. 2386). (*See* DTX 3020.) Put another way, since 1964 the art has contained knowledge that 14-hydoxy in its salt form can be hydrogenated to form oxycodone in its salt form.

c) The prior art taught that 8,14-dihydroxy dehydrated to form 14-hydroxy.

A skilled artisan would understand the chemistry of a dehydration reaction. "Dehydration is a reaction that leads to loss of water from compounds . . . where the hydroxyl group, an OH group, is next to a carbon atom bearing a hydrogen. So it's a process that leads to the formulation of a molecule of water from that with the simultaneous formation of a compound that now has a carbon-carbon double bond." (Wuest 2012 Tr. 553–54.)

A molecule of 8,14-dihydroxy can dehydrate because it has an OH group next to a carbon atom

bearing a hydrogen atom. "[S]o under proper conditions of exposure to acid solvent with incubation, a molecule of water can be lost to form [14-hydroxy]." (*Id*. at 554.) The resulting compound contains a carbon-carbon double bond. (*Id*.)

The Weiss reference illustrates this reaction. (*See* DTX 727.) That article taught the existence of 8,14-dihydroxy compound in the cis configuration, which we know now as 8ß. (*Id*.; Heathcock 2012 Tr. 1119, 1141–42.) Weiss further taught that 8ß dehydrates to form 14-hydroxy when treated with hydrochloric acid in a boiling water bath. (Heathcock 2012 Tr. 1141–42, 1187; *see also* DTX 715 at P1057637.) The same conditions disclosed in Weiss for the conversion of 8ß to 14-hydroxy will also, necessarily and inherently, convert 8α to 14-hydroxy. (Heathcock 2012 Tr. 1142; Wuest 2012 Tr. 1336–38.)

d) The prior art taught oxycodone hydrochloride API in sustained-release oral dosage forms.

Each of the patents at issue identified earlier forms of OxyContin as relevant prior art. Those earlier forms of OxyContin represent known oxycodone hydrochloride API compositions of various dosage strengths, including oral dosage forms with sustained-release features. (*See*, *e.g.*, PTX 2 at 1:29–32; PTX 3 at 1:29–32; PTX 4 at 1:29–32.)

3. Differences between the prior art and the claims.

Two points principally distinguish the prior art from the patents-in-suit and the asserted claims:

First, the prior art did not disclose the existence of 8α or teach that it converts to 14-hydroxy:

- Proksa reported that 8β formed as a result of oxidizing thebaine; but that reference did not report that 8α formed. (*See* DTX 728; Heathcock 2012 Tr. 1185–86.) Unlike Proksa, Figure 1 of the patents-in-suit teaches that 8α forms during the oxidation of thebaine.
- Weiss reported that 8β converted to 14-hydroxy through acid-catalyzed dehydration; but that reference did not report that 8α converted to 14-hydroxy. Unlike Weiss, Figure 2 of the common specification teaches that 8α can undergo acid-catalyzed dehydration to form 14-hydroxy.

Thus, the patents-in-suit make claims based on the 8α limitations that the prior art did not. The '800 Patent, for example, calls for an oxycodone salt made by preparing "a mixture of oxycodone free base . . . having an [8α] component" and subsequently incubating the mixture to "promote an acid catalyzed dehydration" of 8α to 14-hydroxy. (PTX 3 at 34:30–31.) This feature distinguishes the asserted claims of the '800 Patent from the prior art because the asserted claims recite a process specifically directed at 8α, a compound the prior art never identified. Similarly, the '799 Patent's claim 3 and the '072 Patent's claim 1 describe an oxycodone hydrochloride product containing some amount of 8α-derived 14-hydroxy. The prior art OxyContin that most closely resembles those claims did not have such a limitation. *See*, *e.g.*, U.S. Patent No. 5,266,331; U.S. Patent No. 5,508,042; U.S. Patent No. 5,656,295.

Second, the prior art did not disclose oxycodone API substantially free of 14-hydroxy, whereas the patents-in-suit claim such a product.

- Prior art that disclosed low-ABUK oxycodone mixtures did not disclose low-ABUK oxycodone API compositions. Chiu, for example, disclosed a method for preparing low-ABUK oxycodone free base, but that reference did not teach how to convert its low-ABUK free base into a low-ABUK salt and does not teach the preparation of oxycodone hydrochloride API. (DTX 741; Heathcock 2012 Tr. 1210.) Indeed, Chiu completed his method by adding acetic acid to the free base mixture after testing its purity. Ironically and unbeknownst to Chiu, he likely converted latent 8α into 14-hydroxy when he added acetic acid. (Wuest 2012 Tr. 1308–10.) The Ramanathan reference goes a step farther than Chiu in its hydrogenation disclosure, because Ramanathan teaches the hydrogenation of 14-hydroxy *in its salt form* to yield the salt form of oxycodone. (DTX 3020) Yet Ramanathan does not disclose oxycodone salt substantially free of 14-hydroxy or the reappearance of 14-hydroxy in the oxycodone hydrochloride. (*Id.*; *see* Wuest 2013 Tr. 2316–18; Molander 2013 Tr. 2192–93.)
- Prior art that disclosed oxycodone API did not disclose oxycodone API substantially free of 14-hydroxy. The trial evidence revealed that prior art OxyContin had levels of 14-hydroxy

> at rates greater than 800 ppm. (*See* Kelly 2012 Tr. 510–11; PTX 262 at P2454892–93.)

Thus, the asserted claims that combine oxycodone API with low levels of 14-hydroxy are distinct from the prior art. (*See* PTX 3 at 35:53–59, 38:46–49 (claims 32–34 and 78–79); PTX 2 at 35:8–14, 355:33–36 (claims 3 and 9); PTX 4 at 34:57–60, 35:1–6 (claims 1, 4 and 5).)

The Court finds no effective difference between the patents-in-suit and the prior art based on any purported structural differences between 8α-derived 14-hydroxy and 8ß-derived 14-hydroxy. To a chemist "it doesn't make any difference where the 14-hydroxy comes from"; one molecule of 14-hydroxy is the same as the next. (Heathcock 2012 Tr. 1124–26.)

Further, the Court finds no difference between the patents-in-suit and the prior art on the basis of Purdue's "purification step." (*See* Rider 2012 Tr. 220–21.) The Court credits Dr. Clayton Heathcock's testimony that hydrogenation for "purification" is the same chemical process as hydrogenation for synthesis, distinguished only by a difference in motives. (Heathcock 2012 Tr. 1132–16.) Wuest's testimony confirms the point: hydrogenation of 14-hydroxy converts it to oxycodone, regardless the source of the 14-hydroxy. (*See* Wuest 2012 Tr. 1342–43.)

Finally, the Court finds no difference between the prior art and asserted claims based on the nature of the preparations used. "[I]t would be obvious to a medicinal chemist that you could employ [ ] oxycodone, which is a base, in the form of a hydrochloride salt, which is the most common kind of salt form in this basis." (Heathcock 2012 Tr. 1150–

51.) It would also have been obvious in light of the prior art OxyContin to use sustained release carriers and oral dosage forms to create a medicinal oxycodone hydrochloride product. *See*, *e.g.*, U.S. Patent No. 5,266,331; U.S. Patent No. 5,508,042; U.S. Patent No. 5,656,295.

4. The objective indicia of nonobviousness.

Purdue urges the Court to find the existence of numerous secondary factors, including commercial success, long-felt need, the failure of others, unexpected results, and industry praise. As to those issues, the Court makes the following factual findings:

a) The advances reflected in the '799 , '800, and '072 Patents did not contribute to the commercial success of OxyContin.

After patenting its low-ABUK process and product, Purdue did not promote the low-ABUK nature of its oxycodone to the public. (Gasdia 2012 Tr. 478.) Indeed, Purdue continued to sell OxyContin with higher ABUK levels for years after it had developed low-ABUK oxycodone. (*Id.* at 479–80.) Nor did Purdue advertise the low-ABUK features of its product once its manufacturing shifted entirely to the low-ABUK version of the drug. (*Id.* at 479, 493–94.) What is more, Purdue never requested FDA approval to market OxyContin on the basis of its low-ABUK features. (*Id.* at 488–89.) Thus, the fact that Original OxyContin remained "amongst the top prescribed products in the extend-release opiate category" cannot be attributed to its low-ABUK characteristics. (*Id.* at 484–85.) There is simply no

nexus between OxyContin's commercial success and the low-ABUK technology.[5]

Unlike Purdue, Rhodes did advertise the low-ABUK features of its oxycodone API. (Shamblen 2012 Tr. 96; PTX 288.) But Rhodes did not succeed in selling its product on that basis. During the 2005–2011 time frame, only "three or four" unaffiliated companies requested Rhodes's "technical package" describing low-ABUK oxycodone; and, of those, only one eventually purchased any low-ABUK oxycodone. (Shamblen 2012 Tr. 97.) The Court finds that Rhodes never had commercial success in selling oxycodone API to third-parties.

Rhodes's only significant customer in those years was Purdue, its corporate affiliate. (PTX 412.) Purdue accounted for more than 95% of Rhodes's sales. (*See id*.; Shamblen 2012 Tr. 113–14.) At least three facts reveal that Purdue was not motivated by the low-ABUK nature of Rhodes's product when it chose to obtain its API from Rhodes:

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[5] To the contrary, there is evidence that other factors drove OxyContin sales both up and down during the relevant time period. OxyContin sales decreased between 2004 and 2006 because generic drug manufacturers entered the market. (Gasdia 2012 Tr. 482:20–483:13.) Then, OxyContin sales increased from 2007 to 2009 because generics left the market after negotiating legal settlements with Purdue. (Gasdia 2012 Tr. 483–84.) Later, sales decreased again from 2010 to 2011 as Purdue emphasized its new, abuse-proof formulation of OxyContin, rather than the original formulation of OxyContin. (*See* Gasdia 2012 Tr. 484:20–485:22.) OxyContin's fortunes have changed even though its low-ABUK characteristics have not.

- First, Purdue had decided to invest almost $100 million in the Rhodes facility before scientists developed low-ABUK oxycodone. (*Id*. at 84.) Purdue's commitment to Rhodes came first; Rhodes's low-ABUK API came later.
- Second, Purdue initially invested in Rhodes in order to capitalize on its prediction that then-existing oxycodone manufacturers would not be able to keep up with demand. (*Id*. at 104.) Purdue also understood that it could achieve cost savings by manufacturing oxycodone at its subsidiary rather than purchasing API from an unaffiliated manufacturer. (*Id*.)
- Third, Purdue continued to sell OxyContin with higher ABUK levels even after the FDA approved Rhodes as an oxycodone supplier. (Gasdia 2013 Tr. 479–80.)

The Court finds no "nexus" between the low-ABUK product of the patents and the commercial success of Rhodes. Purdue emphasizes that the low-ABUK process allowed the Rhodes facility to obtain FDA approval and that Rhodes could not have been successful without FDA approval. The Court cannot equate regulatory compliance with evidence of commercial success. In any event, the FDA instructed Rhodes to reduce the level of 14-hydroxy in its product to less than 10 ppm; it did not instruct Rhodes how to do so. (*See* PTX 266; Shamblen 2012 Tr. 108–09.)

b) Although Purdue developed low-ABUK oxycodone API before

its competitors did, no evidence demonstrates that others tried and failed to do so.

On July 22, 2003, the FDA gave Noramco the same choices it would later give Rhodes: reduce the ABUK levels in its oxycodone hydrochloride product to less than 10 ppm or demonstrate that ABUKs are not genotoxic. (PTX 239.)

Noramco initially chose to test the genotoxicity of ABUKs. On December 23, 2003, however, the FDA informed Noramco that 14-hydroxy had tested positive in chromosomal aberration assays. The FDA advised Noramco that it would be setting the limit for ABUK levels in oxycodone at 10 ppm. (PTX 241 at NORA00000187.) Noramco responded to the FDA: "The Agency's requested specification for this impurity represents a technical and scientific challenge both in the synthesis of oxycodone HCL and analysis of the [14-hydroxy] impurity. However, given the results from preliminary laboratory development studies a limit of [10 ppm] appears achievable." (PTX 242.) Noramco set an interim limit of 3,000 ppm 14-hydroxy and agreed to work toward the 10 ppm limit. (*Id*.) Noramco continued to produce oxycodone hydrochloride with more than 10 ppm 14-hydroxy until the summer of 2007. (James 11/4/2011 Dep. 144:08–12; *see* Wuest 2012 Tr. 1313.)

Purdue has not come forward with any evidence to link Noramco's low-ABUK development schedule to the difficulty of manufacturing a low-ABUK product. Rather, Noramco and the FDA agreed to a timetable for producing low-ABUK oxycodone API. (PTX 272; James 11/4/2011 Dep. 167:24–168:02.) Noramco's

development adhered to that timetable. (James 6/15/2012 Dep. 31:04–33:12.) In the meantime, the FDA did not halt the manufacture or sale of oxycodone API with higher ABUK levels by any company with FDA approval. (Wuest 2012 Tr. 531–32; PTX 267 at 6.)

It is true that Rhodes produced low-ABUK oxycodone API faster than its competition did. As of March 2004, Rhodes's competitors' oxycodone API contained 800 ppm to 2,400 ppm 14-hydroxy. (*See* Kelly 2012 Tr. 509–11; PTX 262 at P2454892–93; PTX 304.) By November 2004, Rhodes had reduced its levels to less than 10 ppm. (PTX 269 at P2376232.) But Noramco's slower production schedule is not evidence of failures along the way, and it does not necessarily indicate any particular difficulty of reducing 14-hydroxy in oxycodone API.

c) The Court finds no evidence of long-felt but unaddressed need.

The record contains no meaningful evidence of long-felt but unmet need for low-ABUK oxycodone. Kupper testified that he and others suspected early on in their work at Rhodes "that there might be a regulatory action around [14-hydroxy]" because structurally similar compounds were "known to be genotoxic." (Kupper 2012 Tr. 127–28.) At the time, however, the FDA imposed no regulatory requirement on oxycodone API manufacturers. This status changed only in late 2003, when the FDA began to communicate its concern about ABUK levels in oxycodone API. (*See e.g.*, PTX 241; PTX 265; PTX 266.) Rhodes swiftly met the FDA's goal,

commercializing its low-ABUK process within the year.

d) The art did not expect the existence of 8α, but as a stereoisomer 8α has expected properties.

8α was unknown in the prior art: its very existence was unexpected. Before the inventors' work, the art described 8β as 8,14-dihydroxy. No prior art before the Court recognized 8α as by-product of oxidized thebaine or assumed that such an isomer must have existed. (Wuest 2012 Tr. 1291–92; DTX 727.)

Whereas the existence of 8α was unexpected, the properties of 8α were not unexpected. The evidence showed a difference between 8α and 8β: 8α would react under the same hydrogenation conditions as 8β, but it would react more rapidly. (Heathcock 2012 Tr. 1162–64.) And 8α would react under conditions in which 8β would not. (Wuest 2012 Tr. 1295–97.) The Court finds these differences would not have surprised an ordinary skilled artisan familiar with the arrangement of the atoms in isomers such as 8α and 8β. Heathcock credibly testified that the structural difference between 8α and 8β—especially the different orientations of particular atoms in each respective isomer—suggests to a skilled artisan that 8α should be more sensitive than 8β to acid-catalyzed dehydration. (Heathcock 2012 Tr. 1144–47.) Wuest, who disagreed with Heathcock, made the point that knowing the orientation of a particular hydroxyl group does not allow a skilled artisan to "make a confident prediction about the relative reactivities" of the isomers. (Wuest 2012 Tr. 1304–05.) He justified

this purported uncertainty on possible variations in the orientation of the compound as a whole. (*Id*.) But the fact that one might not have predicted reactivities with confidence does not mean that 8α's relatively greater reactivity amounted to an unexpected result. (*See* DTX 1033 at P3084214 ("[8β] and [8α] are different compounds and are expected and do have different properties.").)

The Court further finds that 8α-derived 14-hydroxy has no unexpected properties. Oxycodone obtained from 14-hydroxy is the same regardless of the source of the 14-hydroxy. (Heathcock 2012 Tr. 1124–26.)

e) Others recognized that Purdue identified the 8α isomer.

In 2007, Noramco filed a patent application for a "Process for Preparing Oxycodone Having Reduced Levels of 14-hydroxycodeinone." *See* U.S. Patent No. 7,906,647. Noramco identified the patents-in-suit as prior art and cited them as disclosing 8α as a by-product of thebaine oxidation. (PTX 221.) The Court finds that this evidence amounts to recognition in the industry that the inventors of the patents-in-suit had identified 8α.

II. Conclusions of Law

A. Infringement

1. Teva's ANDA infringes claims 30–34 and 76–79 of the '800 Patent.

As construed by the Court, claim 1 of the '800 Patent calls for:

> (1) A process for preparing an oxycodone salt API substantially free of 14-hydroxy, which process comprises (2) preparing a mixture of oxycodone free base, solvent and an acid, the oxycodone free base having an 8α component; (3) incubating the mixture under conditions suitable to convert the oxycodone free base to any salt of oxycodone, wherein said conditions promote an acid-catalyzed dehydration consisting of conversion of the 8α component to [14-hydroxy]; and (4) preferentially removing the [14-hydroxy] from the oxycodone salt.

OxyContin Claim Construction, 2013 WL 2509633, at *22. Claim 30 calls for an "[o]xycodone salt prepared according to the process of claim 1" and therefore depends from claim 1. Dependent claim 31 further limits the salt of claim 30 to oxycodone hydrochloride. Dependent claims 32, 33, and 34 restrict the amount of 14-hydroxy present in the oxycodone hydrochloride salt to less than 25 ppm, 15 ppm, and 10 ppm, respectively.

Claim 57 recites a process similar to claim 1, except that it includes a step "reducing an amount of the [14-hdyroxy] formed in [the incubating step] to produce an oxycodone salt composition having less than 25 ppm [14-hydroxy]." Claim 76 calls for "[o]xycodone salt prepared according to the process of

claim 57" and therefore depends from claim 57. Dependent claim 77 limits the salt of claim 57 to oxycodone hydrochloride. Dependent claims 78 and 79 further limit the amount of 14-hydroxy present in oxycodone hydrochloride salt to less than 25 ppm and 15 ppm, respectively.

On the basis of the facts found above, the Court finds that it is more likely than not that Teva's ANDA infringes claims 30–34 and 76–79 of the '800 Patent.

Teva's tablets use an oxycodone API substantially—but not entirely—free of 14-hydroxy prepared according to the process of claim 1 and therefore infringe claim 30. (Wuest 2012 Tr. 588–92, 599–603; PTX 207; DTX 939.) These proposed tablets will, moreover, use "oxycodone hydrochloride" salt and therefore infringe claim 31. (Wuest 2012 Tr. 603; DTX 939.) They will contain a non-zero amount of 14-hydroxy less than 25 ppm, 15 ppm, and 10 ppm and therefore infringe claims 32, 33, and 34. (Wuest 2012 Tr. 603; DTX 939.)

Teva's tablets will use an oxycodone API substantially—but not entirely—free of 14-hydroxy prepared according to the process of claim 57 and therefore infringe claim 76. (Wuest 2012 Tr. 589–92, 603–04; DTX 939.) The proposed tablets will further use oxycodone hydrochloride and therefore infringe claim 77. (Wuest 2012 Tr. 604–05; DTX 939.) The proposed tablets will contain less than 15 ppm 14-hydroxy and therefore infringe claims 78 and 79. (Wuest 2012 Tr. 605; DTX 939.)

2. Teva's ANDA infringes claims 1, 4, and 5 of the '072 Patent.

As construed by the Court, claim 1 of '072 Patent requires (1) oxycodone hydrochloride API, (2) containing more than zero and less than 25 ppm 14-hydroxy, and (3) some of the 14-hydroxy present in the API must have been derived from 8α. Dependent claims 4 and 5 incorporate the limitations of claim 1, but specify lower levels of 14-hydroxy (less than 15 ppm and less than 10 ppm, respectively).

On the basis of the facts found above, the Court finds that it is more likely than not that the ANDA at issue infringes claims 1, 4, and 5 of the '072 Patent. Teva's tablets will use Noramco oxycodone hydrochloride API. (2013 Stip. ¶¶ 85, 88, 110, 112.) The oxycodone hydrochloride API will contain an amount of 14-hydroxy greater than zero but less than 10 ppm. (Wuest 2012 Tr. 589–92, 605–06; DTX 939.) A portion of the 14-hydroxy present in the oxycodone API will have been derived from 8α. (Wuest 2012 Tr. 605.)

3. Teva's ANDA infringes claims 3 and 19 of the '799 Patent.

As construed by the Court, claim 3 of the '799 Patent requires (1) an oral dosage form (2) containing "from about 5 mg to about 320 mg of oxycodone hydrochloride" API, (3) the presence in the oxycodone hydrochloride of more than zero and less than 25 ppm 14-hydroxy, (4) some of which must have been derived from 8α "during conversion of oxycodone free base to oxycodone hydrochloride," and (5) a pharmaceutically acceptable excipient. Claim 19 depends from claim 3, and therefore incorporates its

elements, but further calls for the "acceptable excipient" to be a "sustained release carrier."

On the basis of the facts found by the Court, Teva's ANDA infringes claims 3 and 19 of the '799 Patent. The tablets proposed in the ANDA constitute oral dosage forms, they contain 5 mg to 320 mg of oxycodone hydrochloride, and they include a sustained release carrier as an excipient. (Wuest 2012 Tr. 606–07.) The oxycodone hydrochloride API contains more than zero and less than 25 ppm 14-hydroxy, and some portion of the 14-hydroxy is derived from 8α during the formation of oxycodone hydrochloride. (*Id*. at 589–92, 607.)

4. Teva's use of the Noramco API constitutes an act of infringement.

At the 2012 trial, Actavis challenged Purdue's infringement case on the grounds that Actavis did not itself practice the Noramco manufacturing steps that contribute to the infringement of the patents. But *Abbott Laboratories v. Sandoz, Inc.*, 566 F.3d 1282 (Fed. Cir. 2009) (en banc), on which Actavis relied for that arguement, does not require that the entity selling the infringing product be the same entity that practices the process steps of the invention. *See id*. 566 F.3d at 1296. Use of the infringing products made by a patented process brings Teva within the scope of the patent statutes. *See* 35 U.S.C. § 271(a); Herbert F. Schwartz & Robert J. Goldman, Patent Law & Practice 183–84 (7th ed. 2011); *cf. FieldTurf Int'l, Inc v. Sprinturf, Inc.*, 433 F.3d 1366, 1369–70 (Fed. Cir. 2006). Because Noramco practices the relevant process steps, Teva's sale of tablets that will use Noramco's API will

infringe a patented product. *See* 35 U.S.C. § 271(a), (g); *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 483–84 (1964).

B. Obviousness pursuant to 35 U.S.C. § 103

Teva principally attacks the validity of the asserted claims on the ground that they lack the nonobviousness required by 35 U.S.C. § 103. For the purposes of validity, the Court considers only the product limitations of a claim, not process limitations or source limitations that add no patentable significance to the end product. *See In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985). The asserted claims of the '799 , '072, and '800 Patents are product-by-process claims.[6] Therefore, the Court assesses the validity of the low-ABUK oxycodone API product—and its various purity and oral dosage form limitations—not oxycodone API with 14-hydroxy obtained from 8α.

1. The invention would have been obvious to a skilled artisan.

Having set forth factual findings on the scope and content of the prior art, the differences between the prior art and the claimed invention, the level of ordinary skill in the art, and the secondary indicia of

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[6] At the claim construction stage, the parties stipulated that the asserted claims of the '800 Patent are product-by-process claims (Pfs.' Opening Claim Construction Br., Case No. 11 Civ. 2038, Dkt. No. 90, filed June 17, 2013, at 38–39; Defs.' Opening Claim Construction Br., Case No. 11 Civ. 04694, Dkt. No. 52, filed June 6, 2013, at 4–5), and in its Claim Construction Order and Opinion the Court concluded that the asserted claims of the '072 and '799 Patents are also product-by-process claims, *OxyContin Claim Construction* 2013 WL 4509633, at *25–26.

nonobviousness, *see supra*, section I.D, the Court concludes that the patented products are obvious.

At the time of the invention, an ordinary skilled artisan would have known that the FDA desired low-ABUK oxycodone API. The FDA communicated its desire to those in the industry, explicitly setting a 14-hydroxy limit so low that no manufacturer could immediately meet it. Further, at the time of the invention, a skilled artisan had command of the techniques necessary to convert 14-hydroxy to oxycodone. These techniques had been used both for the purpose of synthesis and for the purpose of purification. The scientists at Rhodes deployed the technique of hydrogenation for its known purpose and in pursuit of the product the FDA required the market to produce. To their credit, Rhodes's scientists succeeded. But their success, borne of common sense and guided by routine experimentation, is not "more than [a] predictable use of prior art elements according to their established functions." *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 417 (2007). The product claimed by their patents is therefore invalid as obvious.

a) Skilled artisans had a reason to develop low-ABUK oxycodone API.

A skilled artisan would have been motivated to produce low-ABUK oxycodone. Not only had the scientific community suspected the possibility of regulatory action around ABUKs for some time (*see* Kupper 2012 Tr. 129–32), but also over the course of 2003 and 2004 the FDA had recognized a need for manufacturers to eliminate impurities in oxycodone,

see Chapman v. Casner, 315 F. App'x 294, 297 (Fed. Cir. 2009). The FDA communicated to Rhodes, Purdue, Noramco, and others that it would require oxycodone API manufacturers to produce low-ABUK oxycodone API. (*E.g.*, PTX 266.)

b) It would have been obvious to a skilled artisan to hydrogenate at or during the salt formation step.

Faced with the problem of excess 14-hydroxy in oxycodone API compositions, ordinary skilled artisans would have considered solving the problem by using hydrogenation. Indeed, Heathcock testified that hydrogenation was a basic technique in organic chemistry: "I used to teach a course for introductory organic chemistry students. If I had given this problem on one of my midterm exams—Here's an oxycodone and here's an impurity, how would you solve this problem?—I would say all 100 students would come up with the same answer: Hydrogenation." (Heathcock 2012 Tr. 1160.)

The evidence supports Heathcock's boast. 14-hydroxy contains a carbon-carbon double bond. Adding molecular hydrogen—H^2—to a compound with a carbon-carbon double bond causes each carbon atom to pair with a hydrogen atom and to form a single bond between the two carbon atoms. (*Id.* at 1161–62; Kupper 2012 Tr. 125.) In the case of 14-hydroxy, the addition of the hydrogen molecule transforms 14-hydroxy into oxycodone. (Heathcock 2012 Tr. 1161–62.) Thus, hydrogenation of 14-hydroxy achieves two goals simultaneously: (1) it removes an impurity (14-hydroxy) and (2) it creates more of the desired compound (oxycodone). An

ordinary skilled artisan would not have overlooked the possibility that hydrogenation could solve the problem of excess 14-hydroxy.

c) It would have been "obvious to try" to use hydrogenation after the salt formation step.

Purdue's argument in favor of nonobviousness rests on its view that the prior art taught *away* from a final, rather than intermediate, hydrogenation step. When a prior art reference "teaches away" from the inventors' path by pointing toward a "divergent" path, that reference is less likely to render a claim obvious. *See In re Kubin*, 561 F.3d 1351, 1357 (Fed. Cir. 2009). According to Purdue, prior art such as Chiu taught toward a solution based on oxycodone free base and would have discouraged a solution based on hydrogenation of a salt made from a free base. The evidence has demonstrated otherwise.

Purdue's argument does not rest on a chemical distinction between hydrogenation of an oxycodone intermediate and hydrogenation during or after the oxycodone salt formation step. Indeed, Purdue did not introduce evidence that 14-hydroxy would behave any differently when hydrogenated during or after the final salt formation step rather than during or after an intermediate step. Nor could it have. The evidence demonstrated that oxycodone has no carbon-carbon double bond and is therefore inert to hydrogenation. (Wuest 2012 Tr. 615–16.) Thus, hydrogenating a mixture containing substantially oxycodone would not affect the oxycodone molecules but would affect any present 14-hydroxy molecules. Chiu illustrated this point when he repeatedly

hydrogenated an oxycodone acetate mixture to increase the percentage of oxycodone present. (*See* DTX 741.) Thus, Chiu confirms, rather than undercuts, the intuition that hydrogenation would solve the excess 14-hydroxy problem.

What distinguishes Purdue's solution from the prior art, and Chiu in particular, is the *sequence* of its process steps. Unlike Chiu, Purdue used hydrogenation to convert 14-hydroxy to oxycodone during or after salt formation and not solely to form an oxycodone free base. More or less, Purdue's arguments to the Examiner distinguished Chiu in this way. (*See* PTX 10 at P1052803–04; PTX 11 at P1034148–49; PTX 12 at P1045682–83.) Thus, according to Purdue, recognition of 8α as a source of 14-hydroxy in oxycodone salts permitted the inventors to conclude that the application of a hydrogenation step after a salt formation step would produce low-ABUK oxycodone. The Court does not agree.

First, the Court finds the discovery of 8α to be immaterial to the low-ABUK product claimed by the patents. As a matter of law, the 8α-derived limitation of the asserted product claims is disregarded as a process limitation. *See SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1316–17 (Fed. Cir. 2006). As a matter of fact, identification of a source of the 14-hydroxy in the end product does not have any effect on the structure or nature of the end product. One molecule of 14-hydroxy is the same as the next, whether derived from 8α or 8β. (Heathcock 2012 Tr. 1124–25.) And low-ABUK oxycodone formed from 8α-derived 14-hydroxy is the

same as low-ABUK oxycodone formed from 8ß-derived 14-hydroxy molecules. (*Id*. at 1126.)

Second, 8α proved largely irrelevant to the process used by Purdue to obtain the product claimed by the patents. Purdue's low-ABUK process hinges on hydrogenation—not on 8α. Nonetheless, Purdue urges that "understanding [ ] where the 14-hydroxy compound is coming from is critical to understanding how to get rid of it." (Wuest 2012 Tr. 1307.) Given that hydrogenation converts 14-hydroxy into oxycodone regardless of its source, Purdue's distinction is practical rather than chemical. (*Id*. at 1342–43.) For example, the inventors' knowledge of 8α defined a universe of possible 8α-specific processes to achieve low-ABUK oxycodone. Rider testified that Purdue contemplated filtering out 8α from the oxycodone free base or altering the oxidation step to minimize the formation of 8α. (*See* Rider 2012 Tr. 219–21.) The inventors' 8α knowledge did not make hydrogenation more or less effective as a technique for converting 14-hydroxy to oxycodone. And nothing about the claimed products—essentially, low-ABUK oxycodone API—has any feature tied to 8α.

At bottom, Purdue's reliance on 8α-derived 14-hydroxy underscores its impoverished view of the capacity of the ordinary skilled artisan at the time of the invention. According to Purdue, that skilled artisan would not have considered a second hydrogenation step until he or she discovered that 14-hydroxy was reappearing from 8α and not being carried through from an earlier step. If the challenge facing the art was to decide where in the synthetic scheme to add hydrogenation, the nature of the problem yielded a finite number of identified,

predictable solutions. That one of those solutions achieved the desired result does not indicate that the invention is anything other than the product of ordinary skill and common sense. *KSR Int'l Co.*, 550 U.S. at 416. The inventors' path illustrates the point. They first changed the conditions of the initial hydrogenation step on the theory that the most obvious source of the 14-hydroxy was 14-hydroxy carried over from the oxidation step. When that did not work, they attempted to hydrogenate the oxycodone salt. Not surprisingly, one of the inventors explained: "Once the mechanism of formation was known, the hydrogenation was the first thing that popped into my mind." (Kupper 2012 Tr. 197.)

The success of the inventors' path would have been apparent at the time of the invention. Whether or not it was most obvious to focus on the initial hydrogenation reaction, it at least would have been obvious to try to hydrogenate after the salt formation step, too. After all, the Court must keep in mind that "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton." *KSR Int'l Co.*, 550 U.S. at 421. This principle applies doubly when, as here, the ordinary skilled artisan is highly trained and educated. In sum, at the time of Purdue's claimed invention, "a skilled artisan would have been motivated to combine the teaching[s] of the prior art references to achieve" low-ABUK oxycodone API. *OSRAM Sylvania, Inc. v. Am. Induction Techs., Inc.*, 701 F.3d 698, 706 (Fed. Cir. 2012) (quotation marks omitted).

d) The patent claims extend to the obvious, even if they could be practiced in a nonobvious way.

Invoking the rule that "[o]bviousness cannot be predicated on what is unknown," *In re Newell*, 891 F.2d 899, 901 (Fed. Cir. 1989), Purdue insists that it could not have been obvious to, for example, use alcohol rather than acid during the second hydrogenation step or raise the pH of the final solution to prevent the dehydration of additional 8α . (*See* PTX 3 at Examples 1, 2, and 3.) To the same effect, Purdue relies on the fact that the patent discloses a method for detecting 14-hydroxy at extremely low levels. (*See id*. at Examples 4 & 6.) Those features might have been relevant to show nonobviousness if the asserted claims had recited them. The claims, however, simply recite an oxycodone API and tablet substantially free of 14-hydroxy. *Cf. Kubin*, 561 F.3d at 1356 (noting that patentee of obvious product could not distinguish its product on the basis of unclaimed process differences).

Moreover, it would have been obvious to a person of skill to identify conditions suitable to cause 8β to convert to 14-hydroxy, as the Federal Circuit has already concluded. *See Chapman*, 315 F. App'x at 297–98. The Court does not accept that the specification's particular hydrogenation mixtures would have been beyond the ken of the skilled artisan because the patent's only direct explanation of the conditions under which 8α converts to 14-hydroxy is "during salt formation reactions known in the art." (*E.g.*, PTX 3 at 8:07–10.) Those reaction conditions were known to cause dehydration of 8,14-dihydroxy. (*See* DTX 727 (Weiss); Heathcock 2012 Tr. 1141–42.)

Therefore, a skilled chemist could choose reaction conditions for hydrogenation that accounted for a chemical reaction known to the art.

The Court agrees that with its knowledge of 8α Purdue had the capability to practice its claims in a way that would have been nonobvious. That is, Purdue could practice its claims by tailoring them to 8α. "What matters," however, "is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103." *KSR Int'l Co.*, 550 U.S. at 419. Instead of claiming 8α directly, Purdue claimed low-ABUK oxycodone API in various forms. Its contribution to the science of that reaction was to identify additional explanations for why known techniques, used for their known purpose, would create the product. Invention requires something more. *Gen. Elec. Co. v. Jewel Incandescent Lamp Co.*, 326 U.S. 242, 249 (1945) ("It is not invention to perceive that the product which others had discovered had qualities they failed to detect.").

e) The secondary considerations do not demonstrate nonobviousness.

The secondary considerations offered by Purdue do not make the evidence on obviousness less than clear and convincing. No commercial success can be attributed to low-ABUK oxycodone API as Purdue never marketed OxyContin on the basis of its low-ABUK features. Nor can the Court conclude that because Noramco did not develop low-ABUK oxycodone API sooner, it had been trying and failing to do so. Nor does the record disclose any long-felt, unmet need for low-ABUK oxycodone. The evidence demonstrated a need for low-ABUK oxycodone, to be

sure, but once the FDA established a low-ABUK target, Rhodes promptly met it.

The other secondary evidence does not tilt the analysis in Purdue's favor. The record reveals that Noramco has recognized that Purdue identified 8α as a by-product of thebaine oxidation and that Purdue developed its low-ABUK product first. The Court concludes that this evidence has little weight in demonstrating the nonobviousness of the claimed invention. As to Purdue's identification of 8α, the invention does not claim 8α. As to Purdue's timing in the development of low-ABUK oxycodone salt, the Court notes that no manufacturer made low-ABUK oxycodone until the FDA required it. Moreover, if Purdue is correct and low-ABUK oxycodone was nonobvious to a skilled artisan, then whichever company first achieved the FDA's purity limit would have had a patentable product. The Court is skeptical.

2. The asserted claims are invalid pursuant to 35 U.S.C. § 103.

Based on the forgoing, the Court concludes that Teva has demonstrated by clear and convincing evidence that claims 30–34 and 76–79 of the '800 Patent are obvious:

- As construed by the Court, claims 30 and 76 call for an oxycodone API substantially free of 14-hydroxy. How to produce such a product would have been obvious to an ordinary skilled artisan. Prior art OxyContin, among other references, teaches how to create oxycodone API. Chiu and Ramanathan taught to hydrogenate an oxycodone salt to

remove 14-hydroxy. A skilled artisan would have been motivated to apply the known technique of hydrogenation to a final oxycodone salt to form an oxycodone API substantially free of 14-hydroxy.

- Claims 31 and 77 add the limitation that the oxycodone API be hydrochloride. Oxycodone hydrochloride is one of the most common forms of salt for oxycodone and it would have been obvious to a skilled artisan to produce oxycodone hydrochloride API. (*See* Heathcock 2012 Tr. 1137, 1151.)
- Claims 32–34 and 78–79 add purity limitations. It would be obvious to a skilled artisan to meet those purity limits by using hydrogenation and, as Chiu illustrated, repeat that hydrogenation if necessary to complete the reaction. (*Id*. at 1137–38, 1130–31; *see also* Wuest 2012 Tr. 1356 (Chiu resulted in "oxycodone acetate salt" that is "substantially free of 14-[hydroxy].").)

The Court concludes that Teva has demonstrated by clear and convincing evidence that claims 1, 4, and 5 of the '072 Patent are obvious:

- As construed by the Court, the product of claim 1 is oxycodone hydrochloride API having less than 25 ppm. The process and source limitation of claim 1—that the product be achieved through a reaction of 8α to form 14-hydroxy—adds no patentable significance for the purposes of validity. *See In re Thorpe*, 777 F.2d 695, 697–98 (Fed. Cir. 1985). A skilled artisan could achieve this product by

combining well-known oxycodone hydrochloride teachings with Chiu's demonstration that low-ABUK levels can be achieved in an oxycodone salt mixture. Applying hydrogenation to oxycodone hydrochloride to obtain a 25 ppm purity level would have been obvious.

- As construed by the Court, claims 4 and 5 recite purity levels of 15 ppm and 10 ppm, respectively. Achieving these purity levels would have been obvious in light of Chiu.

The Court concludes that Teva has demonstrated by clear and convincing evidence that claims 3 and 19 of the '799 Patent are obvious:

- As construed by the Court, claim 3 of the '799 Patent calls for an oral dosage form comprising (1) 5 mg to about 320 mg of oxycodone hydrochloride (2) having less than 25 ppm 14-hydroxy and a pharmaceutically acceptable excipient. Other than the low-ABUK oxycodone hydrochloride, the other elements of claim 3 were obvious in light of prior art OxyContin. (*See*, *e.g.*, PTX 2 at 1:29–32.) Moreover, creating oral dosage forms of this sort would have been routine to a skilled artisan. (Heathcock 2012 Tr. 1151.) As to the low-ABUK oxycodone hydrochloride, such a composition would have been obvious in light of Chiu.
- As construed by the Court, claim 19 calls for the product of claim 3, but specifies that the pharmaceutically acceptable excipient is a sustained release carrier. This type of oral

dosage form would have been routine to a skilled artisan (*id.*), and would have been obvious in light of prior art OxyContin.

The party challenging a patent's validity "must demonstrate by clear and convincing evidence that the invention would have been obvious to a person of ordinary skill in the field of the invention at the time the invention was made." *In re Rosuvastatin Calcium Patent Litig.*, 703 F.3d 511, 517–18 (Fed. Cir. 2012). Because Teva has met that burden here, the Court declares the asserted claims of the '799 , '800, and '072 Patents invalid as obvious.

C. Invalidity pursuant to 35 U.S.C. § 112.

Teva has attempted to prove that Purdue has violated the "written description" and "enablement" clauses of 35 U.S.C. § 112.

1. The written description of the '799, '800, and '072 Patents satisfies 35 U.S.C. § 112.

The invention that must be adequately described is measured by the asserted claims. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1565 (Fed. Cir. 1991). The claims of the '800 Patent incorporate a process for preparing an oxycodone salt substantially free of 14-hydroxy. The claimed process requires incubating oxycodone free base, acid, and a solvent under conditions suitable to convert 8α to 14-hydroxy. The asserted claims of the '072 Patent concern oxycodone hydrochloride API with low levels of 14-hydroxy, wherein at least a portion of the 14-hydroxy was derived from 8α. The asserted claims of the '799 Patent concern an oral dosage form of the same product.

Teva does not challenge the adequacies of the disclosure of the API or the oral dosage form limitations. (Defs.' Post-Trial Mem. dated Nov. 6, 2013 [hereinafter Teva Mem.] at 40–43; *cf.* Wolf 2012 Tr. 1002–06.) Rather, Teva focuses on 8α. (Teva Mem. at 41.) Each patent includes Figure 1, which illustrates the claimed synthetic scheme—including the creation of 8α as a byproduct of the oxidation of thebaine. Figure 2 discloses that 8α will dehydrate to form 14-hydroxy in the presence of acid. And the patent invokes prior art references to disclose that 8,14-dihydroxy converts to 14-hydroxy "[d]uring salt formation reactions known in the art." (PTX 3 at 8:4–10.) Teva contends that these disclosures are insufficient to demonstrate (1) the creation of 8α in Purdue's synthetic scheme or (2) its later conversion into 14-hydroxy. The Court disagrees.

As to the first issue—the creation of 8α—the Court credits the testimony of Wuest that Figure 1 discloses to a person of ordinary skill in the art that the over-oxidation of thebaine leads to 8α. (*See* Wuest 2012 Tr. 1269–70, 1328–29.) True, the specification does not disclose a pH range at which 8α will or will not form. (*See* Rider 2012 Tr. 278–79; Wuest 2012 Tr. 1330–31.) Nor does it identify a method for detecting 8α. (*See* Kupper 2012 Tr. 191; Wuest 2012 Tr. 1324–25.) But the description recites the chemical structure of 8α and the nature of the reaction that produces it. That recitation, combined with references to prior art oxidation schemes (PTX 3 at 1:34–40), suffices to convey that the inventors possessed the invention.

As to the second issue—the conditions supporting the conversion of 8α to 14-hydroxy—the description in Figure 2 is meager, but the Court cannot say that

the evidence clearly and convincingly shows deficient disclosure. The patents' written description does not explicitly identify conditions that transform 8α, but not 8β, into 14-hydroxy. (*See*, *e.g.*, Rider 2012 Tr. 278.) But Wuest testified that Example 3 of the specification demonstrates to a skilled artisan conditions that convert 8α into 14-hydroxy. (Wuest 2012 Tr. 1258.) Wuest further explained that a skilled artisan "would understand that the 8β compound is essentially inert under these conditions and would not undergo this acid-induced transformation." (*Id.*) As explained above, plaintiffs' attempts to show 8β's reactivity in such conditions miss the mark, principally because they extrapolate from a reaction in 6N HCl to conclude that a reaction occurs in 2N HCl. *See supra*, section I.B.3. The Court credits Wuest's testimony on this point. Moreover, Teva has not persuaded the Court that the absence of test data calls into question whether 8α converts into 14-hydroxy. In light of the Weiss reference invoked by the patent itself, a skilled artisan would know that 8,14-dihydroxy compounds dehydrate into 14-hydroxy. (Wuest 2012 Tr. 1289–91; DTX 727.) Indeed, that is what Figure 2 shows.

The Court accepts that Rider and Kupper, two of the named inventors, had additional information that convinced them of 8α's role in the reappearance of 14-hydroxy. (*See*, *e.g.*, Kupper 2012 Tr. 144–47, 164–67; Rider 2012 Tr. 250–51.) But the fact that the inventors could have provided more information in their written description does not render inadequate the description they did provide. Similarly, the fact that 8α, as distinct from 8,14-dihydroxy, appears only three times in the patents' written description does

not lessen the value of the two drawings that disclose it. Indeed, there is no magic number of times a particular feature must be disclosed to satisfy Section 112. *See In re Dossel*, 115 F.3d 942, 946 (Fed. Cir. 1997).

In sum, the Court cannot agree with Teva that clear and convincing evidence demonstrates that the written description of the '800 Patent fails to "reasonably convey[ ] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). The Court does not have the abiding sense, based on the specification, that the patent describes a mere wish or plan for obtaining a process for making low-ABUK oxycodone API or oral dosage forms of the same product. *Cf. Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1351 (Fed. Cir. 2011) (describing asserted claims as a wish list for a product that patentee did not have).

2. The patents meet the enablement requirement of 35 U.S.C. § 112.

Teva challenges whether the low-ABUK patents "teach[ ] those in the art enough that they can make and use the invention without undue experimentation." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1335 (Fed. Cir. 2003). Teva focuses its enablement argument on 8α. According to Teva, the specification does not enable a

skilled artisan to synthesize 8α, detect it, or monitor its conversion to 14-hydroxy.[7] (Teva Mem. 41–43.)

The Court cannot agree that Teva has proven the specification to be non-enabling by clear and convincing evidence. First, the level of skill in the art is high. As the Court has found, a skilled artisan is a Ph.D. chemist with experience in organic and synthetic chemistry. Second, the patent provides adequate direction and guidance that such a skilled artisan could practice the claimed invention. For example, the specification identifies 8α, its molecular structure, and the nature of the reaction that produces it. (Wolf 2012 Tr. 1008–11, 1021; Wuest 2012 Tr. 1251, 1269.) And the specification identifies that 8α forms during oxidation reactions disclosed in the prior art. (Wolf 2012 Tr. 994–95). Third, the specification includes a working example where 8α converts to 14-hydroxy in the presence of acid. (Wuest 2012 Tr. 1254–57; *see* PTX 3 at Example 3.) This information would allow a skilled artisan to practice the inventions as claimed.

Teva has not persuaded the Court that the patent is invalid for failing to communicate the conditions under which isomers of 8,14-dihydroxy, including 8α, will or will not form. Figure 1 illustrates conditions under which 8α will form. (Wolf 2012 Tr. 990–91, 1018–19; Wuest 2012 Tr. 1251–52, 1269–70.) And

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[7] To the extent that anyone doubts whether the patents enable the remainder of the claims—reducing 14-hydroxy levels in oxycodone salt, forming low-ABUK API, and incorporating low-ABUK API into an oral dosage form—the Court rejects that argument. The patents provide ample guidance as to those claims and recite working examples, solutions, and compositions.

the patent invokes prior art references to establish when 8,14-dihydroxy—including 8α—will form. (PTX 3 at 1:35–63.) Again, that information allows a skilled artisan to practice the invention as claimed. The Court notes that the written description of the patent does not teach when the oxidation of thebaine will not form 8α and therefore when a given synthetic scheme does not practice the patent's claims. Nevertheless, the Court cannot conclude that the absence of that information constitutes non-enablement.

Additionally, Teva has not persuaded the Court that a skilled artisan would need to undertake extensive experimentation to test for 8α and to synthesize a reference sample. Indeed, the Court does not conclude that a skilled artisan would need to isolate 8α or synthesize a reference standard to practice the claims of the patents. Rather, the evidence demonstrated that inference and routine experimentation suffice. The Court takes Rider's experiments as a persuasive counterexample: Rider conducted a relatively simple experiment in which he analyzed the oxycodone hydrochloride synthesis process, discovering that the levels of 14-hydroxy rose after salt formation, the levels of an unknown compound fell, and that 8β remained constant. (Rider 2012 Tr. 211–19; PTX 312 PTX 331; PTX 332; PTX 386.) HPLC analysis confirmed the compound to be a stereoisomer of 8β. The tools of Rider's experiment—and the sense to use them—were within the reach of an ordinarily skilled artisan. (Wolf 2012 Tr. 1026–27.)

Finally, the Court finds that the process of synthesizing 8α did not require undue

experimentation in any event. One of the expert witnesses at the 2012 trial, Dr. Christian Wolf, testified that isolating an 8α reference standard "would be quite a lot of work." (Wolf 2012 Tr. 976–77.) But Wolf later testified that all of the techniques one would use to isolate 8α were within the reach of a skilled artisan. (*Id*. at 1021–23.) And, in practice, Dr. Alfred Avey, an organic chemist, managed to isolate 8α after a mere two failed experiments and "a good 15 days worth of work." (Avey 2012 Tr. 340–41.) For such a sophisticated discipline, the Court concludes that fifteen days' work is not undue. Avey's initial projection that the work would take even less time than it took and cost even less money than it cost does not persuade the Court otherwise. (*See id*. at 326–27.)

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Therefore, the Court concludes that Teva has not demonstrated by clear and convincing evidence that the patents-in-suit fail the disclosure requirements set forth in 35 U.S.C. § 112.

D. Collateral estoppel does not apply.

Finally, Teva asserts that Purdue is collaterally estopped from taking the position that the asserted claims are valid due to the result of a prior interference before the Board of Patent Appeals and Interferences. Teva argues that the Chapman Application—the subject of the interference—is not materially different from the asserted claims. (Defs.' Reply Post-Trial Mem. dated Nov. 27, 2013, at 17–18.) As noted above the Board found the asserted claims of the Chapman Application and the Casner patent all invalid as obvious. *See supra*, section B.1. The

Federal Circuit affirmed this decision. Drawing on this result Teva contends that Purdue is collaterally estopped from prosecuting this lawsuit.

"Collateral estoppel, or issue preclusion, prevents parties or their privies from relitigating in a subsequent action an issue of fact or law that was fully and fairly litigated in a prior proceeding." *Marvel Characters, Inc. v. Simon*, 310 F.3d 280, 288 (2d Cir. 2002). "Because the application of collateral estoppel is not a matter within the exclusive jurisdiction of" the Federal Circuit, a district court applies the law of its local court of appeals—in this case, the U.S. Court of Appeals for the Second Circuit. *Vardon Golf Co., Inc. v. Karsten Mfg. Corp.*, 294 F.3d 1330, 1333 (Fed. Cir. 2002) (quotation marks omitted). The Second Circuit has elaborated four requirements for collateral estoppel to apply:

> (1) the identical issue was raised in a previous proceeding; (2) the issue was actually litigated and decided in the previous proceeding; (3) the part[ies] had a full and fair opportunity to litigate the issue; and (4) the resolution of the issue was necessary to support a valid and final judgment on the merits.

Wyly v. Weiss, 697 F.3d 131, 141 (2d Cir. 2012) (quotation marks omitted, alteration in original). As to the first element, the Federal Circuit has counseled that collateral estoppel may still be available if "'the issue of invalidity common to each action is substantially identical . . . .'" *Purdue Pharma L.P. v. Ranbaxy Inc.*, No. 10 Civ. 3734, 2012 WL 3854640, at *3 (S.D.N.Y. Sept. 5, 2012) (quoting

Westwood Chem., Inc. v. United States, 525 F.2d 1367, 1372 (Ct. Cl. 1975)).

But "issues are not identical when the legal standards governing their resolution are significantly different." *Computer Assocs. Int'l, Inc. v. Altai, Inc.*, 126 F.3d 365, 371 (2d Cir. 1997); *see also* Restatement (Second) of Judgments § 28(4). At the 2012 trial, Purdue adduced from defense expert Gerald Bjorge that in the interference, Casner, as the junior party, bore the burden of establishing the invalidity of the Chapman Application by only a preponderance of the evidence. (Bjorge 2012 Tr. 1103.) Bjorge correctly stated the law on this issue. *See Velander v. Garner*, 348 F.3d 1359, 1369–70 (Fed. Cir. 2003); *Bruning v. Hirose*, 161 F.3d 681, 686 (Fed. Cir. 1998). In the present actions, by contrast, the patents-in-suit are accorded a presumption of validity that can be overcome only on the basis of clear and convincing evidence. *See In re Baxter Int'l, Inc.*, 678 F.3d 1357, 1364 (Fed. Cir. 2012) ("[A] challenger that attacks the validity of patent claims in civil litigation has a statutory burden to prove invalidity by clear and convincing evidence . . . . In contrast, in PTO reexaminations the standard of proof—a preponderance of the evidence—is substantially lower than in a civil case." (citations and internal quotation marks omitted)). The difference in the two standards precludes collateral estoppel.

The cases Teva cites to dispute this point miss the mark. In *Kosakow v. New Rochelle Radiology Assocs., P.C.*, 274 F.3d 706 (2d Cir. 2001), the Second Circuit was discussing the New York State law of collateral estoppel—not the federal standard applicable in this action. *See id.* at 732. The same is true of the non-

precedential *Constantine v. Teachers College*, 448 F. App'x 92, 94–95 (2d Cir. 2011). And *Coakwell v. United States*, 292 F.2d 918 (Ct. Cl. 1961), addressed the finality element, not whether the issue in a subsequent proceeding was identical to the issue adjudicated in the prior action. *See id*. at 920.

Therefore, even assuming that the invalid claims in the Chapman Application are identical or substantially similar to the claims in issue in this action, the substantial difference between the legal standards applied prevents this Court from applying collateral estoppel.

III. Conclusion

The dispute over the low-ABUK patents concerns the line between patentable invention and commendable improvement. The three patents at the center of this dispute describe an improved oxycodone API product containing less of the 14-hydroxy impurity than any oxycodone API available at the time of the invention. This product is an improvement but not an invention. Low-ABUK oxycodone stood within reach of any person of ordinary skill with the desire to use routine science and common sense to improve the existing oxycodone API product.

The key to the invention rests with using a hydrogenation step during or after the salt-formation step. Hydrogenation transforms 14-hydroxy molecules to oxycodone molecules. Organic chemists have known this for decades. But manufacturers of oxycodone, such as Rhodes, had traditionally used one hydrogenation step at an earlier stage in the synthesis process. What stood between existing

oxycodone products and low-ABUK oxycodone API was not a technical barrier or challenge of chemistry, but rather the insight to use hydrogenation twice to solve the same problem.

Purdue holds out 8α as its contribution to the art. And, indeed, identifying 8α was genuine insight. But the evidence overwhelmingly proved that 8α imparts no significance to the structure of 14-hydroxy. It imparts no distinguishing characteristics to oxycodone. And it imparts no significance to the product claimed by the patents. Knowledge of 8α permits a skilled artisan to understand why 14-hydroxy reappears in a synthetic scheme with a salting step. But knowledge of 8α does not explain how to fix the problem. The solution has everything to do with hydrogenation, and that solution would have been obvious to a person of skill in the art, whether that person knew of 8α or not.

In summary, the Court concludes that Purdue met its burden to show that Teva's ANDA infringes each of these three patents. The Court concludes, however, that Teva has demonstrated by clear and convincing evidence that each of the asserted claims is invalid as obvious pursuant to 35 U.S.C. § 103. Accordingly, the Court finds in Teva's favor on its counterclaim of invalidity.

The Court does not find the patents-in-suit otherwise invalid. Because Teva did not demonstrate that a single prior art reference included each limitation of the patents-in-suit, Teva did not prove the patents lacked novelty pursuant to 35 U.S.C. § 102. Further, Teva did not demonstrate by clear and convincing evidence that the written description

of the patents was inadequate to demonstrate that Purdue actually invented what it claimed it had or that the description did not enable others to practice the claimed invention. Finally, Purdue was not estopped from contesting the obviousness of its claims.

PART 3. THE ABUSE-PROOF PATENTS

I. Factual Background: Abuse of OxyContin became tragically rampant, generating a public health crisis and responses.

Opioid analgesics have provided therapeutic pain relief to ailing patients for centuries. (*See* Sellers 2013 Tr. 79.) And for centuries, some people have abused opioids, either consuming more of the drug than they medically need or without any legitimate medical need at all. (*See id.*) In the past two decades, the United States has seen a sharp rise in the abuse of prescription opioids, to such an extent that the FDA considers opioid abuse and misuse "a public health epidemic." (PTX 2157 at 4; *see generally* PTX 2189.) In 2010, prescription opioid overdoses accounted for greater than three-quarters of all prescription drug overdose deaths in the United States, amounting to 16,651 deaths. (PTX 2157 at 4.) Among the prescription opioids at the center of that epidemic has been OxyContin, viewed by abusers as "a suitable substitute for heroin." (PTX 2147 at 1.)

The same attributes that made OxyContin beneficial for legitimate patients also made it attractive to abusers. What OxyContin added in pharmaceutical value was its aggregate strength and extended release profile, providing sustained pain relief over an extended period of time. (Sellers 2013 Tr. 81–82.) It combined several doses worth of oxycodone—a powerful opioid—into a single tablet that released the oxycodone over time. (*Id.*) Thus, a twelve-hour extended-release OxyContin tablet holds twice as much oxycodone as a six-hour oxycodone

tablet does, and it releases the active drug over twice as long a time period. (*See id*.)

Original OxyContin was susceptible to tampering, since abusers could crush the tablets easily into powder, which resulted in the time release aspect of the formulation being destroyed and the opioid being released at once. If the abuser snorted the powder, or dissolved the powder into a liquid and injected the solution intravenously, then the abuser would experience an opioid "high." (PTX 2189 at 222, 224.) The first wide-scale public acknowledgements of the trend of OxyContin abuse came in 2001, from the Department of Justice (*see* Sellers 2013 Tr. 82–83; PTX 2147) and from OxyContin's manufacturer, Purdue (*see* Sellers 2013 Tr. 100; PTX 2148). By 2003, the College of Problems on Drug Dependence referred to the "substantial amount of public attention" paid to OxyContin abuse, and it noted a significant increase in abuse, especially in 2001 (the most recent year for which it had complete data). (PTX 2189 at PRF0022167.)

If the bad news was the rising tide of OxyContin abuse, then the countervailing good news was the capacity of the public health community, law enforcement, and policymakers to address the problem. As Dr. Edward Sellers explained at trial, "[d]rug abuse is an open economy," because abusers have the ability to switch their drug of choice relatively easily. (Sellers 2013 Tr. 97.) In such a market, even small changes can shift behavior: introducing an obstacle or cost to abuse of a particular drug can marginally suppress abuse of that drug, relative to others. (*Id*.) And indeed, proposed responses abounded. Policymakers, for

example, turned to increased penalties for OxyContin-related crimes. (PTX 2147 at 5.) Substance abuse doctors suggested design changes to the tablets that would make them more difficult to abuse or that would alter the API's chemical reactions if abused. (PTX 2189 at 222, 224–25.)

In the early 2000s, Purdue sat awkwardly at the intersection of strong profits from OxyContin sales (*see* PTX 2667) and public concern over the rampant abuse of the drug (*see*, *e.g.*, Sellers 2013 Tr. 100; PTX 2148). In 2001, Purdue and the FDA changed the label of Original OxyContin to warn doctors about the potential for abusers' tampering with the dosage form. (Sellers 2013 Tr. 100–01; PTX 2148.)

Meanwhile, Purdue investigated ways to reformulate OxyContin to deter abuse. It had begun to develop abuse-deterrent technologies in the 1990s. Those initial efforts focused on other frequently abused drugs besides OxyContin; and they focused on addressing other methods of abuse besides snorting and injecting. (Kaiko 2013 Tr. 139.) When the abuse of Original OxyContin drew Purdue's attention in 2001, its research and development team considered (among other ideas) creating a tablet that would be difficult to crush and difficult to syringe. (*Id*. at 554–56.) But Purdue's in-house efforts led to dead ends while the OxyContin abuse debacle grew in salience. (*Id*. at 143.) Purdue began to search for technologies invented elsewhere. (*Id*.)

In 2003, Purdue became aware of technology developed at Grunenthal GmbH that gave tamper-resistant properties to tablets. (*Id*. at 146–47.) The Grunenthal technology made tablets extremely hard

(in order to prevent crushing) and formed a gel upon dissolution in water (in order to prevent injecting). (*Id*. at 147; Mannion 2013 Tr. 182–83; PTX 2301 at 1–2.) A Purdue representative visited Grunenthal's facilities in Achen, Germany, and was impressed at the projects. (PTX 2301 at 1–2.) After further due diligence on Purdue's part (*see* PTX 2309), Grunenthal and Purdue began a series of "long and tough" multi-year negotiations that led eventually to a license agreement for Purdue to use Grunenthal's technology. (Strassburger 2013 Tr. 272; *see* PTX 2177.)

Purdue submitted a New Drug Application to the FDA in November 2007, proposing a Reformulated OxyContin. (PTX 2424 at PRF2397743.) The FDA initially rejected the NDA. (*Id*.) The rejection letter suggested further studies that might overcome the deficiencies in the NDA. (*Id*. at PRF2397743–45.) Purdue obliged, conducting seven further *in vitro* studies and producing thousands of pages of results. (Weingarten 2013 Tr. 236–38.) Those studies went into an "NDA re-submission package" in March 2009. (*Id*.; *see also* PTX 2137.) At a September 2009 briefing to the FDA Advisory Committee, Purdue explained the results, calling Reformulated OxyContin an "incremental improvement" but conceding that the impact of the abuse-proof formulation would remain unknown until it hit the market. (Weingarten 2013 Tr. 246; *see* PTX 1941.) In April 2010, the FDA approved Reformulated OxyContin. (Weingarten 2013 Tr. 246; PTX 2132.)

Four months later, in August 2010, Reformulated OxyContin launched. (Weingarten 2013 Tr. 247.) The market debut of Reformulated OxyContin was

not marked by any fanfare, because the FDA would not approve any changes to the drug's label until after it saw the real-world effects of the new formulation. (Sellers 2013 Tr. 95; Weingarten 2013 Tr. 248–51.) As Russell Gasdia, Purdue's Vice President for Sales and Marketing, explained, when Purdue first introduced Reformulated OxyContin on the market "if a health care professional asked what was different between the reformulation [and] the original, the most the [sales] rep could say is the intent of the reformulation was to minimize abuse through manipulation, but that until the package insert reflected any specific information, there was nothing else they could share." (Gasdia 2013 Tr. 485.) This official silence on abuse deterrence did not mean that the market was completely ignorant: third-party analysts, trade journals, and a press release described the changes to the formulation. (*Id*. at 485.)

Almost immediately upon Reformulated OxyContin's entrance in the market, Purdue and the FDA began the task of designing a post-marketing epidemiological study to understand the new product's real-world effectiveness at deterring abuse. (Weingarten 2013 Tr. 247–50.) Purdue undertook several long-term studies, and it began sending regular updates to the FDA. (*Id*. at 250.) By July 2012, those updates noted reductions in OxyContin's diversion, abuse, and street price. (*Id*.; PTX 2134.) Although abusers tried to evade the abuse-deterrent properties of the drug (Rao 2013 Tr. 1615–16), the more significant trend was abusers' substituting other opiates in the place of OxyContin (*id*. at 1614; PTX 2732).

On April 16, 2013, the FDA withdrew its approval for Original OxyContin and stopped accepting ANDAs that proposed generic versions of it. (PTX 2157 at 7.) The FDA reasoned that, with Reformulated OxyContin available to provide the same benefits with lower risks of abuse and misuse, "the benefits of [O]riginal OxyContin no longer outweigh its risks." (*Id.*) On the same day, the FDA approved a new label that finally allowed Purdue to market Reformulated OxyContin on the basis of its abuse-deterrent properties. (*See* PTX 2133.)

The technology underlying these abuse-deterrent properties arises from a variety of fields that surround pharmaceutics and chemical engineering. Thus, for purposes of the abuse-proof patents, a person of ordinary skill in the art has an advanced degree and substantial experience drawn from the fields of medicine, chemical engineering, polymers, pharmaceutical sciences, pharmaceutics, pharmacokinetics, and pharmacology. (*See* Davies 2013 Tr. 1646; Muzzio 2013 Tr. 1369–70.)

II. The '383 Patent: Thermoforming Technology

Purdue argues that Teva's ANDA infringes claims 1, 2, 5, 7, and 8 of the '383 Patent. Because of the patent's heavy reliance on the concept of a "thermoformed dosage form" (*see* PTX 1602 at 1:6–7, 2:8, 21:2) this patent has been known informally as "the Thermoforming Patent." As the Court has construed it, claim 1 discloses:

> 1. A dosage form that is formed by the application of pressure to the components with the

simultaneous or preceding application of heat comprising:

i) one or more active ingredients with abuse potential (A) selected from the group consisting of opiates and opioids,

ii) optionally physiologically acceptable auxiliary substances (B),

iii) at least [60%] by weight of polyalkylene oxide (C) having a molecular weight of 1–15 million according to rheological measurements, and

iv) optionally at least one wax (D),

wherein said dosage form has a breaking strength of at least 500 N and wherein the active ingredient with abuse potential (A) is present in a controlled release matrix of component (C).

OxyContin Claim Construction, 2013 WL 4509633, at *15. Although the PTO issued the '383 Patent with the limitation "at least 30% by weight of polyalkylene oxide" (*see* PTX 1602 at 21:8), the parties have stipulated that the patent actually claims "at least 60% by weight of polyalkylene oxide" (2013 Stip. ¶ 30(e)).

The other claims at issue are:

2. The dosage form according to claim 1, which is in the form of a tablet.

. . .

5. A process for the production of a dosage form according to claim 1, said process comprising mixing components (A), the optionally present component (B), component (C) and the optionally present component (D) to form a

> mixture and, optionally after granulation, press-forming the mixture with preceding, simultaneous, or subsequent exposure to heat.
>
> . . .
>
> 7. A dosage form obtained by the process of claim 5.
>
> 8. The dosage form according to claim 1, wherein the active ingredient with abuse potential (A) is oxycodone or a physically acceptable salt thereof.

(PTX 1602 at 21:15–16, 22:3–8, 22:11–14.)

By contrast to claim 1, which discloses either the simultaneous application of heat and pressure or a sequence of heat followed by pressure, Teva's process applies pressure first and heat second. Teva's proposed tablets therefore include the "thermoformed" claim limitation only if its manufacturing process is equivalent to thermoforming.

A. Teva's ANDA infringes the '383 Patent

1. Grunenthal's search for abuse-deterrent formulations led it to a thermoformed, PEO-based tablet.

As the opioid abuse crisis bloomed at the turn of the Twenty-First Century, the German pharmaceutical company Grunenthal began to research abuse resistance properties for its opioid product, tapentadol. (Bartholomaeus 2013 Tr. 379–83, 393–94.) At the time, Dr. Johannes Bartholomaeus was the head of pharmaceutical development for Grunenthal. (*Id.* at 379.) At his direction, Grunenthal scientists considered an array of abuse deterrence strategies, resulting in a

brainstorming list that reads like a macabre litany of tortures: additives that, upon abuse, would prompt such side effects as micro-embolisms or blocked blood vessels. (*Id*. at 390–93; *see* PTX 2456 at 3.)

A critical moment in Grunenthal's development of an abuse-deterrent formulation came in October 2002, when Johnson & Johnson proposed a joint venture with Grunenthal, using Johnson & Johnson's osmotically controlled-release oral delivery system (known by the acronym "OROS") to deter abuse of tapentadol. (Bartholomaeus 2013 Tr. 393–95.) The OROS technology takes the form of a tablet whose outer shell limits the flow of the API from an inner core, with the help of a "push compartment" in the tablet that expands to force the API through the outer shell. (*Id*. at 395.) The OROS system uses high molecular weight polyethylene oxide ("PEO") in the hard outer shell. (*Id*. at 399–400.) Bartholomaeus became dissatisfied with the design's effectiveness at tamper resistance, however, when he found that he could easily crush the OROS tablet manually with a mortar and pestle. (*Id*. at 395–99.)

The Grunthenal team set out to strengthen tapentadol's dosage form by making the entire tablet—not merely its outer shell—resistant to crushing. (*Id*. at 399–400.) As Bartholomaeus tells it, his arrival at the basic invention was easy and intuitive: "And so we thought we'd take this high molecular weight [PEO] that was in [OROS's] push layer, but not containing the drug, and then do an intimate mixture of the drug with this high molecular weight [PEO], include it in a matrix tablet that releases then the drug ...." (*Id*. at 400.) In other words, whereas OROS used two separate layers—an

inner layer with the API and a hard outer layer with the high molecular weight PEO—Bartholomaeus thought to combine them into a tablet that contained a matrix of API and PEO throughout the tablet.

PEO's appeal came from its structure. A molecule of polyethylene oxide is, as the name implies, many iterations of ethylene oxide. (Zhang 2013 Tr. 331–33.) The molecular weight of the PEO depends on how many repeating units of ethylene oxide are on the molecular chain. (*Id*.) A company can be picky about its PEO, choosing its molecular weight by lining up more or fewer units of ethylene oxide. PEOs of high molecular weight (*i.e.*, greater than one million Daltons) have two key advantages: first, an API encased in a matrix of high molecular weight PEO releases from the PEO at a sustained rate over time (PTX 2359 at 133), and second, a high molecular weight PEO with its correspondingly longer molecular chain of ethylene oxides allows for more cohesion between the PEO particles and thus a stronger solid after the PEO particles are heated and cooled (*see* Davies 2013 Tr. 690 (calling the "PEO chains" a "strong mechanical strap")).

Bartholomaeus's team set to work. Critically, Bartholomaeus's early experimentation with PEO demonstrates the different results that follow from different ways of heating PEO. When he was interested in seeing how PEO responded to heat, Bartholomaeus set a small mound of PEO on a hot plate. (Bartholomaeus 2013 Tr. 404–05.) Despite the heat applied to the PEO there, the PEO did not form an especially hard solid. (*Id*.) By contrast, when Bartholomaeus's team heated the PEO at the same time as pressing it in dies, that process "increase[d]

th[e] contact area between the particles" and thereby "form[ed] a strong scaffold." (*Id.* at 405.) Once that scaffold formed between the cooled PEO particles, the resulting solid resisted breaking by a hammer, by a mortar and pestle, and even by a breaking strength test that exerted 500 Newtons (500N) of force. (*Id.*) Further testing demonstrated that applying simultaneous heat and pressure also provided a controlled release of an API from the tablet. (*Id.* at 406.)

Thus, Grunenthal had found a process for manufacturing crush-resistant tablets. The company's management team approved the design after seeing firsthand that neither a hammer nor a mortar and pestle could crush the PEO-based, simultaneously heated and compressed tablets. (*Id.* at 410–11.) The technology gave rise to the '383 Patent. (*See* PTX 1602; Bartholomaeus 2013 Tr. 412.) Johnson & Johnson forsook its OROS technology and obtained a license from Grunenthal that involved joint product development. (Kraus 2013 Tr. 458–60; PTX 2569 at 59–64; *see* Bartholomaeus 2013 Tr. 417–18.) A similar license issued to Endo Pharmaceuticals. (Kraus 2013 Tr. 458–59; PTX 2568 at 18–35.) Purdue, by contrast, was uninterested in a joint development project and opted instead to obtain a license limited to Grunenthal's intellectual property, which Purdue would then use in developing its own products. (Strassburger 2013 Tr. 270–72; PTX 2177.)

The agreement gave Purdue the right to use the technologies disclosed in scores of patents and patent applications, including at least ten U.S. patents. (PTX 2177 at 12–19.) The list of the licensed patents and patent applications occupies nearly four pages of

the agreement. (*Id*. at 7–11). That list includes the '314 and '383 Patents. (*Id*. ¶¶ 1.1.19(i)(a)(6), (i)(f)(9).) Purdue has paid Grunenthal approximately $161.2 million in royalties pursuant to the terms of the license, including $64.2 million in 2012 alone. (PTX 2163.) It has also paid Grunenthal approximately $64.8 million for certain regulatory milestones having been met, of which $43.6 million relate to milestones achieved in the United States. (PTX 2164; *see* Strassburger 2013 Tr. 272, 283–84.)

2. Teva compresses and then cures its tablets, making them extremely hard.

Teva's ANDA provides information about the proposed method for manufacturing its generic tablets. (*See* PTX 2013 § 2.3.P.3 ("Manufacture").) The proposed tablets include a PEO—specifically Sentry Polyox WSR301—of the same grade as Purdue uses in its Reformulated OxyContin. (*Id*. at 2–3; Mannion 2013 Tr. 213; Davies 2013 Tr. 686.) That PEO represents between 69% and 89% of each tablet, varying based on the dosage strength of the tablet. (PTX 2013 at 3.) Like Purdue, Teva also adds a small amount of magnesium stearate as a lubricant. (*Id*. at 2–3; Davies 2013 Tr. 687.) And of course Teva's tablets include the API, the oxycodone hydrochloride itself. (PTX 2013 at 2–4.) The ANDA refers to the combination of these ingredients—after some blending and sieving—as the "final blend." (*Id*. at 38.)

After creating the final blend, Teva compresses it in a rotary tablet press. (PTX 2002 at TV0023115–21; Maurin 2013 Tr. 1222.) This compression step lasts for less than one second (Muzzio 2013 Tr. at 1405),

and the product is a "tablet core." (PTX 2013 at 42.) The tablet core has the shape and compactness of a tablet. (*See* Bartholomaeus 2013 Tr. 415; Zhang 2013 Tr. 332.) Critically, up to this point Teva applies no heat. (Davies 2013 Tr. 824.)

Finally, the tablet cores enter a large drum called a "vector coater" or a "perforated pan coater." (Maurin 2013 Tr. 1222–23; PTX 2013 at 43–49.) The pan coater is a 55- or 80-liter cylinder, rotating at an angle, like a gigantic clothes dryer tipped upward toward the ceiling. (Maurin 2013 Tr. 1223; PTX 2013 at 42.) The tablets undergo two processes in the pan coater: curing and film-coating. (Maurin 2013 Tr. 1223–24; PTX 2013 at 42.) Curing heats the tablets; film-coating paints them. (Davies 2013 Tr. 691; Mannion 2013 Tr. 200; PTX 2013 at 42.) In order to cure the tablets, hot air blows through the pan coater. (Davies 2013 Tr. 691, 706–07.) When Teva cures its tablets, air enters the pan system at 75°C and leaves the system at 70°C. (PTX 2013 at 43-49; Davies 2013 Tr. 706–07.) The curing lasts for 60 minutes. (PTX 2013 at 43–49; Davies 2013 Tr. 707.) After that curing period, the pan coater is "cooled until an exhaust temperature of about 30°C [is] achieved." (PTX 2013 at 42.) The tablets then receive a cosmetic coating, which is color-coded to indicate each tablet's dosage strength. (*Id*.)

The products of Teva's manufacturing process are sustained-release oxycodone hydrochloride tablets. (PTX 2002 at TV0022582.) Moreover, breaking strength tests performed on Teva's tablets show that they are extremely hard, as they withstand breaking strengths up to 500N. (*See* Davies 2013 Tr. 786–87; PTX 2070; PTX 2071.)

3. Comparing Teva's process to that of the '383 Patent, the asserted claims read on Teva's tablets.

Teva's process does not literally practice claim 1's limitation, as construed, of "the application of pressure to the components with the simultaneous or preceding application of heat." *See OxyContin Claim Construction*, 2013 WL 4509633, at *15; *cf. id.* ("Pressure and prior or simultaneous heat are simply the essence of the claimed invention."). The question before the Court, then, is whether the proposed tablets infringe under the doctrine of equivalents—whether Teva's compress-then-cure sequence is substantially the same as thermoforming

The Court credits Dr. Martyn Davies's opinion that Teva's proposed tablets are substantially equivalent in way, function, and result to thermoformed tablets.[8] (*See* Davies 2013 Tr. 770). The point of thermoforming in the '383 Patent is to melt and cool the PEO in a manner that creates a dense scaffolding

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[8] By contrast, the Court cannot credit Maurin's explanation as to why Teva's tablets are substantially different from thermoformed tablets. Maurin justifies how the compression step *alone* differs from thermoforming, but he does not explain how the compression and curing steps as a process differs from thermoforming. (Maurin 2013 Tr. 1227.)

Nor can the Court give weight to Muzzio's opinion that the accused process differs from thermoforming because thermoforming "results in *fast* fusing of the particles." (Muzzio 2013 Tr. 1409 (emphasis added).) The disparate speeds at which the fusion occurs, as between Teva's process and thermoforming, is an insubstantial distinction in the way of the invention. The slower fusion in Teva's process does not alter any meaningful aspect of the process.

structure, thereby imparting to the tablet a breaking strength of at least 500N. The point of Teva's compress-then-cure sequence is to melt and cool the PEO to create a dense scaffolding structure, thereby imparting on each tablet a breaking strength of at least 500N. These twin statements encapsulate the function, way, and result of the claim limitation and of Teva's manufacturing process.

Function.— The function of thermoforming is to fuse the PEO in order to create a scaffolding structure among the PEO. (*See id*. at 770–71.) PEO's centrality to the technology arises from the hardening property of a high molecular weight polymer that has been heated and cooled. (*See*, *e.g.*, Bartholomaeus 2013 Tr. 405, 413–16; Davies 2013 Tr. 729, 770–74; Banakar 2013 Tr. 973; Muzzio 2013 Tr. 1381, 1386, 1409.) But, as Bartholomaeus learned through the failed experiment of heating a loose pile of PEO on a hot plate, temperature alone does not create this scaffolding. (*See* Bartholomaeus 2013 Tr. 404–05.) Rather, the temperature affects the PEO as desired only when the PEO particles are in close contact—for example, as a consequence of thermoforming or of pressure applied before curing. The Court finds that there is no substantial difference between the function of the '383 Patent's thermoforming and the function of Teva's compress-then-cure sequence.

Way.— The way in which thermoforming advances that function involves the melting of the PEO, with the PEO particles pressed against each other to maximize fusion upon melting. (*See* Davies 2013 Tr. 771.) This way relies on two actions: (1) sufficiently heating the PEO particles, and (2) sufficiently

pressing them against each other. The work of these two actions happens at once (or with the heat preceding the pressure) in the '383 Patent. The work of these two actions happens with the pressure preceding the heat in Teva's process. But that distinction is not substantial, because the work is the same, melting PEO with increased contact in service of the function. The Court therefore finds that there is no substantial difference between the way of thermoforming under the '383 Patent and the way of compressing before curing in Teva's process.

Result.— The result of thermoforming is the 500N breaking strength of the tablet produced. (*See id.*) In fact, Bartholomaeus testified that Grunenthal opted for thermoforming over the compress-then-cure sequence precisely because the Grunenthal team did not believe that a compression-curing sequence could achieve this 500N breaking strength. (Bartholomaeus 2013 Tr. 432–33; *see* DTX 1921 at 2 ("[R]egular tabletting process with a subsequent curing process . . . [r]esult[s] [in] tablets hav[ing] a hardness of less than 500N.").) Yet Teva's tablets share the '383 Patent's extraordinary breaking strength of at least 500N. (*See* Davies 2013 Tr. 786–87; PTX 2070; PTX 2071.) The hardness of Teva's tablets, like the hardness of a tablet produced by thermoforming under the '383 Patent, is a result of the scaffolding structure among the PEO. (Davies 2013 Tr. 773–74.)

Teva's proposed process is therefore equivalent to thermoforming. The only distinction between them—the splitting or swapping of steps on a flow chart—is not meaningful to the function, way, or result of the claim limitation.

There is hardly any dispute as to whether the other limitations of the asserted claims read on Teva's proposed tablets. Teva's tablets contain oxycodone hydrochloride, an opioid. (2013 Stip. ¶¶ 106, 119.) The PEO that makes up more than 60% of Teva's tablets is a viscosity-increasing agent. (Davies 2013 Tr. 742, 841; 2013 Stip. ¶ 117.) And that PEO forms a controlled release matrix in which the oxycodone API is suspended. (2013 Stip. ¶ 120.) Moreover, Teva's product is a tablet (*id.* ¶ 109), a dosage form made by a process that involves combining the ingredients, press-forming them, and subsequently exposing them to heat. (*See* PTX 2013 at 42.)

All limitations of claims 1, 2, 5, 7, and 8 of the '383 Patent therefore read on Teva's tablets. The Court concludes that Teva's tablets infringe those claims.

B. The '383 Patent is invalid as anticipated and obvious.

1. The McGinity Application anticipates the '383 Patent.

Long before Bartholomaeus's fateful experiment with PEO on a hot plate, two scientists at the University of Texas developed a hot-melt extrusion process for the manufacture of sustained-release tablets that comprised mainly PEO. (*See generally* Zhang 2013 Tr. 319–47.) The scientists, Dr. James McGinity and Dr. Feng Zhang, developed their formulation in 1995; memorialized their work in an application to the World Intellectual Property Organization, published on December 31, 1997 (*see* DTX 2562); and later received the '963 Patent for their invention (*see* PTX 1600). (*See* Zhang 2013 Tr.

342–43.) This Court has previously construed claim 1 of the '963 Patent[9] as disclosing:

> 1. A controlled release pharmaceutical formulation, which is not a film or comprised of layered films, comprising an effective amount of a therapeutic compound and a high molecular weight poly(ethylene oxide), wherein the poly(ethylene oxide) has a molecular weight of about 1,000,000 to about 10,000,000 Daltons, and wherein the poly(ethylene oxide) and the therapeutic compound comprise a ratio, by weight, of poly(ethylene oxide) to therapeutic compound of from about 99.99:.01 to about 50:50, with the poly(ethylene oxide) comprising at least 50% of the formulation.

OxyContin Claim Construction, 2013 WL 4509633, at *8. Claim 6 further discloses "[t]he non-film controlled release pharmaceutical formulation of claim 1 wherein said formulation is prepared by a process of hot-melt extrusion." (PTX 1600 at 14:51–53.)

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[9] Purdue asserted the '963 Patent against other generic manufacturers at the 2013 trial, and several parties disputed the meaning of terms in claim 1 during the claim construction phase. Those generic manufacturers have all resolved their actions with consent judgments. (*See* Case No. 11 Civ. 2038, Dkt. No. 131; Case No. 11 Civ. 2400, Dkt. No. 147; Case No. 11 Civ. 4694, Dkt. No. 124; Case No. 12 Civ. 5082, Dkt. No. 43; Case No. 12 Civ. 5615, Dkt. No. 52.) Purdue's allegations against Teva do not extend to the '963 Patent, because Teva has not submitted a Paragraph IV certification challenging that patent. (*See* 2013 Stip. ¶ 32.) Nonetheless, the Court draws from the extensive trial evidence regarding the disclosures of the '963 Patent.

The '963 Patent claims priority from the McGinity Application (*id*. at (60); *see* DTX 2562), and the parties agree that the McGinity Application is prior art to the '383 Patent (2013 Stip. ¶ 184). Yet the parties disagree as to whether it discloses all of the limitations of the asserted claims of the '383 Patent.

a) The McGinity Application's disclosures.

At the heart of the McGinity Application and the '963 Patent lies hot-melt extrusion. That process comprises little more than a screw, rotating inside a cylinder, pushing any material inside the cylinder forward until that material passes through a die at the cylinder's end. (*See generally* Zhang 2013 Tr. 320-22, 358–59, 364–65.) In a pharmaceutical application, the process starts by blending an active drug with a polymer. That combined material enters one end of an extruder, a long barrel with a large rotating screw inside. Within the extruder, the material heats up, both because (1) shear friction is generated by the screw's pushing against it and (2) the barrel is heated. (*Id*. at 364–65; Davies 2013 Tr. 918–19.) As the screw's rotation forces the mixture lengthwise through the barrel, the friction and heat increase and the component materials continue to mix together. At the far end of the barrel, the mixture—now molten by the heat and friction—passes through a circular die. (Davies 2013 Tr. 919.) The die shapes the material into a rod. (Zhang 2013 Tr. 358–59.) Before that rod cools and hardens, it is cut into the desired shape. As for possible shapes, the McGinity Application specifically discloses that "the pharmaceutical formulation may be in the form

of a . . . tablet" among other options. (DTX 2562 at 13:21–22.)

When McGinity and Zhang investigated the use of a hot-melt extrusion process with polymer-based mixtures, they considered it a risky endeavor, because many polymers are susceptible to chemical degradation at high temperatures yet a polymer must reach a high temperature in order to flow through the extruder. (Zhang 2013 Tr. 328–29.) In order to mitigate the risk of chemical degradation while ensuring a sustained release of the API, McGinity and Zhang selected high molecular weight PEO as their polymer. (*See id*. at 333–35.)

High molecular weight PEO represents the lion's share of McGinity and Zhang's disclosed formulation. In fact, out of six examples in the McGinity Application, five of them include greater than 60% PEO, with the PEO ranging in molecular weight from one million Daltons to seven million Daltons. (*See* DTX 2562 at 19:11–34; Block 2013 Tr. 1292.) Such a large proportion of PEO is necessary because the PEO "forms a matrix having especially useful properties for use in a sustained release dosage form." (DTX 2562 at 6:20–21.) The purpose of the PEO is to form a "polymer matrix of the formulation" in which "[t]he therapeutic compound may be . . . suspended." (*Id*. at 8:6–7.) In addition to the PEO and the API, further ingredients in the disclosed formulations may include an optional plasticizer and "[o]ther components." (*Id*. at 11:18–21.)

McGinity and Zhang successfully used hot-melt extrusion with a PEO-based formulation. Their process fabricated tablets with slower release profiles

than tablets made through the traditional process of (heatless) direct compression. (Zhang 2013 Tr. 337–38; *cf.* PTX 2359 at 159.) Their research was not specific to opioids or to the goal of abuse deterrence, with the inventors' stated goals addressing only a controlled-release mechanism that could later "be applicable to a very broad range of different drugs." (Zhang 2013 Tr. 339–40.)

Even though McGinity and Zhang's work was not dedicated to opioids, the McGinity Application discloses that its formulation can include opioids. The McGinity Application explicitly notes the use of its process with analgesics to treat pain. (DTX 2562 at 8:11–12, 16, 20). In doing so, the Application lists specific analgesics (and it does not list opioids), but the prefacing words "such as" and the residual words "and the like" (*Id.* at 8:20) demonstrate that the Application discloses a broader group of analgesics than merely those specifically listed (*see* Block 2013 Tr. 1296; DTX 4135 at McGinity Dep. Tr. 332). Moreoever, the McGinity Application is directed primarily to sustained-release dosage forms, and the Court credits Dr. Lawrence Block that every analgesic on the market in a sustained-release form at the time of the McGinity Application was an opioid. (Block 2013 Tr. 1298–99.) The McGinity Application's reference to analgesics therefore includes opioids, and a person of ordinary skill in the art would understand as much. (*Id.* at 1296; DTX 4135 at McGinity Dep. Tr. 332; *compare* DTX 1459 at 1018 (discussing nonopioid analgesics) *with* DTX 1459 at 1019 (discussing opioid analgesics).) Therefore, the McGinity Application discloses a

dosage form comprising, among other ingredients, opioids.

In the same way, the McGinity Application also disclosed the use of its technology with ingredients that are susceptible to abuse. (*See* Block 2013 Tr. 1308–09.) A person of ordinary skill in the art would understand the McGinity Application as referring to opioids, and opioids have abuse potential. (*Id*. at 1309; Sellers 2013 Tr. 78–80.) Even more specifically, the Court credits Block that a person of ordinary skill in the art would have thought of an oxycodone API upon reading the Application, due to oxycodone's prominence in prescription, use, and abuse, compared to the other opioids that the Application might have referred to. (Block 2013 Tr. 1299.)

Of all the McGinity Application's disclosures, the most hotly debated among the parties is the breaking strength of the claimed formulation. The McGinity Application does not say that its tablets have any particular breaking strength, but it inherently discloses a breaking strength in excess of 500N. The pivotal evidence in this regard is a series of breaking strength tests that Dr. Fernando Muzzio performed in preparation for this litigation. Muzzio thermoformed thousands of tablets according to the McGinity Application disclosures. (Muzzio 2013 Tr. 1399–1400) He used a variety of chemical compositions, extruder temperatures, screw speeds, and die diameters. (*Id*.) He tested a vast number of the resulting tablets, and without exception they withstood forces greater than 500N. (DTX 1549; Muzzio 2013 Tr. 1383–85, 1400.) In fact, Muzzio often exerted forces in the thousands of Newtons and

never had a tablet break. (DTX 1549; Muzzio 2013 Tr. 1400.)[10]

In contrast with this persuasive experimental evidence, plaintiffs have not put forward any evidence that any tablet produced according to the McGinity Application can ever break when a force of 500N is applied to the tablet. Instead, they attack Muzzio's breaking strength results. They say that his tablets are not fair replications of the McGinity Application because he did not determine whether his extruder differed from the extruders available at the time of the McGinity Application; but Muzzio carefully ensured his equipment did not materially differ from McGinity and Zhang's equipment, even consulting the manufacturer of McGinity and Zhang's equipment on that question. (*See* Muzzio 2013 Tr. 1377.) Plaintiffs say that Muzzio's failure to measure the extruder's torque undercuts his results; but because torque is not an input or setting in the extrusion process, the lack of torque data does not

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[10] Consistent with Muzzio's findings is a letter from McGinity himself to the European Patent Office ("EPO") in opposition to the '383 Patent's European counterpart. (DTX 4056.) McGinity explained to the EPO that he had made tablets according to the McGinity Application and tested their breaking strength, observing no breaking after applying 500N of force. (DTX 4056 at 1; *see* Block 2013 Tr. 1303–05.) He reported that he also sent his tablets to an outside laboratory, which found that the tablets did not break even "at pressures up to 2.5kN." (DTX 4056 at 1.) But in extruding the tablets for these tests, McGinity used different parameters—for example, a twin screw instead of a single screw—than the McGinity Application taught. (*See*, *e.g.*, Banakar 2013 Tr. 1090; Muzzio 2013 Tr. 1400.) McGinity's deviations from his own Application undermine the reliability of those breaking strength tests as direct evidence of inherency.

affect the reliability of Muzzio's process as a replication of the McGinity Application's process. (*See id*. at 1378–79.) Plaintiffs say that Muzzio's extrudate exhibited less "die swell" than did McGinity's extrudate—in other words, that as Muzzio's formulation exited the die of the hot-melt extruder, it formed a rod of smaller diameter than McGinity's—but the McGinity Application does not include a die swell measurement (*see* DTX 2562), leaving plaintiffs to rely on die swell measurements that are themselves based on different extruder parameters than those used in the McGinity Application (*compare* Muzzio 2013 Tr. 1500–01; PTX 2361 at 243 (die diameter of six millimeters), *with* Muzzio 2013 Tr. 1379–80; DTX 2562 at 18:24–25 (die diameter of one centimeter)). The Court credits Muzzio that he recreated the McGinity Application's process fairly, accurately, and with no material variation.

Plaintiffs next attack Muzzio's breaking strength testing, saying that Muzzio provided too little documentation to support his opinions. But Muzzio has supplemented his own credibility with abundant documentary support in the form of raw data (*see*, *e.g.*, DTX 1548), photographs (*see*, *e.g.*, DTX 1549), and force curves (*see*, *e.g.*, DTX 7014). In short, these attacks do not seriously lessen the weight the Court assigns to Muzzio's vast empirical results and credible opinion on the inherency of a 500N breaking strength. The Court finds that the McGinity Application inherently discloses a breaking strength greater than 500N, because the experimental results indicate unanimously, reliably, clearly, and convincingly that any tablet made according to the

McGinity Application would exhibit this characteristic.

b) Every limitation in the asserted claims of the '383 Patent is in the McGinity Application.

The '383 Patent claims a dosage form with specific characteristics. A comparison of those characteristics with the disclosures of the McGinity Application reveals how extensively the two overlap.

Where the '383 Patent claims "[a] thermoformed dosage form" (PTX 1602 at 21:2), the McGinity Application deals with "hot-melt extrudable pharmaceutical formulations" (DTX 2562 at 1:8–9). The process of hot-melt extrusion undoubtedly constitutes thermoforming, because the extruder heats the material in order to push it through a die to form a rod shape.

Where the '383 Patent further claims "[a] dosage form obtained by the process of claim 5" (PTX 1602 at 22:11), the McGinity Application discloses the same by noting that the product of its hot-melt extrusion "may be easily . . . tableted . . ." (DTX 2562 at 11:30–31). Where the '383 Patent claims the form of a tablet (PTX 1602 at 21:15–16), the McGinity Application also discloses that "the pharmaceutical formulation may be in the form of a . . . tablet" (DTX 2562 at 13:21–22).

Where the '383 Patent's dosage form includes "one or more active ingredients with abuse potential [ ] selected from the group consisting of opiates and opioids" (PTX 1602 at 21:3–5), the McGinity Application made the same disclosure to a reader of ordinary skill in the art by referring to pain-relieving

analgesics in the context of sustained-release dosage forms.

Where the '383 Patent claims a composition of its formulation "wherein the active ingredient with abuse potential [ ] is oxycodone or a physiologically acceptable salt thereof" (*id.* at 22:12–14), the McGinity Application discloses this formulation as an embodiment of its invention because a person of ordinary skill in the art would have interpreted the Application as suggesting the invention's use with oxycodone API (Block 2013 Tr. 1299).

Where the '383 Patent's ingredients include "optionally physiologically acceptable auxiliary substances" and "optionally at least one wax," those attributes are not required limitations but merely optional features. (PTX 1602 at 21:6–7, 11.) If the McGinity Application had been invented after the '383 Patent and not before, then an inquiry into its infringement of the '383 Patent would be unaffected by the inclusion or exclusion of these optional features. Just the same, the optional elements of auxiliary substances and waxes do not affect the anticipation inquiry. *Cf. In re Johnston*, 435 F.3d 1381, 1384 (Fed. Cir. 2006); *Upsher-Smith Labs., Inc. v. Pamlab, LLC*, 412 F.3d 1319, 1322 (Fed. Cir. 2005).

Where the '383 Patent's dosage form includes "at least [60%] by weight of polyalkylene oxide [ ] having a molecular weight of 1–15 million" (PTX 1602 at 21:8; 2013 Stip. ¶ 34(e)), the McGinity Application made the same disclosure, listing five embodiments of its dosage form that include greater than 60% high molecular weight PEO (DTX 2562 at 19:11–34).

Where the '383 Patent's API "is present in a controlled release matrix" of the polyalkylene oxide (PTX 1602 at 21:13–14), the McGinity Application discloses the same in providing that "[t]he therapeutic compound may be . . . suspended in the polymer matrix of the formulation" (DTX 2562 at 8:6–7).

Where the '383 Patent's claim 5 teaches a "process comprising mixing [the API], [an optional auxiliary substance], [the polyalkylene oxide], and [optionally at least one wax] to form a mixture and, optionally after granulation, press-forming the mixture with preceding, simultaneous, or subsequent exposure to heat" (PTX 1602 at 22:3–8), the McGinity Application provides for that process in its hot-melt extrusion of PEO, an API, an optional plasticizer, and "[o]ther components" (*see* DTX 2562 at 11:18–33).

Where the '383 Patent discloses a tablet with "a breaking strength of at least 500 N" (PTX 1602 at 21:12–13), the McGinity Application inherently discloses the same breaking strength because any tablet made according to the Application necessarily has that attribute.

The McGinity Application discloses every required limitation of claims 1, 2, 5, 7, and 8 of the '383 Patent. The Court therefore concludes that the McGinity Application anticipates those claims. The '383 Patent recapitulated what the McGinity Application had already contributed to the art.

2. At the time of the '383 Patent's development, the prior art made the process obvious.

a) The prior art renders the '383 Patent obvious.

Even if the McGinity Application did not anticipate the '383 Patent, a person of ordinary skill in the art would have had sufficient knowledge and motivation to make the invention claimed by the '383 Patent.

Public demand for an extremely hard version of a controlled-release opioid tablet would have given motivation to those in the art. The interest in a tamper-resistant dosage form of oxycodone was well-documented. (*See*, *e.g.*, PTX 2189 at 224; Sellers 2013 Tr. 86.) More specifically, those in the art understood that a common first step in oxycodone abuse was crushing or chewing the tablet, in order to break it up into a powder that could be swalled, snorted, or injected. (Sellers 2013 Tr. 81–82; Kaiko 2013 Tr. 139–40; Davies 2013 Tr. 1765–66.) Thus, ordinarily skilled artisans were motivated to make oxycodone tablets that resisted crushing. (Block 2013 Tr. 1329; *see also* Kaiko 2013 Tr. 153; Davies 2013 Tr. 1720–22; *cf*. DTX 2483 at 43 (referring to a different abuse-prone drug's abuse-resistant formulation as "difficult to crush, and therefore [ ] difficult to snort or inject").) There was even motivation to reach a degree of crush-resistance of several hundred Newtons, because the median human bite force is 408N for males and 243.5N for females (DTX 1481 at 594 tbl. 3) and the maximum voluntary human bite force is 593N (DTX 1480 at 1161).

Moreover, a person of ordinary skill in the art would have understood that one avenue to extremely hard dosage forms was the use of high molecular weight PEO. In fact, prior art dating back to 1967 included information about high molecular weight PEO's strength properties. (*See* PTX 2101 at 4; Mannion 2013 Tr. 212–14.) This principle was so well known by the time of the '383 Patent that at least one such dosage form was on the commercial market: Concerta, a methylphenidate for the treatment of attention deficit hyperactive disorder (*see* Sellers 2013 Tr. 94), uses high molecular weight PEO and is resistant to crushing. (*See* Muzzio 2013 Tr. 1432–33; Davies 2013 Tr. 1720–21; DTX 1473 at IMPAX052974; DTX 2483 at 43.)

The knowledge of high molecular weight PEO's ability to strengthen a tablet was far from abstract: the prior art included disclosures that hot-melt extrusion (one way of thermoforming) specifically promoted this strengthening property. Writing while still a Ph.D. student, Zhang applied basic principles of polymer chemistry and hot-melt extrusion to conclude, "[s]ince the polymeric carrier is in its melt state during hot-melt extrusion and is pressurized inside the extruder, the hot-melt extrudate is anticipated to possess a higher physical strength and lower porosity than tablets prepared by wet granulation and direct compression methods." (PTX 2359 at 68–69.) If that reasoning would not have occurred naturally to one of ordinary skill in the art before Zhang committed it to paper in 1999, then it certainly became part of the art at that time.

Moreover, even if the McGinity Application had not disclosed formulations including oxycodone, a person

of ordinary skill in the art would still have understood that the process described in the McGinity Application would have the same desired effect upon substituting oxycodone as the API. The Court credits Block that oxycodone does not have any property that would lead an ordinarily skilled artisan to worry that it might alter the properties of the formulation made by the McGinity Application. (Block 2013 Tr. 1301–02.)

Finally, a person of ordinary skill in the art would have readily understood from McGinity and Zhang's work that a PEO-based, hot-melt extruded tablet would have controlled release properties. (*See*, *e.g.*, DTX 2562 at 1:11; DTX 2012; DTX 2013; PTX 2361.)

The Court therefore finds by clear and convincing evidence that the prior art included the motivation and the capability to invent the '383 Patent's claimed product. The Court finds no substantial difference between the scope of the prior art and the asserted claims of the '383 Patent.

b) Objective Indicia of Nonobviousness

(1) Plaintiffs' evidence of commercial success lacks a nexus to the '383 Patent.

The parties and their experts fought to prove or disprove the commercial success of the technologies at issue. There has been no evidence, however, that Reformulated OxyContin has been more commercially successful than the Original OxyContin that came before it. Comparing the data for OxyContin sales and pricing before and after the 2010 introduction of Reformulated OxyContin, the

new product that included the asserted patent claims did not prompt increased sales or an increased price. (Rao 2013 Tr. 1584–85; PTX 2667.)[11] The other moment when one might expect to see evidence of commercial success is the 2013 label change permitted by the FDA; but at the time of trial this change was too recent for anyone to present data on whether the change affected the commercial success of the OxyContin product line. (Hausman 2013 Tr. 517, 533.)

In any event, even if the Reformulated product has been a success, Purdue has shown no evidence of a nexus between that success and the '383 Patent. The Court can make no finding that the '383 Patent has been successful on the market.

Plaintiffs also argue that Grunenthal's license agreements for its abuse deterrence technologies demonstrate the commercial success of the '383

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[11] Purdue's expert, Dr. Jerry Hausman, disagrees: he opined at trial that because Reformulated OxyContin has made money for Purdue, it is a commercial success. (Hausman 2013 Tr. 513–14.) Hausman told the Court that "the net sales are about 2 billion [dollars] and the product contribution is about 1.67 billion [dollars], so to an economist that means this drug is quite successful." (*Id*. at 514.) He did not compare that degree of success with anything else—including with the market's reception of Original OxyContin. (*Id*. at 513.) When confronted with the apparent simplicity of his approach he provided no further analysis, saying: "That's pretty good. That's it. That's the bottom line." (*Id*. at 514.) The Court credits Hausman as to whether $2 billion is a lot or a little to an economist, but the witness's failure to confront the more complex question of how the market has responded to a technology that is embedded in an improved formulation of a drug renders his testimony not useful to the Court.

Patent. But those license agreements cover many patents and patent applications. (*See* PTX 2177 at 7–11.) No party even attempted to allocate the value of those license agreements between the scores of patents and patent applications therein. The Court is impressed at Grunenthal's success in licensing its technology generally, but it has no basis for a factual finding about the value of licensing the '383 Patent in particular.

(2) The '383 Patent did not fulfill a long-felt but unmet need.

There is no evidence of a long-felt but unmet need that the '383 Patent fulfills. The public health crisis of OxyContin tampering and abuse began in 2001, when the government and Purdue first acknowledged the problem. (*See* Sellers 2013 Tr. 82–83; PTX 2147; PTX 2148.) Grunenthal filed the first patent application related to the '383 Patent's technology in August 2003. (2013 Stip. ¶ 29(b).) The Court finds that the two-and-a-half-year period in between did not give rise to a *long-felt* need.

C. Conclusion

The asserted claims of the '383 Patent describe, broadly speaking, a PEO-based oxycodone tablet hardened by the thermoforming process. Teva's proposed product is, broadly speaking, a PEO-based oxycodone tablet hardened by an equivalent of the thermoforming process. The McGinity Application disclosed a PEO-based oxycodone tablet hardened by a particular thermoforming process. Although Teva's tablets infringe, the '383 Patent is invalid as anticipated. Moreover, the Court concludes that

the '383 Patent is invalid as obvious, in light of the findings that the prior art included the motivation and capability to create the '383 Patent with a reasonable expectation of success.

III. The '314 Patent: Gel Test Technology

According to Purdue, Teva has infringed claims 1, 2, 6, and 9 of the '314 Patent. Claims 2, 6, and 9 all depend from claim 1, which the Court construed to read as follows:

> 1. A solid dosage form for oral administration with reduced potential for parenteral abuse, comprising, in addition to one or more active ingredients with potential for abuse selected from the group consisting of opiates, opioids, tranquillizers, stimulants and narcotics, at least one viscosity-increasing agent in a quantity equal to or greater than 5 mg per dosage form and such that an aqueous extract obtained from the dosage form with 10 ml of water at 25° C. forms a gel which can still pass through a needle having a diameter of 0.9 mm and, when introduced by such a needle into a further quantity of an aqueous liquid at 37° C., a largely cohesive thread is initially obtained which, while it may be broken up into smaller fragments by mechanical action, remains substantially insoluble and cohesive and cannot straightforwardly be dispersed in such a manner that it can safely be administered parenterally, in particular intravenously.

OxyContin Claim Construction, 2013 WL 4509633, at *12. [12] The dependent claims at issue add the following limitations:

> 2. A dosage form according to claim 1, wherein the active ingredient is an opiate, opioid, tranquilizer or a narcotic selected from the group consisting of . . . 4,5,alpha.-epoxy-14-hydroxy-3—methoxy-17-methyl-6-morphinanone (oxycodone) . . . .
>
> . . .
>
> 6. A dosage form according to claim 1, comprising at least one active ingredient at least partially in controlled release form . . . .
>
> 9. A dosage form according to claim 1, comprising at least one viscosity-increasing agent in a quantity of ≥5 mg per administration unit.

(PTX 1601 at 12:32–15:6, 16:8–10, 16:15–18.) If Teva does not infringe the independent claim (claim 1), then it does not infringe any dependent claims (claims 2, 6, and 9). *See Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1553 (Fed. Cir. 1989).

A. Teva's ANDA does not infringe the '314 Patent, because Purdue has not put forward reliable and relevant evidence of infringement.

The parties have shown competing experimental evidence to the Court, each purporting to test tablets

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[12] "Parenteral refers to any way of getting a substance into one's body other than orally." *OxyContin Claim Construction*, 2013 WL 4509633, at *9.

in accordance with the Court's construction of claim 1. No expertise is necessary to examine the experimental evidence and to assess the extent to which the photographs and video footage depict infringing tablets. (*See*, *e.g.*, Davies 2013 Tr. 836, 870.) Having reviewed this experimental evidence, the Court finds no reliable proof of infringement.

1. Purdue's evidence of infringement is based on a gel test that is not designed to replicate the '314 Patent's gel test.

The parties' various scientific testing relies on a so-called "gel test" embedded in the Court's construction of claim 1 of the '314 Patent. A gel test demonstrating infringement would incorporate the various components of the patent's test: It would begin by combining a ground accused tablet with 10 ml of water at 25°C to form an aqueous extract. It would query: does that aqueous extract form a gel? If a gel has formed, the gel test would then attempt to pass that gel through a needle with a diameter of 0.9 mm. It would query: can the gel pass through that needle? If the gel can pass through that needle, the gel test would introduce the gel by the needle into a further quantity of aqueous liquid at 37°C. It would query: is a largely cohesive thread initially obtained? If a largely cohesive thread is initially obtained, the gel test would then apply mechanical action to the solution. It would query: does the largely cohesive thread remain substantially insoluble and cohesive, and can it not straightforwardly be dispersed in such a manner that it can safely be administered intravenously? To show by a preponderance of the evidence that Teva's tablets infringe, Purdue must

demonstrate that under the circumstances of such a test, it is more likely than not that a gel would form, the gel would be able to pass through the needle, a largely cohesive thread would be initially obtained, the thread would remain substantially insoluble and cohesive, and the thread would not be susceptible of straightforward dispersion in such a matter that it can safely be administered intravenously.

The purpose of the gel test is to distinguish infringing from non-infringing formulations. It is useful as a way of describing the claimed invention and as a way of assessing whether the claim 1 reads on future formulations. The specific test, however, has no independent value: while the general gelling property of the invention is a deterrent, and while a further deterrent arises from that gel's capacity to pass through a needle and remain viscous after injection, it is implausible that would-be abusers ever run the specific test described in the patent, observe the test, or read about the test in the scientific or patent literature. Thus, the principles that should govern the conduct of the gel test, to the extent the patent is ambiguous, have nothing to do with abusers' behavior and everything to do with the way in which an ordinary skilled artisan would conduct the test.

Purdue's evidence of the Teva tablets' behavior under the conditions of the gel test arises out of experimental testing. Davies wrote the laboratory protocol for this gel testing, and a Catalent team led by Benjamin Porter performed the tests. (*Id*. at 738; Porter 2013 Tr. 544, 549.) According to Davies, he wrote that protocol to reflect his understanding of abusers' behavior. (*See*, *e.g.*, Davies 2013 Tr. 738–39.) He designed his test to replicate what an abuser

would do with an oxycodone tablet; he did not even attempt to replicate how a chemical engineer, pharmacologist, or other ordinary skilled artisan would run the laboratory experiment as described in the '314 Patent. To the extent that the patent's definition of the gel test left variables undefined, Davies filled those gaps in the way he thought an abuser would fill them. For example, the patent does not disclose any particular injection speed. Filling this gap, Davies preferred using a relatively slow injection speed, so that the injection would take "30 seconds to a minute or two," which he thought reflected an abuser's manner of injection. (*Id*. at 858; *see id*. 804.) The patent does not disclose any particular way to agitate the aqueous liquid, other than the broad concept of "mechanical action." (PTX 1601 at 2:27–28.) Filling this gap, Davies preferred using only "gentle stirring" as the mode of mechanical action, in order to approximate what would occur inside the abuser's vein. (Davies 2013 Tr. 804.) In this way, Davies's protocol does not purport to represent how a person of ordinary skill in the art would conduct the gel test. Indeed, that was not his aim: his aim was to replicate the steps an abuser would take.

As Davies himself asserted, a person of ordinary skill in the art is versed in chemical engineering, medicine, pharmaceutical science, pharmaceutics, pharmacokinets, and pharmacology. (*See id*. at 1646.) Thus, a person of ordinary skill in the art would seek to resolve any of the gel test's ambiguities with the practices of laboratory scientists, and not those of drug abusers. Because Davies resolved those ambiguities without reference to what an ordinary

skilled artisan would do, his experiment offers no information about whether Teva's tablets infringe the patent.

2. Purdue's evidence of infringement is based on a gel test conducted in an unreliable manner.

Competent scientific evidence requires, at the very least, testing conducted in an unbiased fashion. (*Cf.* Porter 2013 Tr. 586.) Setting aside for a moment the fact that Davies's protocol did not approach the gel test in the way a skilled artisan would, the *performance* of the test was neither reliable nor unbiased.

The testing protocol had embedded ambiguities and biases that undercut any experimental results emerging from the protocol. The ultimate question of the gel test is whether a gel forms and whether it dissolves. This ultimate question would find an objective answer through scientific and quantitative measurements of viscosity and solubility, which are available to laboratory scientists. (*See id*. at 603–05, 646–49.) Yet Davies did not ask Catalent to measure viscosity or solubility in any objective or quantitative way. (Davies 2013 Tr. 818.) Even within subjective observations of viscosity and solubility, the documentation Davies requested was short on specificity: he asked only whether the material was "substantially insoluble," "largely cohesive," and could be "straightforwardly dispersed." (Porter 2013 Tr. 646–48.) Davies further instructed the laboratory technicians to look for "a thread-like component." (*See id*. at 594–96.) The Court is highly skeptical that an unbiased answer could follow from this

protocol, because the protocol primes an analyst to observe a specific formation (that is, "a thread-like component"). More specifically, the protocol's many references to a "thread-like component" in several consecutive steps (*see*, *e.g.*, DTX 4033 at 2) likely created an anchor for the analysts.[13] And indeed the analysts made exactly the observation that the Davies protocol was priming them to make. Specifically, in the open-ended field for "Comments" in the Catalent lab notebooks, where the analysts could write any words to record what they saw, most entries contain simply the phrase "thread-like" and nothing more. Catalent completed 35 experimental runs on Purdue's OxyContin tablets; in the 35 Comments fields the Catalent technicians completed, they wrote "thread-like" 35 times and never wrote any other comment. (PTX 4028.) In the 35 experimental runs Catalent performed on Impax tablets, the technicians wrote "thread-like" 35 times in the Comments fields and never wrote any other comment. (DTX 4033.) Catalent's 35 experimental runs on Sandoz's tablets produced 34 identical Comments fields ("thread-like"), and for the other run, the word "thread" appears crossed out with the phrase "thread-like" next to it. (PTX 2063.) These comments reveal the effect of anchoring in Davies's protocol.

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[13] The heuristic device of anchoring and adjustment diminishes the quality of objective observations. The device relies on "an initial value, or 'anchor,' from which [people] make insufficient adjustments." Cass R. Sunstein, *Behavioral Analysis of Law*, 64 U. Chi. L. Rev. 1175, 1188 (1997). The anchor, whether its source is arbitrary or sensible, "may be hard to dislodge" and therefore may unduly influence a judgment. *Id*.

Porter insisted in his trial testimony that the priming and anchoring in Davies's protocol did not bias the performance or documentation of Catalent's testing. (Porter 2013 Tr. 599.) But the remainder of his testimony, the lab notebooks, and the video footage of the testing all tell a different story. Most directly, Porter admitted, "[n]ot being already given the term thread-like, I'm not sure that would have been a term that we would have come up with on our own." (*Id*. at 600.)

The video footage of Catalent's gel test most undermines the test's reliability. Specifically, during the first trial run of the gel test, a lab technician (apparently expecting more resistance to the force she was exerting on the plunger) expels the syringe's contents into a beaker of water quickly. The material that flows out of the needle diffuses almost completely in the water. The technician exclaims: "Oops." Moments later, she explains, "Okay . . . . It's not thread-like." In response, another female voice suggests, "maybe after they stir it." Ultimately, Porter chimes in, saying, "[t]here's some threads in there." Cautiously, the first technician, the same one who initially observed "[i]t's not thread-like," asks: "So discernable thread-like component that does not mix with water, we're going to say yes?" The rest of the team responds affirmatively, and that first technician agrees with an "Okay." (DTX 1357.)

In the next run (also videotaped) the effort appears to be focused on increasing the likelihood that the resulting formation will be thread-like. The material that flows out of the needle is more cohesive than in the first trial run, prompting a technician to say "there you go" and to ask how the injecting technician

achieved the result she was getting ("Are you doing it really slow?"). Porter asks the technician from the first run, "What did you do?" She responds, "I went too fast." (Comparing the video footage of the first and second runs, it appears that the faster injection in the first run resulted in greater dispersion—and less cohesiveness—of the injected material in the water.) Later, the technicians agree that they "gotta go slow," "[j]ust gotta go slow with that," and "[b]e careful." (DTX 1359.) In other words, they were trying to perform this experiment in the way that yielded the more cohesive material on the second run and to not repeat the mistake of the first trial run.

The Court assigns no weight to the testing performed by Catalent pursuant to Davies's protocol.

3. To the extent that any experimental evidence is probative, it suggests that Teva's tablets do not infringe.

Teva has put forward experimental results of its own, which it believes demonstrate that its tablets do not infringe the '314 Patent because they do not satisfy the gel test. This evidence is based on gel tests devised by its own expert, Dr. Michael Maurin.

Maurin's gel test led him to the opinion that Teva's tablets do not infringe the '314 Patent. (Maurin 2013 Tr. 1215.) Maurin's results benefit from an added assurance of integrity over the various other tests discussed at the 2013 trial. In order to standardize his results, Maurin first made a prior art tablet that the '314 Patent's inventors identified as failing the gel test; he tested that tablet according to the same protocol that he used in testing Teva's tablets; and he

credibly determined that Teva's tablets displayed even less cohesiveness and gelling than did the prior art tablet. (*Id*. at 1213–15; *see* DTX 1773; DTX 1775.) The Court viewed the gel test that Maurin conducted, both on the prior art tablet and on Teva's tablets, and the Court agrees that if the prior art tablet fails the gel test then Teva's tablets most certainly fail the gel test.[14] (*Compare* DTX 1788; DTX 1789; DTX 1790, *with* DTX 1791; DTX 1792; DTX 1793; DTX 1794; DTX 1795; DTX 1796; DTX 1797; DTX 1798; DTX 1799; DTX 1800; DTX 1801; DTX 1802; DTX 1803; DTX 1804; DTX 1805; DTX 1806; DTX 1807; DTX 1808; DTX 1809; DTX 1810; DTX 1811; DTX1812; DTX 1813; DTX 1814; DTX 1815; DTX 1816; DTX 1817; DTX 1818; DTX 1819; DTX 1820.)

Even Catalent's testing, biased in favor of satisfying the gel test, suggested that several of Teva's tablets do not infringe. Unlike Catalent's testing of Purdue, Impax, and Sandoz's tablets, the test results of Teva tablets stood out as producing comments other than "thread-like." (*Compare* PTX 2067 (Teva) *with* PTX 4028 (Purdue); DTX 4033 (Impax); PTX 2067 (Sandoz).)

Of Catelent's experiments on the Teva 10 mg tablets, every run yielded a "turbid but not viscous"

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[14] To be sure, Maurin's protocol shared many of the imperfections of Davies's protocol. For example, he did not call for a quantitative measure of viscosity or solubility, even though such an objective measurement would have provided the most reliable results for at least a part of the gel test. But at a minimum Maurin's gel test is equally probative as Davies's. To the extent Purdue's gel test evidence suggests infringement, this countervailing gel test militates just as strongly in favor of noninfringement.

suspension; only four out of ten runs yielded a "discernible thread-like component that does not mix with water"; in none of the ten runs was the diameter of that component discernible; and only in five of the ten runs did the technician agree that "after stirring, thread fragments remain visible to the eye." (PTX 2067 at 10.) Similarly, for a majority of experimental runs on Teva's 20 mg and 30 mg tablets, the technicians could not discern the threads' diameter, the thread fragments did not remain visible after stirring, and the material ultimately dispersed. (*Id.* at 12–13.) For the 15mg, 20mg, and 30mg tablets, every experimental run yielded only a "turbid but not viscous" suspension (*id.* at 11–13), meaning that no gel formed (*see* Porter 2013 Tr. 562). Therefore, even if the Court accepted the Catalent testing as reliable and relevant, that testing would tend to show that Teva's 10mg, 15mg, 20mg, and 30mg tablets are not described by the gel test of claim 1 of the '314 Patent.

All told, the Court finds that Purdue has failed to carry its burden of proving infringement of the '314 Patent, because it has not shown that claim 1's gel test describes any of Teva's tablets.

B. The '314 Patent is invalid as indefinite.

The conclusion that Teva has not infringed the '314 Patent ends the inquiry as to the '314 Patent for purposes of this trial. In the alternative, the Court sets out below its findings of fact and conclusions of law with respect to validity.

1. The "gel test" gives a skilled artisan insufficient guidance to conduct a replicable experiment.

The '314 Patent defines the scope of its claimed invention partly through a "gel test." Specifically, the patent discloses a formulation according to this test:

> [T]he active ingredient-containing gel formed by extraction from the dosage form with the assistance of a necessary minimum quantity of aqueous liquid, when introduced with a hypodermic needle with a diameter of 0.9 mm into a further quantity of aqueous liquid at 37° C., remains substantially insoluble and cohesive and cannot straightforwardly be dispersed in such a manner that it can safely be administered parenterally, in particular intravenously. The material preferably remains visually distinguishable for at least one minute, preferably for at least 10 min.
>
> The increase in viscosity of the gel with the assistance of the selected viscosity-increasing agent means that, although this has been rendered more difficult, the gel may still be passed through a needle or injected. It also means that when the resultant extract or gel is introduced at 37° C. into a further quantity of aqueous liquid, for example also by injection into blood, a largely cohesive thread is initially obtained which, while it may be broken up into smaller fragments by mechanical action, it cannot be dispersed or even dissolved in such a manner that it may safely be administered parenterally, in particular intravenously.

(PTX 1601 at 2:9–30.) This Court held in its Claim Construction Opinion and Order that claim 1's use of the term "visually distinguishable," which the patent defines with the above test, incorporates the same test into the claim limitation. *OxyContin Claim Construction*, 2013 WL 4509633, at *12.

The patent's gel test does not define any variables regarding the extraction, injection speed, or subsequent mechanical action. The test serves the function of distinguishing infringing from non-infringing formulations; it refers to a test that an ordinary skilled artisan would conduct in a laboratory and does not refer to how an abuser would treat the formulation. *See supra*, section III.A.1. Any gaps should therefore be filled as an ordinary skilled artisan would fill them, to the extent an ordinary skilled artisan would know how to fill them.

One cannot expect a prose description of an experiment to disclose each and every parameter that an experimenter might select—from altitude to humidity to time of day to lunar phase—but the description must give an ordinary skilled artisan enough information to reliably replicate the experiment. It must, at a minimum, disclose the most manifestly outcome-determinative details of the experiment.

In the case of the gel test, injection speed directly impacts the results. Yet the patent says nothing about injection speed or force. (*See* Davies 2013 Tr. 795, 1736; Maurin 2013 Tr. 1268–69.) In fact, claim 1 directs only that the gel be "introduced into a further quantity of aqueous liquid." (PTX 1601 at 12:30–31.) The patent specification uses the same

language when describing the test. (*Id.* at 2:14.) Later, it analogizes this step to an intravenous injection, but only by way of an example to explain the significance of the gel test. (*Id.* at 2:24–26 (". . . introduced at 37° C. into a further quantity of aqueous liquid, for example also by injection into blood ...").) The injection speed affects whether a thread forms, the cohesiveness of the material, and the dissolution of any thread that does form. (Davies 2013 Tr. 1755; Maurin 2013 Tr. 1268; *see* DTX 1357; DTX 1359; DTX 1361; DTX 1362.) This relationship between injection speed and gel test results explains how the Catalent lab technicians achieved a more distinguishable thread, greater cohesiveness, and less dissolution after they slowed down their injection speed. (*Compare* DTX 1357 *with* DTX 1359.) Even Davies explains the difference between Catalent's results and Maurin's results as a product of Maurin's faster injection speed. (Davies 2013 Tr. 858, 1755; *see* Maurin 2013 Tr. 1246; Davies 2013 Tr. 1672.)

The Court therefore finds that the proper injection speed for the '314 Patent's gel test is insolubly ambiguous: the patent gives no information whatsoever to ordinarily skilled artisans, and that choice (between reasonable alternatives) determines the outcome of the gel test.[15]

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[15] The Court would reach the same finding even if the gel test were intended to mimick an abuser's intravenous injection as Davies claims it is. (*See*, *e.g.*, Davies 2013 Tr. 801–02.) After all, abusers' intravenous injection speeds are highly variable and encompass the full range of injection speeds used by the various experts in this litigation. (*See* Sellers 2013 Tr. 78.) Thus, the patent would still fail to guide an ordinary skilled artisan in the

Mechanical action is another outcome-determinative parameter that the '314 Patent does not define. After the injection of the gel into the further aqueous liquid, the patent recites that the gel "may be broken up into smaller fragments by mechanical action, [however] it cannot be dispersed or even dissolved." (PTX 1601 at 2:27–30.) An ordinary skilled artisan would interpret mechanical action as stirring with a glass rod. (*See*, *e.g.*, Davies 2013 Tr. 748; Banakar 2013 Tr. 1113–14.) Yet the same ordinary skilled artisan would have no idea for how long or with what intensity he should stir. (Muzzio 2013 Tr. 1464; *see* Davies 2013 Tr. 804; Muzzio 2013 Tr. 1424–25.) The video footage in evidence depicts experiments with differing approaches to the stirring, and that footage makes manifest that longer and more aggressive stirring times lead to categorically greater dissolution. (*See* Banakar 2013 Tr. 1052–54; DTX 8516.) In fact, as Dr. Umesh Banakar showed at trial, an experimenter whose gel test leaves undissolved material after five seconds of stirring can dissolve that remaining material with ten additional seconds of stirring. (Banakar 2013 Tr. 1053, 1059–60; DTX 8516.)

The Court therefore finds that the mechanical action element of the '314 Patent's gel test is an outcome-determinative and insolubly ambiguous parameter.

Finally, even if a person of ordinary skill in the art had enough information to faithfully replicate the actions involved in the gel test, that person would not

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proper injection speed, and the artisan's choice would still determine the outcome of the test.

know whether the resulting material is "visually distinguishable" as required by the patent. Claim 1 requires that the material "remain[ ] visually distinguishable" at the end of the gel test (PTX 1601 at 12:29–30), and the Court construed that requirement to mean that the material "remains substantially insoluble and cohesive and cannot straightforwardly be dispersed in such a manner that it can safely be administered parenterally, in particular intravenously." *OxyContin Claim Construction*, 2013 WL 4509633, at *12. In arriving at that construction, the Court used all of the interpretive aids that the patent and its prosecution history availed. Any more detailed interpretation would superimpose on the claim new limitations found neither in the patent nor in its prosecution history nor in an ordinarily skilled artisan's interpretation of those sources.

Yet the Court's construction still leaves the term most certainly open to subjective and therefore inconsistent application. The relevant art does not contain a standard for determining whether a substance is "visually distinguishable," "cohesive," or "straightforwardly dispersed." (Porter 2013 Tr. 593; Davies 2013 Tr. 1823–25.) Experts at trial could not agree on whether the same video footage could or could not be described by the patent language. Even Purdue's expert vacillated on the question of how much material must remain in order to satisfy the patent's description. (*Compare* Davies 2013 Tr. 1823–24 *with* Davies 2013 Tr. 1825.) The Court therefore finds that the term "visually distinguishable" is not susceptible to any construction more helpful to those of ordinary skill in

the art than the construction that the Court has already provided, and even that construction does not allow a person of ordinary skill in the art to tell an infringing from noninfringing product.

Claim 1 defines the invention according to a gel test, but it leaves a person of ordinary skill in the art unable to replicate that test or assess its results. Teva has overcome the presumption of definiteness and has proved by clear and convincing evidence that no possible construction resolves the ambiguity as to injection speed, injection force, mechanical action, and determination of visual distinguishability. To put a finer point on it: the claim language is insolubly ambiguous as to an accused product's ambiguous insolubility.

2. The '314 Patent is both novel and nonobvious.

The parties disagree about whether one prior art reference disclosed all of the asserted claim limitations and, more broadly, whether the prior art in general made the '314 Patent obvious. A review of the prior art reveals that the '314 Patent departed meaningfully from the dosage forms disclosed before it.

a) Prior art

Concerta is an extended release tablet for the treatment of attention deficit hyperactive disorder. (*See* Muzzio 2013 Tr. 1403, 1431–32, 1512; Sellers 2013 Tr. 94; DTX 1550.) The FDA approved Concerta in 2000. (DTX 1550 at 0032.) Concerta is an OROS formulation. *See supra*, section II.A.1. It therefore contains PEO, a viscosity-increasing agent. (Muzzio 2013 Tr. 1432, 1443–44.) Muzzio testified that a

Concerta tablet contains at least five milligrams of PEO. (*Id*. at 1442.) The gelling properties of the PEO in Concerta were specifically designed to deter abuse, an advantage that was publicly known by November 2002. (*See*, *e.g.*, DTX 2799A at 5; DTX 2523 at 0009, 0014; DTX 2475 at 0003–05.)

Muzzio attempted to perform the '314 Patent's gel test on the Concerta tablets. (Muzzio 2013 Tr. 1430–31.) However, in conducting the gel test, Muzzio did not use "aqueous liquid at 37°C," as the patent prescribes. (*Id*. at 1520; Davies 2013 Tr. 1832–34.) Instead, Muzzio's acqueous liquid—a beaker of water—sat in a shallow 37°C bath, exposing only the bottom of the beaker to the bath and leaving most of the beaker at a cooler room temperature. (Muzzio 2013 Tr. 1520–21; Davies 2013 Tr. 1832–34; *cf*. *id*. at 756, 796.) Thus, the aqueous liquid itself was cooler than the specified temperature of 37°C. (Davies 2013 Tr. 1832–34.) Muzzio did not replicate the conditions of the '314 Patent's gel test, so the Court cannot credit his results as indicative of how Concerta would behave under the conditions described in the patent.

Teva points to several other references as evidence that the prior art used gelling agents to deter intravenous injection. Indeed, U.S. Patent No. 4,070,494 ("Hoffmeister"), filed in 1975 (DTX 2170 at [22]), and International Application No. WO 95/20947 ("Bastin"), invented in 1994 (DTX 1927 at (30)), recite such technology. Hoffmeister uses gelling to prevent "[a]ttempts to extract the medicinal agent for parenteral abuse . . . ." (DTX 2170 at [57].) Bastin uses the gelling property to prevent the syringing of an extraction. (*See* DTX 1927 at 26:4–11.)

Another prior art reference, U.S. Provisional Patent Application No. 60/310,534 ("Wright-Oshlack"), filed in 2001, goes a step beyond Hoffmeister and Bastin. Its gelling property seeks to prevent drawing the extract into conventional needles. (DTX 1494; Davies 2013 Tr. 1680–90.) And it discloses the use of visual cues to make injection unappealing: it uses gelling excipients and dyes that give the gel a "creamy texture and milk like color." (DTX 1494 at 47; *see* Muzzio 2013 Tr. 1475.) The same visual cues are the deterrent of choice for Concerta's OROS technology: abusers cannot easily obtain "a clean extract solution" free of colorants and air bubbles. (DTX 2486 at 132.)

b) Differences between the '314 Patent and the Prior Art

Although Concerta shares many characteristics with the '314 Patent, it lacks a key limitation of claim 1. Specifically, the Court cannot find that the patent's gel test describes Concerta, absent evidence of Concerta's behavior in the conditions of the gel test as described in the patent. Teva's evidence does not rise to the level of clear and convincing proof of anticipation. The legally presumed novelty of the '314 Patent therefore remains intact.

Other prior art that used gelling agents used them for related, but distinct, purposes. For example, Hoffmeister used a gelling agent to prevent the extraction of the drug. (Davies 2013 Tr. 1687; DTX 2170.) Bastin used a gelling agent to prevent the syringing of the extraction. (Davies 2013 Tr. 1687–88; DTX 1927 at 0027–29.) And Wright-Oshlack similarly used a gelling agent to prevent drawing gel

into conventional needles, adding the visual cue of an unpleasant milky appearance. (Davies 2013 Tr. 1689–90; DTX 1494.)

The '314 Patent differs from those prior art references: the extraction explicitly *can* be injected, yet upon injection its gel either creates a visual cue in a beaker or creates a bodily threat in the bloodstream. (*See*, *e.g.*, Bartholomaeus 2013 Tr. 386–87.) This different goal represents a different approach to deterrence. Hoffmeister, Bastin, and Wright-Oshlack sought to deter intravenous injection by making their dosage forms difficult to inject. Wright-Oshlack added the possibility of visual cues to make injection unappealing. The '314 Patent's approach goes much further in its deterrence. Unlike the prior art, the '314 Patent's gel remains viscous even after injection into the bloodstream, introducing new risks to intravenous abuse and thereby deterring such abuse. (DTX 1304 at PRF7665–67.)

Unlike the entire prior art, a formulation consistent with the '314 Patent is susceptible to injection but presents visual cues and bodily risk upon injection. This combination of goals—not found in any of the prior art—requires a very specific balance of viscosity. Too viscous and it cannot be injected; too runny and it will lack deterrent effect. (*See* Bartholomaeus 2013 Tr. 384–87.) Teva has not demonstrated that this combination of goals and balance of viscosity was obvious at the time of the invention.

c) Objective Indicia of Nonobviousness

(1) All evidence of commercial success lacks a nexus to the '314 Patent.

Although the parties intensely debated the commercial success of the '314 Patent—as with the other patents—no evidence of commercial success can be connected to this invention. While OxyContin has been profitable for Purdue since the 2010 introduction of Reformulated Oxycontin (*see* Hausman 2013 Tr. 513–14), the record contains no support for the proposition that any of that profit derived from the '314 Patent. Moreover, Reformulated OxyContin—the new product that contains the '314 Patent's gelling technology—has seen roughly the same commercial success as Original OxyContin—the preceding product that did not include a viscosity-increasing agent. (Rao 2013 Tr. 1584–85; PTX 2667.) The Court cannot find any commercial success of the '314 Patent on the basis of Reformulated OxyContin's performance on the commercial market. *See supra*, section II.B.2.

Plaintiffs also argue that the licensing history of the '314 Patent proves its commercial success. But the license agreements in the record cover too many patents and patent applications for the Court to find a nexus between the '314 Patent in specific and the success of those licenses. (*See* PTX 2177 at 7–11.) The Court has not been presented with any method to disaggregate the various intellectual property contained in the license history. Therefore it has no

basis to make a factual finding concerning the commercial value of licensing the '314 Patent.

(2) The technology did not fill a long-felt but unmet need.

The '314 Patent did not fill a long-felt but unmet need, on the evidence before the Court. The earliest public acknowledgements of a trend in OxyContin tampering came in 2001. (*See* Sellers 2013 Tr. 82–83; PTX 2147; PTX 2148.) Grunenthal's scientists invented the technology in the '314 Patent no later than June 2002. (2013 Stip. ¶ 29(a).) The eighteen months in between do not justify a finding of a long-felt need.

C. Conclusion

Claim 1 of the '314 Patent, as construed, limits the invention to a dosage form that behaves in a particular way under particular conditions. The claim leaves ambiguity as to how to recreate those conditions. Ambiguity need not be fatal to an infringement claim or to a patent's validity, but it is fatal to both in this case. First, Purdue's gel test did not even attempt to resolve that ambiguity in the way that an ordinary skilled artisan would, so Purdue put forward no evidence of how Teva's tablets behave in the conditions of the gel test. Second, alternatively, some of that ambiguity is incapable of resolution through the permissible tools of claim construction, making the patent invalid and indefinite.

PART 4. CONCLUSION AND RELIEF

A valid patent provides a powerful right to its holder: the right to exclude all others from practicing the technology embodied in the patent. Patent law delicately balances the reward and encouragement of this right with a countervailing public interest in broad access to practice the known art at any given moment.

This Court has found that Teva has infringed Purdue's Low-ABUK Patents—the '799, '800, and '072 Patents—by filing its ANDA. However, the Court also concludes that Teva escapes liability for that infringement, because Teva has demonstrated with clear and convincing evidence that the Low-ABUK Patents are obvious. The Low-ABUK Patents reflect scientific research that culminated in the identification of 8α as the source of the ABUK impurities, but the patents' solution to that problem did not advance the art beyond what was already known to a person of ordinary skill.

A similar analysis applies to the '383 Patent. Teva's ANDA relies on a process that is equivalent to thermoforming, and therefore its proposed tablets infringe the '383 Patent. Yet Teva is not liable for infringement, because the patent did not introduce to the art anything more than the McGinity Application had already contributed. The '383 Patent lacks novelty and is accordingly invalid.

The dispute surrounding the '314 Patent does not require nearly the same level of analysis: the Court cannot find by a preponderance of the evidence that the accused tablets infringe the '314 Patent in the first place. The burden-shifting scheme of the Hatch-

Waxman Act is critical to this determination. Plaintiffs have the burden of proving infringement, and they have not carried their burden with respect to the '314 Patent.

With respect to every patent-in-suit, either (1) Teva's ANDA does not occupy the technological space where plaintiffs enjoy the right to exclude others or (2) plaintiffs' right to exclude others is based on an invalid patent. Based on the findings of fact and conclusions of law articulated above, the Court hereby ORDERS the following:

1. Each of plaintiffs' requests for relief is denied.
2. The following declaratory judgments shall enter in favor of Teva and against plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., Rhodes Technologies, and Grunenthal GmbH:
    a. Claims 3 and 19 of U.S. Patent No. 7,674,799 are invalid.
    b. Claims 30–34 and 76–79 of U.S. Patent No. 7,674,800 are invalid.
    c. Claims 1, 4, and 5 of U.S. Patent No. 7,683,072 are invalid.
    d. Teva's proposed products do not infringe claims 1, 2, 6, and 9 of U.S. Patent No. 7,776,314.
3. A further declaratory judgment shall be entered, in favor of Teva and against plaintiffs Purdue Pharma L.P. and Grunenthal GmbH, that claims 1, 2, 5, 7, and 8 of U.S. Patent No. 8,114,383 are invalid.

4. No attorneys fees will be awarded, because the prevailing party, Teva, has not demonstrated that this is an exceptional case.

Dated: New York, New York
January 14, 2014

SO ORDERED:

s/ Sidney H. Stein
Sidney H. Stein, U.S.D.J.

APPENDIX C

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re: OXYCONTIN ANTITRUST LITIGATION	*ORDER AMENDING FINDINGS OF FACT AND CONCLUSIONS OF LAW AND THE JUDGMENT IN THESE ACTIONS*
PURDUE PHARMA L.P., et al., Plaintiffs, -against- TEVA PHARMACEUTICALS, USA, INC., Defendant.	04 Md. 1603 (SHS) *This document relates to*: 11 Civ. 2037 (SHS) 12 Civ. 5083 (SHS)

SIDNEY H. STEIN, U.S. District Judge.

After a consolidated bench trial on the above-captioned actions, this Court issued Findings of Fact and Conclusions of Law on January 14, 2014. (Dkt. No. 634.) Judgment was entered on January 22, 2014. (Dkt. No. 637.) Defendant Teva Pharmaceuticals, USA, Inc., has now moved to amend the Judgment to include a declaration that claims 1, 2, 6, and 9 of U.S. Patent No. 7,776,314 are invalid. (Case No. 11 Civ. 2037, Dkt. No. 153.) Plaintiffs do not oppose the motion. (Case No. 11 Civ.

2037, Dkt. No. 162.) Accordingly, the Court grants Teva's motion.

It is therefore ORDERED that:

1. The January 14, 2014, Findings of Fact and Conclusions of Law are amended by adding the following italicized language to page 108: "The following declaratory judgments shall enter in favor of Teva and against plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., Rhodes Technologies, and Grunenthal GmbH: . . . *e. Claims 1, 2, 6, and 9 of U.S. Patent No. 7,776,314 are invalid*."
2. The January 22, 2014, Judgment is amended by adding the following italicized language to page 1: "The following declaratory judgment shall enter in favor of Teva and against plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., Rhodes Technologies, and Grunenthal GmbH: . . . *e. Claims 1, 2, 6, and 9 of U.S. Patent No. 7,776,314 are invalid*."
3. The January 22, 2014, Judgment is further amended by adding the following italicized language to page 2: "The following declaratory judgment is entered in favor of Teva and against plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., Rhodes Technologies, and Grunenthal GmbH: . . . *e. Claims 1, 2, 6, and 9 of U.S. Patent No. 7,776,314 are invalid*."

Dated: New York, New York
April 16, 2014

SO ORDERED:

s/ Sidney H. Stein
Sidney H. Stein, U.S.D.J.

APPENDIX D

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re: OXYCONTIN ANTITRUST LITIGATION	*ORDER AMENDING FINDINGS OF FACT AND CONCLUSIONS OF LAW AND THE JUDGMENT IN THESE ACTIONS*
PURDUE PHARMA L.P., et al., Plaintiffs, -against- TEVA PHARMACEUTICALS, USA, INC., Defendant.	04-Md-1603 (SHS) *This document relates to*: 11-Civ-2037 (SHS) 12-Civ-5083 (SHS)

SIDNEY H. STEIN, U.S. District Judge.

This Court issued Findings of Fact and Conclusions of Law on January 14, 2014, in these actions following a bench trial. (Case No. 11 Civ. 2037, Dkt. No. 149.) Judgment was subsequently entered on January 22, 2014. (Dkt. No. 150.)[1] The parties then became concerned that the U.S. Court of Appeals for the Federal Circuit might misconstrue

[1] The Court later amended the Findings of Fact and Conclusions of Law, as well as the Judgment, on April 16, 2014. (Dkt. No. 164.)

the Judgment to limit that court's appellate jurisdiction. The parties now jointly ask this Court to amend the Judgment, although they disagree as to the language of the amendment.[2]

Plaintiffs sued defendant Teva Pharmaceuticals, USA, Inc., for infringement of several patents, and Teva responded with counterclaims for declarations of non-infringement and invalidity. This Court found that Teva's proposed products would infringe claims 3 and 19 of U.S. Patent No. 7,674,799 ("the '799 Patent") (Dkt. No. 149 at 47); claims 30–34 and 76–79 of U.S. Patent No. 7,674,800 ("the '800 Patent") (*id.* at 45); claims 1, 4, and 5 of U.S. Patent No. 7,683,072 ("the '072 Patent") (*id.* at 46); and claims 1, 2, 5, 7, and 8 of U.S. Patent No. 8,114,383 ("the '383 Patent") (*id.* at 90). However, the Court concluded that those patent claims were invalid. (*Id.* at 108–08.) "[I]nvalidity operates as a complete defense to infringement." *Weatherchem Corp. v. J.L. Clark, Inc.*, 163 F.3d 1326, 1335 (Fed. Cir. 1998) (citing *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313 (1971)). Accordingly, with respect to the '799 , '800, '072, and '383 Patents, the Court denied plaintiffs' requests for relief and entered a Judgment that declared those patents to be invalid. (Dkt. No. 150 at 2.)

The Court sees no ambiguity in its adjudication of all the parties' claims and counterclaims on the merits to final judgment, but in light of the parties' joint request to amend the Judgment, the Court will

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[2] Although Teva filed a memorandum of law "In Opposition of Plaintiff's Motion," it writes in that memorandum that "the judgment should be amended." (Dkt. No. 173 at 1.)

clarify that the infringement issues have been fully adjudicated to final judgment.

The parties disagree over how the Court should articulate this, with each side requesting that a different reason be provided in the Judgment. (*Compare* Pls.' Mem. of Law in Support of Their Mot. to Enter a Final Judgment, Dkt. No. 171, Exh. A ("Teva's Counterclaims . . . of non-infringement . . . are denied as the Court has found that Teva infringes those claims"), *with* Def.'s Mem. of Law in Opp. of Pls.' Mot. to Enter a Final Judgment, Dkt. No. 173, Exh. A ("Teva's counterclaims . . . of non-infringement . . . are denied as moot.").) But the Judgment need not reiterate reasoning available in the Court's Findings of Fact and Conclusions of Law.

Accordingly, it is hereby ORDERED that the January 22, 2014, Judgment is amended by adding the following language to the end of the paragraph beginning "Whereas" on page 1 *and* to the end of the decretal paragraph on page 2: "5. Teva's counterclaims for declaratory judgment of non-infringement of claims 3 and 19 of U.S. Patent No. 7,674,799; claims 30–34 and 76–79 of U.S. Patent No. 7,674,800; claims 1, 4, and 5 of U.S. Patent No. 7,683,072; and claims 1, 2, 5, 7, and 8 of U.S. Patent No. 8,114,383 are denied."

Dated: New York, New York
July 14, 2014

SO ORDERED:

s/ Sidney H. Stein
Sidney H. Stein, U.S.D.J.

APPENDIX E

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re: OXYCONTIN ANTITRUST LITIGATION	04 Md. 1603 (SHS)
PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., RHODES TECHNOLOGIES, and GRUNENTHAL GMBH, Plaintiffs, -against- AMNEAL PHARMACEUTICALS, LLC, Defendant.	*ORDER* This document relates to: 11 Civ. 8153 (SHS)
PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., and RHODES TECHNOLOGIES, Plaintiffs, -against- MYLAN PHARMACEUTICALS INC. and MYLAN INC., Defendants.	12 Civ. 2959 (SHS)
PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., and RHODES TECHNOLOGIES,	13 Civ. 683 (SHS)

Plaintiffs,

-against-

EPIC PHARMA, LLC,

Defendant.

SIDNEY H. STEIN, U.S. District Judge.

In the above-captioned actions, plaintiffs claim that defendants have infringed a variety of patents. In *Purdue Pharma L.P. et al. v. Amneal Pharms., LLC*, Case No. 11 Civ. 8153, plaintiffs allege infringement of four patents: U.S. Patent No. 7,674,799; U.S. Patent No. 7,647,800; and U.S. Patent No. 7,683,072 (collectively, "the Low-ABUK Patents"); as well as U.S. Patent No. 7,776,314 ("the '314 Patent"). (*See* Compl. ¶ 23.) In *Purdue Pharma L.P. et al. v. Mylan Pharms. Inc. et al.*, Case No. 12 Civ. 2959, plaintiffs allege infringement of the three Low-ABUK Patents. (*See* Compl. ¶ 23.) In *Purdue Pharma L.P. et al. v. Epic Pharma, LLC*, Case No. 13 Civ. 683, plaintiffs again allege infringement of the three Low-ABUK Patents. (*See* Compl. ¶ 19.)

On January 14, 2014, this Court issued findings of fact and conclusions of law in *Purdue Pharma L.P. et al. v. Teva Pharms., USA, Inc.*, Case Nos. 11 Civ. 2037 and 12 Civ. 5083. (*See* Case No. 04 Md. 1603, Dkt. No. 634.) The Court held, inter alia, that the Low-ABUK Patents and the '314 Patent are invalid. On the same day, the Court ordered plaintiffs to show cause "why they are not collaterally estopped from asserting the Low-ABUK Patents and why the Court should not dismiss all claims in these litigations that rely on the Low-ABUK Patents." (Case No. 04 Md. 1603, Dkt. No. 635.)

Plaintiffs responded in a submission dated January 24 that although they intend to appeal the *Teva* decision, they "agree[ ] that collateral estoppel based on the *Teva* decision precludes Plaintiffs' claims for relief" in the three-above captioned actions. (*See* Case No. 04 Md. 1603, Dkt. No. 638 at 1.)

Although the order to show cause referred only to the Low-ABUK Patents, plaintiffs recognize that collateral estoppel applies with equal force to the '314 Patent. (*See id.* (conceding that all claims for relief in "the 2011 *Amneal* action"—which asserts both the Low-ABUK Patents and the '314 Patent—are precluded).) Plaintiffs are correct. With respect to the '314 Patent, the Court decided the *Teva* actions in the defendant's favor on alternative grounds: (1) that the defendant did not infringe the '314 Patent and (2) that, in any event, the '314 Patent is invalid. (*See* Case No. 04 Md. 1603, Dkt. No. 634, at 98, 106.) "The general rule in [the Second] Circuit is that 'if a court decides a case on two grounds, each is good estoppel.'" *Gelb v. Royal Globe Ins. Co.*, 798 F.2d 38, 45 (2d Cir. 1986) (quoting *Irving Nat'l Bank v. Law*, 10 F.2d 721, 724 (2d Cir. 1926)); *see Purdy v. Zeldes*, 337 F.3d 253, 258 n.6 (2d Cir. 2003).[1]

Because the Court found in *Purdue Pharma L.P. et al. v. Teva Pharms., USA, Inc.*, Case Nos. 11 Civ.

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[1] The above-captioned actions recite patent claims within the exclusive appellate jurisdiction of the U.S. Court of Appeals for the Federal Circuit. However, "the application of general collateral estoppel principles . . . is not a matter within the exclusive jurisdiction of [that] court." *Pharmacia & Upjohn v. Mylan Pharms.*, 170 F.3d 1373, 1381 (Fed. Cir. 1999). Rather, the applicable law is "the law of the circuit in which the district court [ ] sits." *Id.*

2037 and 12 Civ. 5083, that the Low-ABUK Patents and the '314 Patent are invalid (*see* Case No. 04 Md. 1603, Dkt. No. 634), plaintiffs are precluded from arguing that those patents are valid in the above-captioned actions. The Court therefore directs that the above-captioned actions be dismissed.

Dated: New York, New York
January 29, 2014

SO ORDERED:

s/ Sidney H. Stein
Sidney H. Stein, U.S.D.J.

APPENDIX F

NOTE: This order is nonprecedential.

United States Court of Appeals for the Federal Circuit

PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., RHODES TECHNOLOGIES,
Plaintiffs-Appellants

v.

EPIC PHARMA, LLC,
Defendant

2014-1294

Appeal from the United States District Court for the Southern District of New York in No. 1:13-cv-00683-SHS, Senior Judge Sidney H. Stein.

PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., RHODES TECHNOLOGIES,
Plaintiffs-Appellants

v.

MYLAN PHARMACEUTICALS INC., MYLAN INC.,

Defendants-Appellees

2014-1296

Appeal from the United States District Court for the Southern District of New York in No. 1:12-cv-02959-SHS, Senior Judge Sidney H. Stein.

PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., RHODES TECHNOLOGIES, GRUNENTHAL GMBH,

Plaintiffs-Appellants

v.

AMNEALPHARMACEUTICALS, LLC,

Defendant-Appellee

2014-1306, -1307

Appeals from the United States District Court for the Southern District of New York in No. 1:11-cv-08153-SHS, Senior Judge Sidney H. Stein.

GRUNENTHAL GMBH, PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., RHODES TECHNOLOGIES,

Plaintiffs-Appellants

v.

TEVA PHARMACEUTICALS USA, INC.,
Defendant-Appellee

2014-1311, -1312, -1313, -1314

Appeals from the United States District Court for the Southern District of New York in Nos. 1:11-cv-02037-SHS, 1:12-cv-05083-SHS, Senior Judge Sidney H. Stein.

ON PETITION FOR REHEARING EN BANC AND PETITION FOR PANEL REHEARING AND REHEARING EN BANC

Before PROST, *Chief Judge*, NEWMAN, LOURIE, DYK, MOORE, REYNA, WALLACH, TARANTO, CHEN, HUGHES, *Circuit Judges*, and STARK, *Chief District Judge*.*

PER CURIAM.

O R D E R

Appellants Purdue Pharma, L.P., et al., filed a petition for rehearing en banc, and appellant Grunenthal GmbH filed a combined petition for panel rehearing and rehearing en banc. The petitions were first referred to the panel that heard the appeal, and thereafter the petitions for rehearing en banc were referred to the circuit judges who are in regular active service.

* Circuit Judge O'Malley and Circuit Judge Stoll did not participate. Chief District Judge Stark participated only in the decisions on the petitions for panel rehearing.

Upon consideration thereof,

IT IS ORDERED THAT:

(1) The petitions for panel rehearing are denied.

(2) The petitions for rehearing en banc are denied.

The mandate of the court will issue on May 11, 2016.

FOR THE COURT

May 4, 2016
Date

/s/ Daniel E. O'Toole
Daniel E. O'Toole
Clerk of Court