

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., and  
RHODES TECHNOLOGIES,

Plaintiffs,

-against-

VARAM, INC. and KVK-TECH, INC.,

Defendants.

This document relates to:

10 Civ. 6038 (SHS)

11 Civ. 766 (SHS)

12 Civ. 2814 (SHS)

12 Civ. 6047 (SHS)

OPINION & ORDER

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

Defendants Varam, Inc. and KVK-Tech, Inc. (collectively “Varam”) bring this motion for summary judgment against plaintiffs (collectively “Purdue”) in four related Hatch-Waxman Act actions. Varam asks this Court to rule that U.S. Patent No. 5,508,042 (the “’042 patent” (Hu Decl., Ex. 1)) is invalid and that, in any event, Varam’s generic product will not infringe that patent. For the reasons set forth below, and for the reasons exhaustively elaborated in five prior written opinions concerning the ’042 patent, Varam’s motion is denied.

## I. BACKGROUND

### A. Factual Background

#### 1. *Purdue’s Controlled-Release Oxycodone Patents*

Purdue is the maker of OxyContin, a brand-name drug designed to treat moderate to severe pain. In 1991, Purdue applied for a patent claiming products and methods relating to a controlled-release oxycodone formulation. This formulation releases the drug’s active ingredient into a

patient over an extended period of time in a controlled manner, hence the name. The U.S. Patent and Trademark Office granted Purdue's application, which issued in 1993 as U.S. Patent No. 5,266,331 (the "'331 patent" (Hu Decl., Ex. 6)).

A few months before the '331 patent issued, Purdue applied for another patent covering controlled-release oxycodone. (Hermes Decl., Ex. 34.) This application, No. 08/81,302 (the "'302 application"), was a continuation-in-part from the '331 patent. (*Id.* at 186.) Like the '331 patent, the '302 application claimed both products and methods. (*Id.* at 134–37.) The patent examiner concluded that the product and method claims were patentably distinct, and required Purdue to either restrict its application or select one of these classes of claims to pursue. (*Id.* at 162–65.) Purdue elected to pursue the product claims in the '302 application and pursue the method claims in a divisional application. (*Id.* at 166.) After Purdue filed a terminal disclaimer, the '302 patent issued in August 1996 as U.S. Patent No. 5,549,912 (the "'912 patent" (Hu Decl., Ex. 5)).

In March 1996, while the '302 application was still pending, Purdue filed yet another application—a continuation-in-part of the '302 application, which was itself a continuation-in-part of the '331 patent. This application covered controlled-release oxycodone and once again claimed both products and methods. The Patent Office granted this application, subject to another terminal disclaimer, without requiring Purdue to limit its claims to either products or methods. This patent issued on August 12, 1997 as U.S. Patent No. 5,656,295 (the "'295 patent" (Hu Decl., Ex. 4)).

## 2. *The '042 Patent*

With that background, the Court turns to the '042 patent, the subject of Varam's motion. This patent issued as a division of the '302 application and contains only two process claims:

1. A method for reducing the range in daily dosages required to control pain in human patients, comprising administering an oral controlled release dosage formulation comprising from about 10 to about 40 mg oxycodone or a salt thereof which provides a mean maximum plasma concentration of oxycodone from about 6 to about 60 ng/ml from a mean of about 2 to about 4.5 hours after

administration, and a mean minimum plasma concentration from about 3 to about 30 ng/ml from a mean of about 10 to about 14 hours after repeated administration every 12 hours through steady-state conditions.

2. A method for reducing the range in daily dosages required to control pain in substantially all human patients, comprising administering an oral solid controlled release dosage formulation comprising from about 10 mg to about 160 mg oxycodone or a salt thereof which provides a mean maximum plasma concentration of oxycodone up to about 240 ng/ml from a mean of up to about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration up to about 120 ng/ml from a mean of about 10 to about 14 hours after repeated administration every 12 hours through steady-state conditions.

(Hu Decl., Ex. 1 at 20:18–39.) The '042 patent is due to expire shortly. (Purdue 56.1 ¶ 9.)

### ***3. The '598 Patent***

Finally, Varam has stressed the relevance of a patent issued before the '331 patent that Varam argues renders the '042 patent invalid. That patent, U.S. Patent No. 4,861,598 (the "'598 patent" (Hu Decl., Ex. 3)), claims a particular formulation to be used for controlled-release oral administration of drugs, not just oxycodone. It is undisputed that the '598 patent is prior art to the '042 patent. (Purdue 56.1 ¶ 2.) The '598 patent has long since expired and was never owned by Purdue.

### **B. Prior Actions and Procedural History**

This is not this Court's first encounter with the '042 patent. Twice this Court has issued extensive opinions concerning that patent. The U.S. Court of Appeals for the Federal Circuit has heard three appeals concerning that patent. Because those prior determinations bear directly on many of the arguments Varam raises in its motion for summary judgment, the Court will outline them in some detail and then turn to Varam's motion.

## 1. *Prior Actions Involving the '042 Patent*

### a. *The Boehringer action*

In 1999, Purdue sued three defendants that had filed an ANDA, which allegedly infringed the '042, '912, and '295 patents. *See Purdue Pharma L.P. v. Boehringer Ingelheim GmbH ("Boehringer I")*, 98 F. Supp. 2d 362 (S.D.N.Y. 2000). Purdue moved for a preliminary injunction barring the defendants from making, using, or offering their products for sale. *See id.* at 366–67. Following a four-day fact hearing, this Court granted Purdue's motion, *see id.* at 367, a result the Federal Circuit affirmed. *See Purdue Pharma L.P. v. Boehringer Ingelheim GmbH ("Boehringer II")*, 237 F.3d 1359 (Fed. Cir. 2001).

In deciding Purdue's request for a preliminary injunction, this Court ruled on several disputed issues that are relevant to Varam's motion for summary judgment here. First, the Court determined that "viewing each patent as a whole," and in the context of a preliminary-injunction proceeding, the "the preambles [of the '042 patent's claims] do not state an independent limitation of the claimed inventions . . . ." *Boehringer I*, 98 F. Supp. 2d at 377. Second, the Court held that Purdue was likely to succeed on the merits of its infringement claim based primarily on the defendants' submissions to the FDA, which included studies showing concentration values of oxycodone over time and that "Purdue has made a clear showing in this regard." *Id.* at 378. Finally, the Court rejected the defendants' arguments that the '042 patent was anticipated by the '598 patent, and specifically by Example II(B) of the '598 patent. *See id.* at 387–90.

### b. *The Endo action*

Three years after the preliminary injunction hearing in *Boehringer*, this Court held a multi-week trial in *Purdue Pharma L.P. v. Endo Pharmaceuticals Inc. ("Endo I")*, No. 00 Civ. 8029, 2004 WL 26523 (S.D.N.Y. Jan. 5, 2004). *Endo I* centered on the same patents at issue in *Boehringer*, including the '042 patent. As with that earlier action, Purdue had alleged that the defendants' ANDA infringed these patents, while the defendants claimed that the patents were invalid. The Court concluded that the defendants' ANDA did infringe the patents at issue, but that the patents were invalid due to Purdue's inequitable conduct during their prosecution. *See id.* at

\*27. At first, the Federal Circuit affirmed this Court's judgment. See *Purdue Pharma L.P. v. Endo Pharm. Inc.*, 410 F.3d 690 (Fed. Cir. 2005). On rehearing, however, the Federal Circuit vacated this Court's conclusion that Purdue's patents were invalid and affirmed this Court's conclusion that the patents were infringed. See *Purdue Pharma L.P. v. Endo Pharm. Inc.* ("*Endo III*"), 438 F.3d 1123, 1137 (Fed. Cir. 2006).

The multiple opinions springing out of the *Endo* litigation bear on two issues brought up in Varam's summary judgment motion. First, *Endo I* and *Endo III* clarified the claim construction for the '042 patent. In *Endo I*, this Court declined to revisit its decision in *Boehringer I* that the preambles did not limit the '042 patent's claims. See *Endo I*, 2004 WL 26523, at \*8. The Court did, however, conclude that these claims were limited to "controlled release oxycodone formulations" that "control pain relief in approximately 90% of patients with an approximately four-fold dosage range."<sup>1</sup> *Id.* at \*14. The Court read this limitation into the claim term "controlled release" based on the Court's conclusion that Purdue had surrendered other formulations of controlled release oxycodone while prosecuting the patents. See *id.* at \*8–14. The Federal Circuit reversed this construction of the '042 patent's claims in *Endo III* and held that Purdue's prosecution had not limited the reach of these claims. See *Endo III*, 438 F.3d at 1136–37. In the end, neither the preamble nor the term "controlled release" limit the '042 patent's claims.

Second, this Court held that Endo's ANDA infringed Purdue's patents, a conclusion based on the defendants' own submissions to the FDA. See *Endo I*, 2004 WL 26523, at \*17–19. The defendants also produced studies that showed the time and concentration ranges fell within the ranges set in the '042 patent. See *id.* The Federal Circuit affirmed this conclusion. See *Endo III*, 438 F.3d at 1137.

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<sup>1</sup> A "four-fold dosage range" means, in this context, dosages between 10 and 40 mgs. This was an improvement over the prior art eight-fold dosage range, meaning dosages between 10 and 80 mgs. See *Endo III*, 438 F.3d at 1127.

## 2. *The Varam Actions*

Finally, the Court comes to the latest actions involving the '042 patent. Purdue initiated this action by filing suit against defendants both in this Court (No. 10 Civ. 6038) and simultaneously in the Eastern District of Pennsylvania. The Judicial Panel on Multidistrict Litigation transferred the Pennsylvania action to this Court (where it is No. 11 Civ. 766) for consolidated pretrial proceedings in the multidistrict litigation involving certain OxyContin patents, MDL No. 1603. Varam then filed another, essentially duplicative, ANDA with the FDA. Purdue responded in 2012 by again filing suit both in this district (No. 12 Civ. 2814) and the Eastern District of Pennsylvania. The JPML transferred the latter action to this Court (where it is No. 12 Civ. 6047) over Varam's objections.

After a flurry of motions to 1) dismiss the complaint for failure to state a claim and for lack of personal jurisdiction, 2) transfer the actions to the Eastern District of Pennsylvania, and 3) stay them, Varam has moved for summary judgment in its favor as to the '042 patent.

## II. DISCUSSION

"In a patent case, as in any other, summary judgment may be granted when there are no disputed issues of material fact, or when the non-movant cannot prevail on the evidence submitted when viewed in a light most favorable to it." *Knoll Pharm. Co., Inc. v. Teva Pharm. USA, Inc.*, 367 F.3d 1381, 1384 (Fed. Cir. 2004) (per curiam) (citation omitted). This Court and the Federal Circuit have considered enormous amounts of evidence relating to the '042 patent in the *Boehringer* preliminary injunction hearing and *Endo* trial. Purdue largely prevailed in both proceedings. Varam now asks this Court to reach the opposite result based on considerably less evidence.

The Court will first address the proper construction of the two claims in the '042 patent. The Court will then consider the arguments raised by Varam in turn: that the '042 patent is invalid as anticipated or obvious; for failing the written description requirement, or on double patenting grounds; and that even if the '042 patent is valid, Varam's product does not infringe it.

## A. Claim Construction

“[T]he claims of a patent define the invention 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). “To ascertain the scope and meaning of the asserted claims, [courts] look to the words of the claims themselves, the specification, the prosecution history, and any relevant extrinsic evidence.” *Absolute Software, Inc. v. Stealth Signal, Inc.*, 659 F.3d 1121, 1129 (Fed. Cir. 2011). “The words of a claim are generally given their ordinary and customary meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.” *Medtronic Inc. v. Boston Scientific Corp.*, 695 F.3d 1266, 1275 (Fed. Cir. 2012) (quotation marks and alterations omitted).

As discussed above, this Court and the Federal Circuit have already construed the two claims in the ‘042 patent at length. Varam, however, argues that this Court should reevaluate its conclusion that the preambles do not limit the ‘042 patent’s claims. According to Varam, because “[t]he preambles of the ‘042 claims were critical features in the specification and prosecution history to attempt to overcome the prior art,” they should be read to limit the ‘042 patent’s claimed invention. (Varam Mem. in Supp. at 8.) But this Court and the Federal Circuit have already considered the prosecution history of the ‘042 patent—including the exact language Varam highlights. The Federal Circuit explicitly held that the prosecution history did not limit the substantive terms of the ‘042 patent’s claims. See *Endo III*, 438 F.3d at 1136 (“In this case, the trial court concluded that during prosecution Purdue ‘deliberately and clearly relinquished, disclaimed and surrendered controlled release oxycodone formulations that do not control pain relief in approximately 90% of patients with an approximately four-fold dosage range.’ We agree with Purdue that it made no such disclaimer or disavowal, and the trial court’s holding to the contrary was in error.” (citation omitted)). This Court will not use the preambles to smuggle this language back into the claims.

Thus, the Court will construe the ‘042 patent’s claims consistently with the interpretations of *Boehringer I* and *II*, and *Endo III*.

## B. Anticipation and Obviousness

Varam argues that the '042 patent's claims are invalid as either anticipated or obvious. Whether a patent's claim is anticipated, and thus not novel, is a question of fact. *In re Gleave*, 560 F.3d 1331, 1334–35 (Fed. Cir. 2009). Whether a patent claim is obvious “is a question of law based on underlying facts, as set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966).” *Soverain Software LLC v. Newegg Inc.*, 705 F.3d 1333, 1336 (Fed. Cir. 2013). Because “[a] patent shall be presumed valid,” 35 U.S.C. § 282(a), Varam bears the burden of demonstrating both of these grounds of invalidity by clear and convincing evidence. *See Microsoft Corp. v. i4i Ltd. P'Ship*, 131 S. Ct. 2238, 2242 (2011).

### 1. *Varam Has Not Proved that the '042 Patent's Claims Are Anticipated*

Varam contends that the '598 patent anticipates both claims of the '042 patent. “A claim is anticipated only where each and every limitation is found either expressly or inherently in a single prior art reference.” *ArcelorMittal France v. AK Steel Corp.*, 700 F.3d 1314, 1322 (Fed. Cir. 2012) (quotation marks omitted). Varam's reasoning in support of its argument is succinct: “All prior art controlled release oxycodone-containing tablets that have been taught by the '598 patent and which were analyzed for their clinical properties have been found to inherently anticipate the '042 claims. There have been no exceptions.” (Varam Mem. in Supp. at 10–11 (note omitted).) By “no exceptions,” Varam actually means “one exception” — this Court in *Boehringer I*. Varam acknowledges the Court's prior ruling, but posits that “[t]he *Boehringer [I]* formulation is not relevant to this motion because it was held to be not fairly representative of the '598 teaching and it is thus not evidence of the inherent properties of the '598 patent.” (*Id.* at 11 n.3.) Varam does not cite any authority to support this statement.

In *Boehringer I*, this Court determined that, at the preliminary injunction stage, it could not readily equate *in vivo* concentration data (that is, data that shows the concentration of the drug in an actual person's blood) with *in vitro* concentration data (data that shows the concentration of the drug in a test tube solution). *See Bohringer I*, 98 F. Supp. 2d at 388–



90. The Court reached this determination notwithstanding the language from the '598 patent proclaiming a "strong correlation . . . between the in-vitro dissolution time determined for a dosage form and the in-vivo bioavailability." Hu Decl., Ex. 3 at 2:48–50; see *Boehringer I*, 98 F. Supp. 2d at 388. The Court was also unmoved by an elaborate, but flawed, study the defendants commissioned to prove this correlation. See *Boehringer I*, 98 F. Supp. 2d at 388–90. In addition, the '042 patent contained additional limitations that the defendants did not attempt to prove were anticipated by Example II(B) from the '598 patent. See *id.* at 390.

Varam has presented considerably less evidence than the Court considered during the *Boehringer* proceeding, yet it seeks a more favorable result for itself. The Court cannot oblige. Since Varam has not provided the Court with anything more than what it already considered in *Boehringer I*, the Court concludes that a material question of fact exists as to whether the *in vitro* teachings of the '598 patent anticipate the *in vivo* limitations of the '042 claims, and whether the '598 patent inherently or explicitly teaches "repeated administration every 12 hours through steady-state conditions." *Boehringer I*, 98 F. Supp. 2d at 390.

## 2. *Varam Has Not Proved that the '042 Patent's Claims Are Obvious*

"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 (Fed. Cir. 2012) (quotation marks omitted). While anticipation and obviousness are separate inquiries, Varam has eased the Court's burden by relying on a single piece of prior art—the '598 patent—to prove both. As set forth above, however, genuine issues of fact remain as to the scope and content of the '598 patent's teachings and their comparison with the '042 claims. Varam's meager motion does not satisfy its high burden of proving that the '042 patent would have been obvious to a skilled artisan at the time of the invention.

### C. Written Description Requirement

Varam next contends that the '042 patent fails to satisfy the written description requirement of 35 U.S.C. § 112(a). A patent's "description must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed. In other words, the test for sufficiency is 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." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (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 question is one of fact. *See id.* Varam has the burden of proving the asserted claims' deficiencies by clear and convincing evidence. *See Hynix Semiconductor Inc. v. Rambus Inc.*, 645 F.3d 1336, 1351 (Fed. Cir. 2011).

Based on the facts before the Court, Varam has not produced clear and convincing evidence that the '042 patent fails the written description requirement. In point of fact, Example 18 of the '042 patent describes an *in vivo* study of a 10 mg controlled-release oxycodone tablet that produced plasma concentration and time ranges that fall within the scope of the claims of the '042 patent. (Hu Decl., Ex. 1 at 3:31–34, 17:55–18:17, Fig. 5.) In addition, the '042 patent details repeated dose studies that conform to the claimed invention. (*See id.* at 4:12–24.) These studies standing by themselves certainly preclude the Court from granting Varam summary judgment for failure of the '042 patent to meet the written description requirement of section 112(a).

### D. Double Patenting

Varam also argues that the '042 patent is invalid on double patenting grounds against the '331 patent, the '912 patent, and the '295 patent. "The doctrine of double patenting is intended to prevent a patentee from obtaining a time-wise extension of a patent for the same invention or an obvious modification thereof." *In re Basell Poliolefine Italia S.P.A.*, 547 F.3d

1371, 1375 (Fed. Cir. 2008) (quotation marks and alteration omitted). It comes in two forms: statutory and obvious-type double-patenting. Varam urges that both apply.

“[S]tatutory double patenting [] stems from 35 U.S.C. § 101 and prohibits a later patent from covering the same invention, i.e., identical subject matter, as an earlier patent.” *Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381, 1384 (Fed. Cir. 2010) The judicially created “doctrine of obviousness-type double patenting is intended to prevent the extension of the term of a patent by prohibiting the issuance of the claims in a second patent not patentably distinct from the claims of the first patent. A later patent claim is not patentably distinct from an earlier claim if the later claim is obvious over, or anticipated by, the earlier claim.” *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 689 F.3d 1368, 1376 (Fed. Cir. 2012) (quotation marks, citations, and alterations omitted). Double-patenting is a question of law, *see Sun Pharm.*, 611 F.3d at 1384, but “obviousness-type double patenting is a question of law with underlying findings of fact.” *Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280, 1290 (Fed. Cir. 2012). As with its other challenges to the ‘042 patent’s validity, Varam must prove the underlying facts by clear and convincing evidence. *See Amgen Inc. v. F. Hoffman-La Roche Ltd*, 580 F.3d 1340, 1362 (Fed. Cir. 2009). It has not done so.

**1. *Varam Has Not Proved that the ‘042 Patent Is Patentably Indistinct from the ‘331 Patent***

Varam contends that the ‘042 patent is invalid as against the ‘331 patent on the grounds of obvious-type double patenting. There are “two steps in an obviousness-type double patenting analysis. First, a court construes the claims in the earlier patent and the claims in the later patent and determines the differences. Second, it determines whether those differences render the claims patentably distinct.” *Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 518 F.3d 1353, 1363 (Fed. Cir. 2008) (quotation marks, citations, and alterations omitted). The second step in this process “is analogous to an obviousness analysis under 35 U.S.C. § 103, except that the [earlier] patent is not considered prior art.” *Hoffman-La Roche*, 580 F.3d at 1361.

The process claims in the '331 patent are directed to the *in vitro* characteristics of an oxycodone formulation. (Hu Decl., Ex. 6 at 13:33–14:12.) As already set forth, this Court cannot evaluate whether *in vitro* teachings make the *in vivo* limitations in the '042 patent obvious at this stage based on the record before it. Thus Varam has not met its burden of proving invalidity by clear and convincing evidence.

**2. *Varam Has Not Proved that the '042 Patent Is Effectively Identical to the '912 Patent***

Varam next contends—in a single sentence—that the '042 claims are invalid for statutory double-patenting since they are “effectively identical” to the claims in the '912 patent. (Varam Mem. in Supp. at 14.) That single sentence is as follows: “The claims are all directed to the same formulations for the same administration to produce the same clinical results.” (*Id.*) Varam’s hopeful argument is belied by the prosecution history of the '042 and '912 patents.

Purdue initially filed the '302 application, which claimed both products and methods. (Hermes Decl., Ex. 34 at 134–37.) The patent examiner recognized that these two types of claims were distinct, and directed Purdue to either restrict the application or elect one or the other category of claims. (*Id.* at 162–65.) Purdue opted to restrict the application to the product patents and filed the method claims as a divisional application. (*Id.* at 166–68.) The product claims issued as the '912 patent, while the divisional application issued as the '042 patent. In the final patents, Purdue maintained the division the examiner required: “the process claims remained in separate patents from the [product] claims . . . .” *Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1568 (Fed. Cir. 1996). In other words, “the inventions covered by” the '042 and '912 patents “are not the same, and . . . [thus, there is no] same-invention type double patenting in this case.” *Studiengesellschaft Kohle mbH v. N. Petrochemical Co.*, 784 F.2d 351, 355 (Fed. Cir. 1986) (*per curiam*).

### ***3. The Later-Issued '295 Patent Cannot Invalidate the '042 Patent on Double Patenting Grounds***

Varam also contends that the '295 patent invalidates the '042 claims on obvious-type double-patenting grounds. Purdue applied for the '295 patent on March 19, 1996—approximately three years after it filed the '042 application. The '295 patent was issued on August 12, 1997—almost a year after the '042 patent was approved. Purdue cannot turn back time to find a way to use the '295 patent to invalidate the earlier-applied-for and earlier-issued '042 patent. If either of these patents is void, it is “[t]he last, not the first.” *Suffolk Co. v. Hayden*, 70 U.S. (3 Wall.) 315, 319 (1865); *see also* Patent Law & Practice § 4.I.D.4 (7th ed. 2011).

#### **E. Infringement**

Finally, Varam posits that it is entitled to summary judgment on Purdue’s infringement claims since “Purdue has adduced no evidence that anyone will practice the claimed method.” (Varam Mem. in Supp. at 16.) “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 opposition to Varam’s motion, Purdue pointed the Court to a document in which Varam described administering oxycodone tablets every twelve hours in dosage strengths ranging from 10 to 160 mgs (Hermes Decl., Ex. 37 at 13426, Ex. 38 at 8743; Purdue 56.1 ¶ 18.), as well as data from Varam showing plasma concentration and time ranges that fall with the claims of the '042 patent. (Hermes Decl., Ex. 37 at 13426–27, Ex. 38 at 8743–44.) These alone are sufficient for the Court to deny summary judgment to Varam on the issue of whether anyone will practice the claimed invention. *See Endo I*, 2004 WL 26523, at \*18–19, *aff’d in relevant part*, *Endo III*, 438 F.3d at 1137.

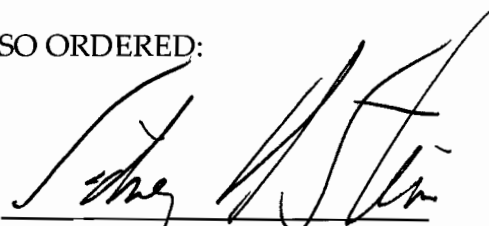
### **III. CONCLUSION**

Varam’s meager motion fails to overturn the extensive, considered opinions crafted by this Court and the Federal Circuit over the past

decade. Defendants' motion for summary judgment on the '042 patent is denied.

Dated: New York, New York  
April 15, 2013

SO ORDERED:



A handwritten signature in black ink, appearing to read 'Sidney H. Stein', is written over a horizontal line. The signature is stylized and cursive.

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