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Nuvo v. Dr. Reddy and the Patentability of Prophetic Pharmaceutical Inventions Based on Unexplained Inventive Insight

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Nuvo v. Dr. Reddy and the Patentability of Prophetic Pharmaceutical Inventions Based on Unexplained Inventive Insight

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In a recent decision, *Nuvo v. Dr. Reddy*, the Court of Appeals of the Federal Circuit invoked the written description requirement to invalidate patent claims reciting a prophetic pharmaceutical invention that was purportedly based solely on the "inventive insight" of the named inventor, with no experimental data or other non-prior art information supporting its efficacy.[1] To my knowledge, this is the first time the Federal Circuit has invoked the written description requirement in this context and for this purpose. Instead, the court has in the past invoked the utility and/or enablement requirements for this purpose, perhaps most notably in the Federal Circuit's controversial 2009 decision in *In re '318 Patent Infringement Litig.*[2] This Report focuses on the patentability of prophetic pharmaceutical inventions, wherein the asserted efficacy is based solely on the purported inventive insight of the named inventor, but the rationale behind the insight is not explained in the patent application as filed.

THE PATENTABILITY OF PROPHETIC INVENTIONS

I often encounter people who mistakenly believe that an inventor must demonstrate that his invention will work prior to seeking patent protection. This is of course not the case. The Federal Circuit has "repeatedly stated that [an] invention does not actually have to be reduced to practice" in order to be patentable.[3] Assuming the various requirements of patentability have been satisfied, it is possible to patent an invention even though at the time the patent application is filed the invention has yet to be proven to work. In this article, I will refer to such an invention as a "prophetic invention." The term "prophetic patent" will be used to describe an issued patent that includes one or more "prophetic claims," *i.e.*, a patent claim with respect to which, as of the filing date, no embodiment falling within the scope of the claim has actually been reduced to practice, either by it having been made (in the case of a product) or performed (in the case of process), or if it has been made or performed, it has not been physically demonstrated that the claimed product or process provides the practical utility that the invention is purported to provide.

In a 2016 blog post, Russ Krajec discusses the distinction between "data-driven" non-prophetic patents versus prophetic patents, which he characterizes as almost purely forward-looking and which are only able to guess as to whether the technology will work.[4] He describes these patents as a "necessary evil," useful in creating a patent portfolio for a start-up company prior to raising funds or entering the market, but potentially very damaging to a company when used badly. The primary danger of prophetic patents discussed in this blog post is that disclosing too much information too early in

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[1] *Nuvo Pharm. (Ireland) Designated Activity Co. v. Dr. Reddy's Labs. Inc.*, 923 F.3d 1368 (Fed. Cir. 2019).
[2] *In re '318 Patent Infringement Litig.*, 583 F.3d 1317 (Fed. Cir. 2009).
[3] *Nuvo*, 923 F.3d at 1380 (citing *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 926 (Fed. Cir. 2004)).
[4] Russ Krajec, *The First Patent: A Roadmap for a Startup's Patent Portfolio*, IP Watchdog (April 26, 2016), available at <https://www.ipwatchdog.com/2016/04/26/first-patent-roadmap-startups/id=68585/>

a prophetic patent can create prior art that will prevent the company from obtaining non-prophetic patents at a later date. This Report will focus more on the converse danger, which is that disclosing too little information in a prophetic patent specification will result in the invalidation of claims in that patent for failing to provide an adequate showing that the invention will work.

A "prophetic example" (sometimes referred to as a "paper example") is an example provided in a patent specification that describes the manner and process of making an embodiment of the invention which has not actually been conducted.[5] In contrast, a "working example" corresponds to work actually performed and may describe tests which have actually been conducted and results that were achieved. Prophetic examples are permitted in patent applications, as are simulated or predicted test results, so long as prophetic examples are not described using the past tense (which is reserved for working examples) and predicted test results are not represented as having actually been achieved.[6] Not surprisingly, however, prophetic examples are given less weight in assessing the utility and enablement of inventions.[7] Note that the presence of a prophetic example in a patent does not necessarily mean that the patent or patent claims themselves are prophetic, since in many cases there is actual data and working examples supporting some embodiments of the claimed invention, with the prophetic examples directed towards other untested, and perhaps more speculative, embodiments falling within the scope of the same claim.

In a recent law review article, Professor Janet Freilich reported her finding that "in chemistry and biology patents issued between 1976 and 2017, at least 17% of the examples are prophetic, and, of patents with examples, at least 24% contain some prophetic experiments."[8] Her study focused on this particular category of patents because "prophetic examples are thought to be particularly useful in pharmaceutical patents." In her article, she postulates that "without prophetic examples, we might see reduced innovation from small companies or those in the pharmaceutical space."

In order for a prophetic invention to be patentable, the disclosure of the patent application as filed must be sufficient to convince one of skill in the art that there is some reasonable degree of likelihood that the invention will work. Allowing patents on entirely speculative prophetic inventions would contravene basic policy considerations of U.S. patent law, by allowing individuals to dream up and patent highly speculative prophetic "inventions," and then claim exclusive rights to the invention if and when someone comes along and actually demonstrates that the invention does in fact work. As the Supreme Court famously observed 1966, "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."[9] More recently, the Federal Circuit has explained that "[a]llowing ideas, research proposals, or objects only of research to be patented has the potential to give priority to the wrong party and to 'confer power to block off whole areas of scientific development, without compensating benefit to the public.'"[10] In another decision, the Federal Circuit explained that while a patent "does not need to guarantee that the invention works,"[11] more than a showing of "mere plausibility" is required for patentability.[12]

> If mere plausibility were the test for enablement under section 112, applicants could obtain patent rights to "inventions" consisting of little more than respectable guesses as to the likelihood of their success. When one of the guesses later proved true, the "inventor" would be rewarded the spoils instead of the party who demonstrated that the method actually worked. That scenario is not consistent with the statutory requirement that the inventor enable an invention rather than merely proposing an unproved hypothesis.[13]

U.S. patent law's utility and/or enablement requirements have served as the traditional doctrinal tools for precluding patents on unproved hypotheses and merely "plausible" inventions, while permitting patents on inventions that have not absolutely

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[5]MANUAL OF PATENT EXAMINING PROCEDURE (MPEP) § 608.

[6]As Hoffman-La Roche learned the hard way with respect to important patent relating to polymerase chain reaction (PCR). *See Hoffman-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354,1367 (Fed. Cir. 2003).

[7]*In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (identifying the "presence or absence of *working* examples" as a relevant factor in assessing enablement (emphasis added)).

[8]Janet Freilich, *Prophetic Patents* (June 25, 2018). Available at SSRN: <https://ssrn.com/abstract=3202493> or< http://dx.doi.org/10.2139/ssrn.3202493>

[9]*Brenner v. Manson*, 383 U.S. 519, 536 (1966).

[10]*In re '318 Patent Infringement Litig.*, 583 F.3d 1317, 1324 (quoting *Brenner*, 383 U.S. at 534).

[11]*Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1310 (Fed. Cir. 2015),

[12]*Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1325 (Fed. Cir. 2005).

[13]*Id.*

been shown to work, but that at least have been shown with some degree of rigor reasonably likely to work, based on the disclosure provided in the patent application as filed as it would be viewed by one of skill in the art in light of the prior art. The statutory basis for the utility requirement can be found in two sections of the Patent Act: the mandate of 35 U.S.C. § 101 that a patent invention must be new and useful, as well as language of Section 112(a) requiring the patent application to enable one of skill in the art to use the claimed invention.[14] Thus, a lack of credible utility can be found to violate § 101 or the "how to use" prong of § 112(a)'s enablement requirement, or both.[15] The standard for satisfying the requirement is essentially the same whether cast in terms of § 101 or § 112(a).

In applying the utility and enablement requirements, patent law has long distinguished between predictable and unpredictable fields of technology. The mechanical and electrical arts, for example, are generally considered predictable, while chemistry and biology are deemed unpredictable. In predictable areas of technology, it is generally possible for one of skill in the art to accurately predict whether or not a prophetic invention will work, although there have been exceptions.[16] With respect to unpredictable technologies, on the other hand, it is often quite difficult, and in some cases impossible, to accurately predict whether or not a prophetic invention will work. That is why actual working examples are much more important in the unpredictable arts as opposed to the predictable arts, and why prophetic patents are easier to obtain in predictable areas of technology. The predictability or unpredictability of the art, as well as the presence or absence of working examples, are two of the *Wands* factors the Federal Circuit has identified as relevant in assessing whether the enablement requirement has been satisfied.[17]

The prophetic nature of an invention in the predictable arts generally does not create patentability issues, because normally one of skill in the art can be quite confident that the invention will in fact work for its intended purpose, based on its prophetic description. The invention at issue in the Supreme Court's decision in *Pfaff v. Wells Elec. Inc.*, a mechanical socket for holding computer chips during testing, provides a good example of this.[18] The Court found that detailed mechanical drawings of the invention were sufficient to satisfy the enablement (and by implication utility) requirement even though the invention had not been made or tested at the relevant point in time. In *Pfaff,* the inventor himself testified that in his business, even without any prototype or other working embodiment, once he has a drawing of his invention he knows that it will work—all that is left to do is the "hard tooling."[19]

In the unpredictable arts, on the other hand, particularly pharmaceuticals, which lie squarely at the junction of chemistry and biology, the utility requirement it is often a nontrivial, if not fatal, obstacle to patenting a prophetic invention. The typical human pharmaceutical invention will remain prophetic until it can be shown that it is in fact effective for treating a human patient, since actual proof of a pharmaceutical invention's efficacy requires notoriously expensive and time-consuming human clinical trials. If proof that a pharmaceutical invention works for its intended purpose were to be required for patentability, it would necessitate a huge investment of time and money to generate the required data.

Fortunately, proof of pharmaceutical efficacy is generally not required for pharmaceutical inventions.[20] As the Federal Circuit explained in *In re Brana*, while proof of safety and efficacy is required

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[14]*In re Ziegler*, 992 F.2d 1197, 1201 (Fed. Cir. 1993) ("The how to use prong of section 112 incorporates as a matter of law the requirement of 35 U.S.C. § 101 that the specification disclose as a matter of fact a practical utility for the invention.").

[15]*Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1358 (Fed. Cir. 1999) ("If a patent claim fails to meet the utility requirement because it is not useful or operative, then it also fails to meet the how-to-use aspect of the enablement requirement.").

[16]*See, e.g.*, *Liebel-Flarscheim v. Medrad, Inc.*, 481 F.3d 1371 (Fed. Cir. 2017) (finding mechanical claim invalid for lack of enablement).

[17]*In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

[18]*Pfaff v. Wells Elec. Inc.*, 525 U.S. 55 (1998).

[19]525 U.S. at 58.

[20]*In re '318 Patent Infringement Litig.*, 583 F.3d 1317, 1324 (Fed. Cir. 2009) ("human trials are not required for a therapeutic invention to be patentable"). *See also Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro S.A. de C.V.*, 464 F.3d 1339, 1350 (Fed. Cir. 2006) (rejecting the argument that the claim term "'no traces of toxic chemicals' should be interpreted as limiting the claim to products in which the levels of all chemicals are below the toxic thresholds set by the [FDA]," because "[n]either the patent nor our claim construction ... makes any reference to toxicity thresholds, whether promulgated by the FDA or otherwise."); *see also Mitsubishi Chem. Corp. v. Barr Labs., Inc.*, 435 Fed. Appx. 927, 934–35 (Fed. Cir. 2011) (refusing to limit a claim covering a pharmaceutical composition "to those compositions that are 'safe, effective, and reliable for use in humans'" because "[t]he specification does not require this restrictive construction, nor is this property necessary for patentability.").

for Food and Drug Administration (FDA) marketing approval of a drug, it is not and should not be required for patentability.[21] If the data necessary for FDA approval were to be required for patentability, it would create a huge "which comes first, the chicken or the egg" problem for drug development. Without a patent on a pharmaceutical invention, it would be difficult for a pharmaceutical company to justify conducting the necessary tests to prove it safe and effective, so a requirement of this level of proof to satisfy the utility requirement could stifle investment in the development and clinical testing of new drugs. As the court observed in *Brana*, "[w]ere we to require Phase II testing [human trials] in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue ... potential cures."[22]

In the pharmaceutical arts, the requirement of a demonstration of credible utility typically is satisfied by the submission of some data or information that demonstrates some substantial likelihood that the invention will work as a pharmaceutical. While human data is generally not required, often animal studies, or at least *in vitro* testing results, will be necessary to demonstrate the necessary likelihood of utility.[23] In some cases, the likelihood that one pharmaceutical invention will work for its intended purpose can be based on similarity to another pharmaceutical product. For example, in some cases a new chemical compound predicted to have pharmaceutical significance can satisfy the utility requirement based on its similarity to a known pharmaceutically active compound.

The showing of utility will often be based on data or information provided by the inventor which is not available in the prior art.[24] For example, the inventor might conduct some sort of animal testing and submit the results to show the purported invention's effect in animals. Although there is no strict requirement that an inventor must submit new data or information to patent a pharmaceutical invention, and the law does not require theory or explanation as to how or why a claimed composition will be effective, as a practical matter it can be difficult to achieve patentability without one or the other, if not both. Part of the reason is that if the assertion of utility is based solely on information that is in the prior art, then it can often be convincingly argued that the invention would have been obvious to one of skill in the art and thus unpatentable under 35 U.S.C. § 103. After all, if it can be shown that the invention is likely to work based solely on information in the prior art, why would one having ordinary skill in the art not have been able to predict that the invention would work based on that same prior art? The reasonable likelihood of success of an invention is an important consideration in the obviousness calculus, and if the prior art would have shown that a pharmaceutical product or method would be likely to succeed and provide therapeutic benefit to patients, it can be difficult to refute the inference that others of skill in the art would likewise have found the invention obvious.

One challenge facing pharmaceutical inventions is that the credible utility must be established as of the application's filing date; experimental data proving the predicted efficacy of a prophetic pharmaceutical invention generated after the filing date is generally deemed insufficient to meet the standard.[25] On the other hand, post-filing data can be used to overcome doubts as to the accuracy of statements appearing in the specification as filed and relating to the invention's asserted utility.[26] In other words, in a case where there is some uncertainty as to whether the specification provides adequate support for the credible utility of a pharmaceutical invention, then post-filing data substantiating the assertion of credibility can be relevant. But in the absence of specific disclosure in the specification that can be confirmed by post-filing evidence, the post-filing evidence will not be considered relevant to the question of patentable utility.[27]

The courts and the U.S. Patent and Trademark Office (USPTO) have acknowledged that a pharmaceutical invention might be patentable, even in the absence of any new experimental data or information by the inventor, under a scenario where the

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[21] *In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995).

[22] 51 F.3d at 1568 (Fed. Cir. 1995).

[23] *Cross v. Iizuka*, 753 F.2d 1040, 1051 (Fed. Cir. 1985) ("We perceive no insurmountable difficulty, under appropriate circumstances, in finding that the first link in the screening chain, *in vitro* testing, may establish a practical utility for the [pharmaceutical] compound in question" in order for a patent to issue.).

[24] *In re '318 Patent Infringement Litig.*, 583 F.3d 1317, 1324 (Fed. Cir. 2009) ("Typically, patent applications claiming new methods of treatment are supported by test results. But it is clear that testing need not be conducted by the inventor.").

[25] *In re Brana*, 51 F.3d 1560, 1567 n.19 (Fed. Cir. 1995).

[26] *Id.* at 1569 n.19.

[27] *In re Sebela Patent Litig.*, 2017 WL 3449054, at *28 (D.N.J. Aug. 11, 2017) ("While post-filing data may be able to substantiate predicted results set forth in the specification, here, the prophetic examples set forth in the specification provide virtually nothing to be substantiated beyond the general statement that 'the symptoms ameliorate' with treatment with the listed doses.").

inventor had some "inventive insight" exceeding that of the ordinary skilled artisan, *i.e.*, if the inventor is able to establish that the pharmaceutical invention is likely to work, based on prior art information and analytic insight, even though one of ordinary skill in the art looking at the same prior art information would not have had the necessary insight to arrive at such an epiphany. Addressing this point, the Federal Circuit's Judge Gajarsa has observed that

> [i]n general terms, an inventor may look at the prior art differently than those before her, arrive at a novel and nonobvious insight, and submit a patent application that compiles the prior art findings that led her to the insight in such a way as to render obvious in hindsight what was wholly nonobvious at the time she filed her application. ... [I]f her patent disclosed those selected findings in such a manner that a person of ordinary skill would credit her insight regarding [the invention's] utility, then the invention is enabled.[28]

Both the USPTO and the Federal Circuit appear to have accepted the possibility that the utility of a pharmaceutical invention might be established by analytical reasoning based on inventive insight. In *In re '318 Patent Infringement Litig.*, for example, the patentee argued that utility may be established by analytic reasoning, without testing a "proposed treatment in the claimed environment or a sufficiently similar or predictive environment." The Federal Circuit responded to this argument by noting that while the USPTO's Manual of Patent Examining Procedure (MPEP) has recognized that "arguments or reasoning" may be used to establish an invention's therapeutic utility, the patentee had been unable to provide a single example of a case in which utility had been established based solely on analytic reasoning.[29]

IN RE '318 PATENT INFRINGEMENT LITIG.

In re '318 Patent Infringement Litig. is a leading example of a case in which the court rejected an assertion of patentable utility that was based solely on the inventor's purported inventive insight and analytic reasoning, with no substantiating non-prior art data.[30] The patent at issue in that case claimed methods for treating Alzheimer's disease with the drug galanthamine. A representative claim recites "[a] method of treating Alzheimer's disease and related dementias which comprises administering to a patient suffering from such a disease a therapeutically effective amount of galanthamine or a pharmaceutically-acceptable acid addition salt thereof."

The specification was unusually brief, little more than one page in length, and did not disclose any non-prior art data supporting its assertion that Alzheimer's disease can be effectively treated using galanthamine. Instead, the specification provided short summaries of six prior art scientific papers in which galanthamine had been administered to humans or animals. A majority of the Federal Circuit panel found that the specification provided almost no basis for its stated conclusion that was possible to administer "an effective Alzheimer's disease cognitively-enhancing amount of galanthamine."[31] In particular, "[t]he specification did not provide analysis or insight connecting the results of any of these six studies to galantamine's potential to treat Alzheimer's disease in humans."

The specification noted that a certain experimental methodology, discussed in the prior art, would "provide[ ] a good animal model for Alzheimer's disease in humans." However, "the specification did not refer to any then-existing animal test results involving the administration of galantamine in connection with this animal model."

During prosecution of the patent, in response to the examiner's original rejection of the application, the applicant stated that (1) "experiments are underway using animal models which are expected to show that treatment with galanthamine does result in an improvement in the condition of those suffering from Alzheimer's disease," and (2) it was "expected that data from this experimental work will be available in two to three months and will be submitted to the Examiner promptly thereafter." After the patent was issued, the results from one such experiment were published; they suggested that galanthamine could be a promising treatment for Alzheimer's. The data was never submitted to the USPTO, however, but the patent claims were allowed to issue nonetheless.

The court rejected the patentee's argument that the post-filing date experimental data could be used to establish patentable utility, noting that enablement is determined as of the effective filing date of the patent's application, and that no relevant

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[28] *In re '318 Patent Infringement Litig.*, 583 F.3d 1317, 1328–29 (Fed. Cir. 2009).
[29] *Id.* at 1326.
[30] *Id.* at 1317.
[31] *Id.* at 1321.

experimental data existed at the time the application was filed. The court found that "at the end of the day, the specification, even read in the light of the knowledge of those skilled in the art, does no more than state a hypothesis and propose testing to determine the accuracy of that hypothesis. That is not sufficient."

The court went on to explain that

> [a] process or product which either has no known use or is useful only in the sense that it may be an object of scientific research is not patentable. ... [I]nventions do not meet the utility requirement if they are objects upon which scientific research could be performed with no assurance that anything useful will be discovered in the end. Allowing ideas, research proposals, or objects only of research to be patented has the potential to give priority to the wrong party and to confer power to block off whole areas of scientific development, without compensating benefit to the public.

The patent was invalid, the Federal Circuit stated, because "[t]ypically, patent applications claiming new methods of treatment are supported by test results," including "results from animal tests or *in vitro* experiments"; but in the case at hand, "neither *in vitro* test results nor animal test results involving the use of galantamine to treat Alzheimer's-like conditions were provided."

The court recognized, without endorsing, the possibility that utility could be established by arguments or reasoning. But it found that the insights that the applicant proffered to establish utility were not described in the patent specification; rather, they were post-hoc arguments made in litigation, and therefore insufficient to establish utility at the time of the application.

The patent owner appears to have been caught in the all-too-common squeeze between satisfying patent law's nonobviousness and disclosure requirements, in which the patentee's attempts to refute allegation that a patent claim is obvious tend to undercut assertions of adequate disclosure, and vice versa. In particular, the court noted that in responding to an obviousness rejection during the prosecution of the patent, and in responding to the obviousness defense at trial, the inventor and witnesses for the patentee explicitly stated that the utility of the invention cannot be inferred from the prior art testing results described in the application. With regard to studies cited in the specification showing galanthamine's ability to reverse amnesia in rats, for example, the inventor stated to the patent examiner that "[n]othing in this teaching leads to an expectation of utility against Alzheimer's disease." The inventor had further stated that "predict[ing] that galanthamine would be useful in treating Alzheimer's disease just because it has been reported [in the prior art studies cited in the specification] to have an effect on memory in circumstances having no relevance to Alzheimer's disease" would be "as baseless as a prediction that impaired eyesight due to diabetes would respond to devices (eyeglasses) or treatments (eye exercises) known to improve the vision of normal persons." The court pointed to the statements and similar statements made by the patentee's expert as evidence that the specification did not establish galanthamine's utility in treating Alzheimer's disease.[32] The court noted that while the patentee argued that the utility of the invention was based on the purported insight of the named inventor, these insights were nowhere described in specification.

Writing in dissent, Judge Gajarsa argued that the case should have been vacated and remanded for failure of the district court to answer the relevant question, *i.e.*, whether, at the time the inventor filed her application, the patent's written description would have credibly revealed to an ordinarily skilled artisan galanthamine's utility for Alzheimer's Disease (AD) treatment.[33] He noted that there was no dispute that the inventor's insight regarding galanthamine's utility for treating AD was correct, and that later animal studies and human clinical trials had proven and confirmed galanthamine's effectiveness.

IN RE SEBELA PATENT LITIG.

In a 2017 decision, *In re Sebela Patent Litig.*, a district court invalidated method claims under facts quite analogous to those present in *'318*.[34] The relevant claims recited methods of using paroxetine to treat thermoregulatory dysfunction, *i.e.*, hot flashes. The specification as filed set forth a variety of dosage ranges which were asserted to be effective, as well as prophetic examples describing the use of some of those dosages to treat thermoregulatory dysfunction, but did not provide any actual

[32] *Id.* at 1325–26.
[33] *Id.* at 1328.
[34] *In re Sebela Patent Litig.*, 2017 WL 3449054 (D.N.J. Aug. 11, 2017).

examples or experimental data substantiating the efficacy of any of those dosages for the claimed purpose. The court found that, based on knowledge available at the time of the decision (long after the filing date), many of these dosages were unlikely to have been effective as described. After the patent application was filed, experimental testing did demonstrate that one particular dosage falling within the ranges set forth in the specification, 7.5 mg/day of paroxetine mesylate, in fact is effective for treating hot flashes. Although the specification as filed did not specifically point out the 7.5 mg per day dosage, the patentee amended the application to include claims directed specifically to this dosage for which efficacy had been demonstrated post-filing, and these claims were allowed to issue.

The court held the claims to be invalid for obviousness in view of the prior art, but went on to state that if the claims had not been found obvious, the court would have invalidated them for lack of credible utility. Although the court made clear that it did

> not intend to suggest that it views this matter as a dichotomy in which the patent is either invalid as obvious or invalid for lack of utility, as among other things in considering utility, unlike obviousness, a [person of skill in the art] would consider the disclosure made by the patent, [in this case the] experts' own testimony would by itself establish to a clear and convincing standard that the patent lacked credible utility given the *de minimis* nature of the disclosure made by the patentee, which did not contain any test data, animal model descriptions, *in vitro* data, or explanation of the mechanism of action of the drug.[35]

As to the post-filing experimental data confirming the actual utility of the claimed method, the court pointed out that this data had been generated too late, given that credible utility must be established as of the filing date. At the time they were filed, the court found that the patent applications added nothing to the prior art beyond highly questionable prophetic examples, and under *'318* claims of this type are invalid for lack of credible utility.

In an interesting twist, the court further concluded that if the claims had not been invalidated for obviousness they would been found invalid for failure to satisfy the written description requirement of 35 U.S.C. § 112, for essentially the same reasons that the claim failed the utility requirement. In order for a patent to meet the written description requirement, it is black letter law that the specification must "reasonably convey[ ] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date."[36] A "mere wish or plan for obtaining the claimed invention is not adequate written description."[37] In *Sebela* the court found that the specification as filed did not in fact convey the inventor's possession of the claimed invention, given that:

> Nothing in the specifications as filed identifies dosing at 7.5 mg/day as consequential; instead, this value is listed alongside many other values that, as explained above, are simply not plausible. Only after the patents were filed and clinical trials were conducted, did the patent applicant amend the claims to limit them to 7.5 mg/day. At the same time, the 7.5 mg/day value anchors all of the present claims. Were the Court to conclude that the patents are nonobvious, it would also conclude that the specification as it was filed does not reasonably convey to those skilled in the art that the inventor had possession of the claimed subject matter at that time.[38]

NUVO V. DR. REDDY'S LABS.

Nuvo v. Dr. Reddy's Labs. is the most recent decision of the Federal Circuit denying patentability to a prophetic pharmaceutical invention where the asserted utility of the invention is only supported by the prior art and the alleged, but unexplained, inventive insight of the named inventor.[39] What distinguishes this case from previous decisions such as *'318* is that the basis for the invalidation is not the utility or enablement requirements, but instead the written description requirement, as presaged by the district court's statements in *Sebela*. In fact, the *Nuvo* court suggests that the invalidated claims might well have been enabled, but that they nonetheless failed to satisfy the written description requirement.

The patent claims at issue in *Nuvo* are directed towards pharmaceutical products comprising a

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[35] *Id.* at *27, n. 32.

[36] *Ariad Pharm. Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010).

[37] *Boston Sci. Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1362 (Fed. Cir. 2011).

[38] *In re Sebela Patent Litig.*, 2017 WL 3449054, *29 (D.N.J. Aug. 11, 2017).

[39] *Nuvo Pharm. (Ireland) Designated Activity Co. v. Dr. Reddy's Labs. Inc.*, 923 F.3d 1368 (Fed. Cir. 2019).

nonsteroidal anti-inflammatory drug (NSAID) present in combination with an acid inhibitor. NSAIDs, such as aspirin and naproxen, control pain, but are associated with undesirable gastrointestinal side effects, such as ulcers and other lesions in the stomach and upper small intestine. It is thought that these side effects result from the interaction of the NSAID with the low pH environment of the gut. The idea behind combining an acid inhibitor with the NSAID is that the acid inhibitor will raise the pH in the gastrointestinal tract, thereby reducing the harmful interaction.

Common acid inhibitors include protein pump inhibitors (PPIs), such as omeprazole and esomeprazole, and although the claims broadly recite an acid inhibitor, the patent specification focuses on PPIs. Of particular significance to the ultimate finding of invalidity, the claims specify that at least some of the acid inhibitor is not surrounded by an enteric coating (the court repeatedly refers to this uncoated acid inhibitor as "uncoated PPI," and so I will do the same in the following discussion). The claims further recite that the uncoated PPI is present in an amount that is therapeutically effective. The specification teaches methods for preparing and making the claimed drug formulations, and provides examples of the structure and ingredients of the drug formulations that comport with the invention. However, the specification provides no experimental data demonstrating the therapeutic effectiveness of any amount of uncoated PPI and coated NSAID in a single dosage form. Furthermore, it was known in the prior art that uncoated PPIs are destroyed by stomach acid prior to reaching the small intestine, and for that reason the prior art taught that PPIs should be coated with an enteric coating in order to shield the PPI from acid while it traverses the stomach. The court pointed out that the patent specification expressly provides that PPIs are often "enteric coated to avoid destruction by stomach acid," and, critically, provides no alternative disclosure explaining that PPI could still be effective to raise pH even though it is uncoated.

As was the case in the *'318* litigation, the patentee was once again caught in the squeeze between the requirements of nonobviousness and adequate disclosure. In defending the claims against allegations of obviousness, the patentee insisted that ordinarily skilled artisans would not have expected uncoated PPI's to be effective. The district court found the claims at issue to be both nonobvious and adequately disclosed, but on appeal the Federal Circuit disagreed, and invalidated the claims based on inadequate disclosure. In arriving at this conclusion, the appellate court pointed out that not only had the patentee conceded that one of skill in the art would not have expected the uncoated PPI to be effective, there was nothing in the specification, either in the form of experimental data or analytical reasoning, that would teach a person having ordinary skill in the art otherwise. What distinguishes this decision from *'318* and other previous Federal Circuit case law is that the basis for the invalidation was failure to comply with the written description requirement of Section 112(a), not the utility and/or enablement requirements.

The *Nuvo* court pointed out that the written description requirement is satisfied only if the inventor "convey[s] with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention,' and demonstrate[s] that by disclosure in the specification of the patent." "The essence of the written description requirement is that a patent applicant, as part of the bargain with the public, must describe his or her invention so that the public will know what it is and that he or she has truly made the claimed invention."

The court found the specification to be fatally flawed for failure to satisfy the written description requirement because it provided nothing more than a mere unsupported assertion that uncoated PPI might work, even though persons of ordinary skill in the art would not have thought it would work. The court explained that the inventor's possession of a mere wish or hope that an invention will work is insufficient to demonstrate that the inventor actually invented what is claimed. The court acknowledged that in fact the specification did teach one of skill in the art how to make and use a therapeutically effective amount of PPI, but while this might have been enough to satisfy the enablement requirement, the fact that the therapeutic efficacy of uncoated PPI was only established after the filing date was insufficient to demonstrate that the inventor was in possession of the invention as of the time of filing.

CONCLUSION

Although the *Nuvo* court could have arrived at the same conclusion by invoking the utility and/or enablement requirement as in *'318*, there is something to be said for the analytic clarity provided by its decision to invoke the written description requirement instead. After all, if the specification as filed does provide sufficient teaching to enable one of skill in the art to make and use a pharmaceutical invention, one could argue that in fact the enablement requirement has been satisfied, even if the

truth of the inventor's assertion of the invention's therapeutic utility is not proven until after the filing date, and the invention is clearly useful. However, the written description requirement explicitly requires that the patent specification convey to the skilled artisan that the inventor was in possession of the invention as of the filing date, and if the sole basis for the inventor's assertion of possession is "inventive insight," unsupported by any external data or analytic reasoning, then it can be reasonably argued that the specification conveys nothing more than the inventor's hope that the invention will work.

There are no doubt some pharmaceutical inventions that would be found to satisfy the utility and written description requirements, even though based solely on an inventive insight, if the rationale behind that insight is sufficiently articulated in the specification. As a practical matter, however, such an explicit recitation of the inventor's thought processes might never make it into the specification. In *Nuvo*, for example, the inventor testified that he thought he "put a rationale in [the specification] as to why [uncoated PPI] would work," but he apparently could not identify any particular part of the specification supporting that understanding.[40] In a case in which a patent specification does not provide any experimental data or non-prior art information, one can see why a patent attorney might hesitate to explicitly explain why the utility of the invention is credible based on the prior art—a patent examiner could easily use this explanation as a roadmap for combining the prior art in an obviousness rejection. However, in a situation where a pharmaceutical invention is based on pure inventive insight, and there is no experimental data or non-prior art information supporting the efficacy of the invention, a patent attorney should consider including whatever rationale the inventor can provide, and possibly avoid the fate of the patents in *'318* and *Nuvo*.

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[40] *Id.* at 1381.