Sterne Kessler
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The PTAB Strategies and Insights newsletter provides timely updates and insights into how best to handle proceedings at the USPTO. It is designed to increase return on investment for all stakeholders looking at the entire patent life cycle in a global portfolio.

We welcome feedback and suggestions about this newsletter to ensure we are meeting the needs and expectations of our readers. So if you have topics you wish to see explored within an issue of the newsletter, please reach out to me.

Additionally, we would like to wish a Happy Lunar New Year to our readers.

Kind Regards,

Jason D. Eisenberg
Editor

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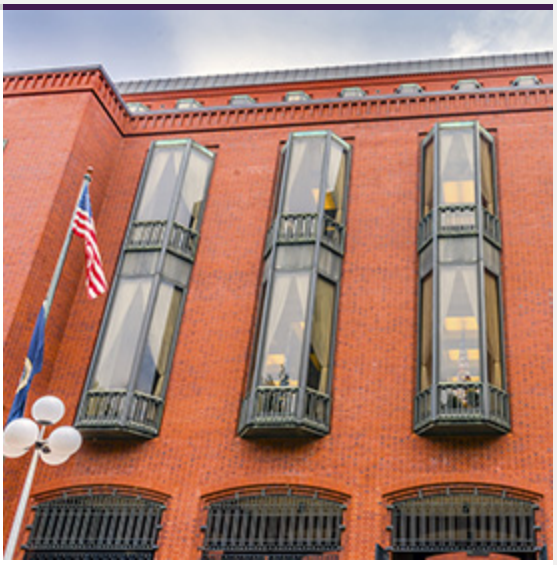

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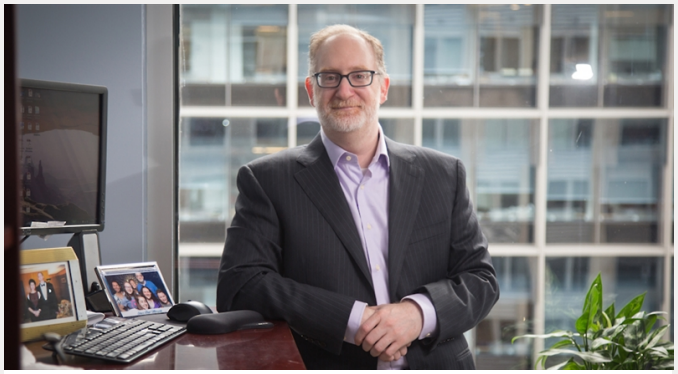

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Does the Limit Exist?: Negative Limitations in Novartis v. Accord

By: Kathleen Wills

In an appeal, *Novartis Pharmaceuticals v. Accord Healthcare, Inc.*, the issue of whether a patent provides sufficient written description of a negative limitation[i] split the panel at the Federal Circuit. *Novartis Pharmaceuticals v. Accord Healthcare, Inc.*, Appeal No. 2021-1070, at *2 (Fed. Cir. Jan. 3, 2022). The case began at the District Court of Delaware with a bench trial that ultimately found HEC Pharm Co., Ltd. and HEC Pharm USA Inc. ("HEC")'s ANDA to infringe Novartis's valid '405 patent. At the Federal Circuit, the majority opinion, drafted by Judge O'Malley, affirmed the lower court's findings, i.e., the patent's negative limitation was supported and thus valid, because there was no clear error[ii].

1. **Majority Opinion, drafted by Judge O'Malley**

To determine the scope and written description of the negative limitation "at a daily dosage of 0.5 mg *without* an immediately preceding loading dose" ('405 patent col. 12 ll. 49–55) the court looked at both the '405 patent and 2006 priority patent specifications. In doing so, the majority found written description for this negative limitation by holding that both specifications identified fingolimod hydrochloride, described the results of an experiment where rats suffered a disease that mimics relapsing remitting multiple sclerosis (RRMS or MS), discussed a prophetic human clinical trial, and described a wide range of potential dosages.

1. **0.5 mg daily human dose limitation was possessed by the inventor**

The majority decided that the evidence demonstrated the 0.5 mg daily dose of fingolimod limitation was possessed by the inventor as of the 2006 priority date. First, two expert witnesses put forth by the patent owner explained the leap from the 0.3 mg/kg weekly rat dosage to the 0.5 mg daily dosage limitation. Second, the clinical trial disclosed dosing RRMS patients at that daily dosage. But the animal experiment did not disclose *in haec verba* this limitation. The majority found that relying on expert testimony to find

the description of this limitation in the experiment's results was proper because it could not "ignore the perspective of the person of ordinary skill in the art." Such a person would recognize that Novartis invented what was claimed.

HEC had argued that the wide range of potential dosages in the '405 patent lacked the necessary "blaze marks" that would direct a skilled artisan to the "claimed species from among a forest of disclosed opinions…" The majority disagreed that such marks were needed in this patent because the daily dosage could be found in the clinical trial and was the starting point of the daily range disclosed in the specification.

1. **But was a loading dose limitation missing, and thus not supported?**

What was missing from both specifications? A loading dose. It is undisputed that neither the animal experiment or clinical trial described in the specification recite a loading dose. Both parties' experts even agreed on the definition of the disputed term: a higher than daily dose that is "usually given as the first dose." But what was also undisputed is that loading doses were well known in the medial field and prior art in connection with MS.

The district court found that the patent describes alternate dosing regimens, but not administering those regimens with a loading dose; therefore, a skilled artisan would believe that the invention did not include the administration of a loading dose. Yet Novartis's three experts testified that one would expect that if a loading dose were in the patent, it would be specified. HEC's own expert agreed that the loading dose is usually given as the first dose. Thus, the district court found the patent provides sufficient written description of the *negative* limitation. The Federal Circuit found no clear error in this finding.

The majority decision summarizes Federal Circuit precedent regarding negative limitations to reiterate that negative claim limitations are adequately supported when the specification describes a reason to exclude it – although the law does not require the specification to provide a reason.[iii] The majority held it is enough that the specification properly describes alternative features of the patented invention. Interestingly, the Court explained that a granted patent is presumed (1) valid and (2) to have a complete written description. Although a negative limitation that is inconsistent with the disclosure is not always adequately described.

Therefore, what is "critical" in the analysis of whether the negative limitation exists is the context, knowledge, and common sense of the skilled artisan – not the exact words used in the specification: a negative limitation "must be accompanied by an original disclosure which conveys to a person of ordinary skill that the inventor was in possession of the claimed invention."[iv]

1. **Dissenting Opinion, authored by Chief Judge Moore**

To the dissent, "[s]ilence is not disclosure." The dissent highlights the Patent Office's MPEP (Manual of Patent Examining Procedure) and the Federal Circuit's precedent to reiterate that silence cannot support a negative limitation. If the specification is silent, there is no evidence that the inventor actually possessed the invention. This principle is a written description requirement. To allow a silent disclosure to exclude a later-added negative limitation is a "fundamental error of law."

What else is missing from the patent? Judge Moore found there was more missing from the specification than just "a loading dose." Language that a loading dose should *not* be administered, alternatives, advantages or disadvantages of a loading dose, or even a reason to exclude a loading dose are also notably absent. The record does show that, to some degree, both parties' experts agree that loading doses are sometimes given to MS patients.

The dissent calls out the majority's "false and inaccurate quotation," disagreeing with the characterization that the clinical trial as described in the specification discloses an initial 0.5 mg daily dose – the first limitation discussed in this article. The word 'initially,' the dissent clarifies, "is basic English" and 'daily' has no special meaning in pharmacology. With the addition of this limitation, (1) Novartis "backdoors a claim construction argument," (2) the district court has rewritten the specification with expert testimony, and (3) the majority opinion "teases an entirely new claim limitation out of an entirely common term."

Lastly, the dissent does not agree that an issued patent is presumed to have a complete written description. Instead, the validity presumption means that the granted patent complies with the written description requirement – the term 'complete' is missing. Such a holding now permits negative limitations to be supported by a specification that simply never mentions them.

1. **Conclusion**

The law surrounding negative limitation, and especially their relationship to the written description requirement, continues to build at the Federal Circuit and this appeal indicates strong views amongst the judges. At a minimum, this opinion shows how adding a negative limitation to a claim during prosecution can implicate the written description requirement. It also brings a heightened importance to factors such as what a skilled artisan would understand from reading the patent, weight of expert testimony, knowledge and information regarding a skilled artisan's common sense, and what implicit or inherent disclosures were made.

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[i] Novartis's '405 patent claims are directed to a 0.5 mg daily dose of fingolimod hydrochloride under the brand name, Gilenya, which treats remitting multiple sclerosis ("RRMS"); the patent claims priority to a British patent filed in 2006.
[ii] The clear error standard means that the appellate court will not overturn the factual findings for written description unless there is a "definite and firm conviction" that a mistake was made.
[iii] *Inphi Corp. v. Netlist, Inc*., 805 F.3d 1350, 1356 (Fed. Cir. 2015) (there is no "new and heightened standard for negative claim limitations."); *Santarus, Inc. v. Par Pharmaceutical, Inc*., 694 F.3d 1344, 1350–51 (Fed. Cir. 2012) (expert testimony properly provided a personal of ordinary skill's understanding of the patent specification); *Nike, Inc. v. Adidas AG*, 812 F.3d 1326, 1348 (Fed. Cir. 2016) (finding that negative limitations are held to the customary standard for the written description requirement); *All Dental Prodx, LLC v. Advantage Dental Prod*., Inc., 309 F.3d 774, 779 (Fed. Cir. 2002) ("[T]he failure of the specification to specifically mention a limitation that later appears in the claims is not a fatal one when one skilled in the art would recognize upon reading the specification that the new language reflects what the specification shows has been invented.").
[iv] *Novartis Pharmaceuticals v. Accord Healthcare, Inc.*, Appeal No. 2021-1070, at *18 (Fed. Cir. Jan. 3, 2022).

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In 2017, Kyocera Senco Industrial Tools Inc. ("Kyocera") filed a complaint at the International Trade Commission (ITC) alleging that Koki Holdings America Ltd. ("Koki") was violating 19 U.S.C. § 1337 by importing certain gas spring nailer products, or nail guns, that infringe certain claims in five patents. The patents at issue generally relate to portable tools that drive staples, nails, or other linearly driven fasteners.

During claim construction, the ALJ adopted Koki's definition of a skilled artisan, which required a minimum of two years' experience designing power nailers. Kyocera offered Dr. Pratt as a technical expert on claim construction, invalidity, literal infringement, and infringement under the doctrine of equivalents. Dr. Pratt has advanced degrees in engineering, and extensive experience in the design and manufacture of fastener driving tools—but he lacked experience in power nailer design specifically.

Because of this, Koki moved to exclude Dr. Pratt's testimony on the grounds that he was incapable of analyzing the issues from the perspective of a skilled artisan. The ALJ found that Dr. Pratt did not meet the requirements for a skilled artisan, but noted that Federal Circuit case law appeared to be inconclusive on whether Dr. Pratt's testimony should be excluded. Finding no case directly on point, the ALJ excluded Dr. Pratt's testimony on infringement under the doctrine of equivalents. Curiously however, the ALJ admitted Dr. Pratt's testimony on literal infringement.

On appeal, the Court held, "[t]o offer expert testimony from the perspective of a skilled artisan in a patent case—like for claim construction, validity, or infringement—a witness must at least have ordinary skill in the art."[i] The Court reasoned that, without ordinary skill, "the opinions would not be based on any specialized knowledge, training, or experience that would be helpful to the factfinder."[ii] The Court further

reasoned that this is true regardless of whether the testimony is directed to literal infringement or infringement under the doctrine of equivalents. “Nothing about literal infringement makes an unqualified witness’ testimony more relevant or reliable… The absence of relevant knowledge and the risk for abuse apply equally to both situations.”[iii]

The Court found their opinion in *Endress + Hauser, Inc. v. Hawk Measurement Sys. Pty. Ltd.* to be consistent with their opinion here.[iv] According to the Court, *Endress* recognized that “it would be improper to require an expert witness to possess ordinary skill in the art and *nothing more*.”[v] But *Endress* also recognized that “to testify as an expert, a witness must be qualified.[vi] Thus, the Court concluded that “to be qualified to offer expert testimony on issues from the vantage point of an ordinarily skilled artisan in a patent case, an expert must at a minimum possess ordinary skill in the art.”[vii] And because Dr. Pratt lacked ordinary skill in the art—based on his lack of experience in power nailer design—the Court held “the ALJ abused his discretion by admitting Dr. Pratt's testimony on any issue that is analyzed through the lens of an ordinarily skilled artisan.”[viii]

Although this case was decided on appeal from the ITC, it has a number of implications for District Court and Patent Trial and Appeal Board litigation, and even original, reissue, and reexamination prosecution. Patent challengers and owners should pay close attention to their own experts’ qualifications in view of the scope of the proposed and/or adopted levels of ordinary skill in the art. An expert that has extensive education and general industry experience may still not be an ordinarily skilled artisan if the level of ordinary skill in the art is crafted narrowly enough. Offensively, practitioners on both sides should seek to exclude an opposing expert’s testimony if he does not meet the narrowly crafted qualifications for a skilled artisan. Patent challengers and owners may also have additional opportunity to specifically craft the level of ordinary skill in the art around the experience of the expert supporting a petition.

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[i] Slip Op., 11.
[ii] *Id*.
[iii] *Id*.
[iv] 122 F.3d 1040, 1042 (Fed. Cir. 1997).
[v] Slip Op., 12 (emphasis in original).
[vi] *Id*.
[vii] *Id*.
[viii] *Id*.