Morgan Lewis

PHARMA REVIEW

ISSUE 2

Dear Readers:

Welcome to the second issue of the Morgan Lewis *Pharma Review,* which summarizes key recent cases from the Federal Circuit and district courts that impact the pharma space, including:

- Federal Circuit and district court decisions in Hatch-Waxman litigations
- Federal Circuit reviews of IPR challenges to Orange book–listed patents
- Appellate and district court decisions in pharma-related antitrust litigations

We hope *Pharma Review* can serve as a one-stop source for your patent and antitrust pharma-related legal developments.

Happy reading!

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PATENTS / PATENT-ELIGIBLE SUBJECT MATTER

Michael J. Abernathy, Maria E. Doukas, and Michael T. Sikora

Federal Circuit Clarifies PTO Guidance Regarding Subject Matter Eligibility

The Federal Circuit found that controlling case law supersedes any US Patent and Trademark Office (PTO) guidance on subject matter eligibility and rejected Example 29 of a May 4, 2016, PTO guidance as inconsistent with prior Federal Circuit law. *Cleveland Clinic Foundation v. True Health Diagnostics, LLC,* No. 2018-1218 (Fed. Cir. 2019) (*Cleveland Clinic II*).

In a prior case, the Federal Circuit addressed a Cleveland Clinic patent that was "directed to the ineligible natural law that blood MPO [myeloperoxidase] levels correlate with atherosclerotic CVD." *Cleveland Clinic II* involved method claims issuing from continuations of that same patent. The Federal Circuit acknowledged a difference between these claims: the continuation claims

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"recite methods of identifying and detecting MPO, in contrast to the [parent] patent's claimed method of assessing atherosclerotic CVD risk from blood MPO levels."

Relying on the immunoassay identification and detection technique, Cleveland Clinic argued that (i) the claims are directed to a *specific technique* for detecting blood MPO levels; (ii) the correlation between blood MPO and atherosclerotic CVD is not a natural law because it could only be detected using certain techniques; and (iii) applying an immunoassay to blood MPO levels supplies an inventive concept. Conversely, True Health argued that (i) the correlation between blood MPO and atherosclerotic CVD is a natural law, regardless of any detection difficulty; and (ii) using "known techniques in a standard way to observe the natural law neither renders the claims directed to something other than this natural law nor supplies an additional inventive concept."

The Federal Circuit agreed with True Health, finding that the continuation claims—like the parent claims in *Cleveland Clinic I*—recited a patent-ineligible natural law:

"The claims are not directed to new techniques for performing an immunoassay to detect a patient's blood MPO levels. They only recite applying known methods to detect MPO levels in plasma, comparing them to standard MPO levels, and reaching a conclusion: that the patient's blood MPO levels are elevated in comparison to a control group. This conclusion is simply another articulation of the natural law that blood MPO levels correlate with atherosclerotic CVD."

It explained that "laws of nature exist regardless of the methods used by humans to observe them," and noted that *Ariosa's* patent-ineligible claim for detecting cffDNA in maternal blood plasma was similarly situated to blood MPO levels here.

The Federal Circuit also held the claims contained no additional inventive concept to make the claims patent eligible. It rejected Cleveland Clinic's argument that "using a known technique in a standard way to observe a natural law can confer an inventive concept," noting that this argument "has been consistently rejected by this court in circumstances nearly identical to this case." It further rejected Cleveland Clinic's assertion that remand was warranted due to the district court improperly resolving factual disputes against it at the pleadings stage, observing that the patents' "specification and prosecution history plainly concede that each of the process steps was well-known in the art."

Cleveland Clinic additionally argued that the district court failed to give appropriate deference to the PTO's guidance regarding subject matter eligibility. Cleveland Clinic specifically relied on Example 29–Claim 1 from the PTO's May 4, 2016, guidance, which it argued was comparable to the asserted claims and deemed patent eligible by the PTO:

Example 29–Claim 1

1. A method of detecting JUL-1 in a patient, said method comprising:
    a. obtaining a plasma sample from a human patient; and
    b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody.

The Federal Circuit, however, found that "Example 29–Claim 1 is strikingly similar to claim 1 of U.S. Patent 6,258,540" at issue in *Ariosa*.

Although it explained that it "greatly respect[ed] the PTO's expertise on all matters relating to patentability, including patent eligibility," the Federal Circuit made clear that it is "**not** bound by its guidance." Moreover, it noted the importance, "especially regarding the issue of patent eligibility and the efforts of the courts to determine the distinction between claims directed to natural laws and those directed to patent-eligible applications of those laws," for "the need for consistent application of [its] case law." Thus, the court explained, "to the extent that Example 29–Claim 1 is analogous to the claims at issue, Ariosa must control."

Practice Note: The Federal Circuit's discussion of Example 29-Claim 1 of the PTO's guidance should influence how practitioners approach claim drafting and illustrates the necessity of remaining mindful of controlling Federal Circuit precedent, not just PTO guidance. Indeed, the divergent opinions as to the patent eligibility of Example 29-Claim 1 highlight the need for practitioners to remain informed about Federal Circuit case law. PTO guidance provides a helpful tool to understand how the PTO, including patent examiners, will evaluate claims for eligibility under Section 101, but practitioners should remain cognizant of how the claims may fare in future litigation. To the extent controlling case law differs from PTO guidance, following the case law will help ensure that the patented claims are not ultimately held patent ineligible under Section 101.

PATENTS / JURISDICTION / NON-INFRINGEMENT

Jeffrey R. Gargano

Federal Circuit Affirms Finding of Non-Infringement

The US Court of Appeals for the Federal Circuit affirmed the district court's judgment as a matter of law (JMOL) of non-infringement because the patentee, which only alleged literal infringement, failed to prove that Perrigo's generic version of Pepcid Complete® met the claimed limitation of providing immediate relief from episodic heartburn. *Brigham & Women's Hospital, Inc. v. Perrigo Company*, Case No. 17-1950 (Fed. Cir. 2019).

In the mid-1990s, Johnson & Johnson Merck Consumer Pharmaceuticals developed a combination histamine H2-receptor antagonist (H2-blocker)/antacid tablet, which it marketed in the United States under the name Pepcid Complete. In 1996, J&J licensed US Patent No. 5,229,137 from BWH. The '137 patent claimed a method of providing immediate and sustained relief from pain, discomfort, or symptoms of episodic heartburn. The '137 patent defined immediate relief as relief that starts within about five to 10 minutes. In 2013, after the '137 patent had expired, BWH brought suit against Perrigo accusing its generic product of infringing the '137 patent and seeking past damages.

Jury Finds in Favor of BWH. At trial, a key dispute was whether Perrigo's generic product provided immediate relief as defined by the '137 patent, i.e., relief that starts within about five to 10 minutes following ingestion of the tablet. In order to show that Perrigo's product provided immediate relief, BWH relied on clinical data from J&J's branded H2-blocker/antacid product, Pepcid Complete®. The clinical data largely consisted of three studies. Study 98 measured esophageal and stomach pH levels after administering Pepcid Complete® and compared changes in these pH values to controls, e.g., antacid alone, H2-blocker alone, and placebo. In addition to the espohogeal pH study, BWH relied upon two symptom relief studies, Studies 110 and 127. These studies measured adequate relief for onset at 15 minutes after administration of Pepcid Complete®. BWH's expert testified that adequate relief at 15 minutes would "correlate to relief within 5-10 minutes," but he admitted on cross-examination that the two parameters were different.

After an eight-day jury trial, the jury found that Perrigo infringed the asserted claims and found willful infringement. The district court entered judgment consistent with the verdict on December 19, 2016, but without specifying damages or resolving BWH's claim for enhanced damages. Several days after the judgment, the parties jointly requested the district court to extend various deadlines for filing post-trial motions. The court granted the extensions in full. Perrigo moved for judgment as a matter of law (JMOL) of non-infringement in compliance with the district court's extension, and BWH moved for enhanced damages.

District Court Grants Perrigo's Motion for JMOL of Non-Infringement. Several months later, the district ruled that the December 19, 2016, judgment was final except for an accounting and therefore triggered the 28-day mandatory deadline set forth in Rule 50(b) for filing renewed JMOL motions. The 28-day deadline fell on January 17, 2017, a week earlier than the agreed-upon day on which Perrigo renewed its JMOL motions. The court thus denied Perrigo's motions for JMOL and notice of appeal as untimely. The district court also denied BWH's motion for enhanced damages because it found Perrigo's conduct was not egregious. Perrigo again moved for JMOL and filed an appeal from the district court's decision.

BWH moved to dismiss Perrigo's appeal for lack of jurisdiction, arguing that Perrigo's JMOL motions and notice of appeal were untimely. The Federal Circuit concluded that the district court's December 19, 2016, judgment was not final because it did not resolve BWH's claim for enhanced damages. The Federal Circuit held that although Perrigo could have appealed from the December 19, 2016, judgment, it was not obligated to do so because such an appeal from a non-final judgment "is permissive, not mandatory." BWH moved for panel reconsideration and a three-judge panel reaffirmed the Federal Circuit's original opinion.

The district court, at the Federal Circuit's insistence, then considered Perrigo's pending JMOL motions and granted JMOL of non-infringement because it concluded BWH failed to present sufficient evidence of direct infringement. Perrigo argued and the district agreed that the clinical data relied upon by BWH either failed to demonstrate any symptom relief (Study 98) or measured a different parameter than the claimed immediate relief within five to 10 minutes (Studies 110 and 127). Consequently, BWH could not prove that Perrigo's generic product met the limitations of the asserted claims.

Federal Circuit Affirms District Court's JMOL of Non-Infringement. BWH appealed the ruling of non-infringement. In opposition to Perrigo's appeal, BWH again raised the issue of the Federal Circuit's jurisdiction, alleging "there is a serious question regarding this Court's jurisdiction to hear Perrigo's appeal." BWH pointed to no error, however, and simply asked the Federal Circuit to "assure [themselves] that [they have] jurisdiction to hear the appeals as presented." The Federal Circuit found its prior decisions regarding jurisdiction (i.e., Perrigo's timeliness) law of the case and refused to disturb them absent extraordinary circumstances, which it found BWH had failed to even allege.

As for the district court's finding of non-infringement, the Federal Circuit agreed with the district court and found that BWH failed as a matter of law to prove that Perrigo's generic product meets the claimed limitation of providing immediate relief from episodic heartburn within about five to 10 minutes. At the outset, the Federal Circuit noted that BWH only alleged literal infringement and did not pursue infringement under the doctrine of equivalents. Next, the Federal Circuit addressed each of the clinical studies upon which BWH's infringement case primarily relied.

The Federal Circuit agreed with the district court's reasoning that because Study 98 defined an episode of acid reflux (the cause of episodic heartburn) as requiring a drop in pH to below 4, but the pH curves in Study 98 never dropped below 4, it could not support the jury verdict. The Federal Circuit acknowledged that while Study 98 showed a rapid rise in esophageal pH after taking Pepcid Complete, that rise was untethered to symptomatic relief. At most, the Federal Circuit found that Study 98 might suggest that Pepcid

Complete® provides relief within five to 10 minutes. Such speculative data, however, could not sustain BWH's burden of proof.

The Federal Circuit then considered Studies 110 and 127, which did report symptomatic relief from heartburn, and like the district court found that these studies could not support infringement because they measured "adequate relief" beginning at 15 minutes, not immediate relief starting five to 10 minutes after administration. The Federal Circuit noted that BWH's expert admitted that the parameters were different. Although BWH's expert testified that the data "correlated to" the claimed immediate relief, the Federal Circuit found data merely correlating to the claimed limitation not enough to prove literal infringement.

ANTITRUST / FTC ENFORCEMENT

Zachary M. Johns

FTC Cannot Seek Immediate Injunction in Federal Court Without Showing Defendant Is or Is About to Violate the Law

The US Court of Appeals for the Third Circuit affirmed a district court's dismissal under Fed. R. Civ. P. 12(b)(6) of the Federal Trade Commission's (FTC's) complaint seeking restitution and to enjoin Shire ViroPharma from future sham petitioning of the FDA. *Federal Trade Commission v. Shire ViroPharma, Inc.,* 917 F.3d 147 (3d Cir. 2019)

The FTC alleged that between March 2006 and April 2012, Shire submitted to the FDA a total of 43 citizen petition related filings and instituted three court proceedings, all of which were intended to delay the approval of generic versions of ViroPharma's Vancocin capsules. At the time of the petitioning, the FDA was considering whether to reassess its bioequivalence testing for locally acting medications such as Vancocin, thereby making generic approval less costly. The FDA was also reviewing abbreviated new drug applications (ANDAs) for Vancocin. On April 9, 2012, the FDA rejected ViroPharma's citizen petition and approved three ANDAs for generic Vancocin capsules.

On February 7, 2017, nearly five years after the FDA rejected ViroPharma's citizen petition, the FTC brought suit under Section 13(b) of the FTC Act and claimed that there is a danger that ViroPharma will engage in similar conduct in the future. The FTC suggested that ViroPharma's past conduct means it could undertake similar conduct with respect to a brand name medication the company then had on the market. Section 13(b) authorizes the FTC to seek an injunction in federal court when it has reason to believe that a person or company "is violating, or is about to violate" any provision of law enforced by the FTC. Section 13(b) was added to the FTC Act by Congress in 1973 and empowers the FTC to quickly address ongoing or impending illegal conduct. Under Section 5(b), the FTC's traditional enforcement mechanism, the FTC must first prevail in an administrative proceeding or federal court before an injunction or other relief would issue.

The Third Circuit concluded that Section 13(b) does not permit the FTC to bring a claim based on "long-past conduct" without some evidence that a defendant "is" committing or "is about to" commit another violation. The court found the language of Section 13(b) was unambiguous in this respect. Moreover, the legislative history explained that Section 13(b) was intended to remedy immediate harms, not "hypothetical conduct or the mere suspicion that such conduct may yet occur." In an attempt to show imminent conduct, the FTC suggested that ViroPharma had incentives to engage in the same pattern of conduct again and could do so for one of its then-largest products. The court rejected this argument; the FTC's allegations of imminent conduct were vague and thus failed to show that ViroPharma is "about to violate" any law the FTC enforces. Significant to the court was the failure of the FTC to identify any supposed sham petition by ViroPharma in the five-year gap between the 2012 cessation in petitioning and the 2017 lawsuit. Although the court declined to evaluate where the "outer reach of "about to violate" lies, it concluded that "the facts in this case do not approach it."

PATENTS / OBVIOUSNESS

Shon Lo

Federal Circuit Upholds Method of Treatment Claims Due to Lack of Data in Prior Art

The US Court of Appeals for the Federal Circuit found patent claims for methods of administering a drug to be non-obvious because the prior art data was insufficient for a reasonable expectation of success. *Novartis v. West-Ward Pharms. Int'l, Ltd*, 923 F.3d 1051 (Fed. Cir. 2019) (Stoll, J.).

Everolimus is the active ingredient in Novartis's AFFINITOR product, which is approved for treatment of advanced breast cancer, advanced kidney cancer, and various types of solid tumors. The independent claim at issue is directed to a method for inhibiting growth of solid excretory system tumors in a subject, consisting of administering a therapeutically effective amount of everolimus. Dependent claims specified the type of tumor, i.e., a kidney tumor. Everolimus belongs to a class of compounds known as mTOR inhibitors. These compounds inhibit the activity of an enzyme known as the mammalian target of rapamycin (mTOR). Rapamycin was known in the art to have antimicrobial, immunosuppressive, and antitumor activities. Rapamycin derivative temsirolimus was known to have antitumor activities. Everolimus is also a rapamycin derivative, and is structurally similar to temsirolimus.

Defendant relied on three primary prior art references: (i) an article discussing the development of rapamycin and temsirolimus that disclosed preliminary results of two phase I clinical trials of temsirolimus; (ii) an article discussing the clinical development of temsirolimus, and reviewing updated results from those same phase I studies, including responses in patients with kidney cancer; and (iii)

two patents disclosing everolimus and other rapamycin derivatives. The phase I studies in the first two references involved 21 and 51 patients each. The everolimus patents did not disclose any preclinical or clinical data on the antitumor activity of everolimus, only that the claimed genus of compounds were useful for preventing transplant rejection, autoimmune disease, tumors, and other conditions.

The district court upheld the claims, and the Federal Circuit affirmed, but not without noting that the district court erred in applying a lead compound analysis. Specifically, the district court should not have required defendant to prove that a POSA would have been motivated to select everolimus in particular over other prior art compounds. Because the claims are directed to methods of using everolimus, not to the compound itself, the more stringent lead compound analysis was not required. Instead, defendant was only required to show that a POSA would have been motivated to pursue everolimus as one of several potential treatment options.

The district court's error was ultimately harmless, however, because the Federal Circuit agreed that a POSA would not have had a reasonable expectation of successfully inhibiting growth of solid tumors with everolimus. The Federal Circuit pointed to the limited data on temsirolimus, testimony that everolimus and temsirolimus had different pharmacological properties (binding affinity and half-life), and a lack of elucidation of the molecular biology underlying the particular type of cancer. For example, inhibiting mTOR does not necessarily result in tumor growth inhibition. In view of these uncertainties, a POSA would not have had a reasonable expectation of success, and therefore the claims would not have been obvious.

Practice note: strategic claim drafting in the patent at issue and generic disclosures in the prior art everolimus compound patent specification was Novartis' recipe for success. To show obviousness of the dependent claim directed to kidney tumors required defendant to argue that a POSA would have had a very specific expectation of success. Demonstrating the particularity of that expectation proved to be an insurmountable bar.

PATENTS / WRITTEN DESCRIPTION

Maria E. Doukas

Federal Circuit Invalidates Vimovo® Patents for Failing to Satisfy Written Description Requirement

The US Court of Appeals for the Federal Circuit reversed the district court's holding that the asserted claims of Nuvo Pharmaceutical's patents relating to a pharmaceutical composition comprising an acid inhibitor and a non-steroidal anti-inflammatory drug (NSAID) satisfied the written description requirement under 35 USC § 112. Nuvo Pharm. (Ireland) *Designated Activity Co. v. Dr. Reddy's Labs., Inc.,* Case Nos. 2017-2473; -2481; -2484; -2486; -2489; -2491; -2492; -2493 (Fed. Cir. 2019) (Clevenger, R.C.).

Nuvo markets Vimovo®, which practices the invention of the asserted patents and is directed to a pharmaceutical composition providing a coordinated release of an NSAID and an acid inhibitor, such as a proton pump inhibitor (PPI). The claims require that the PPI be provided in an amount effective to increase the gastric pH and that at least some of this PPI be uncoated. Dr. Reddy's Laboratories, Inc., Mylan Pharmaceuticals, and Lupin Pharmaceuticals (collectively, the Generics) submitted ANDAs to the US Food and Drug Administration (FDA) to market a generic version of Vimovo®, and Nuvo subsequently sued each for patent infringement. Following a bench trial, the district court upheld the validity of the asserted patents, and the Generics appealed.

On appeal, the Generics argued, among other things, that the asserted patents were invalid for failing to satisfy the written description requirement. In particular, they alleged that no written description support existed for the claim limitation requiring therapeutic effectiveness of uncoated PPI, particularly since those of skill in the art would not have understood the effectiveness of uncoated PPI. In response, Nuvo presented three arguments to support its position that the patent satisfied the written description requirement.

First, Nuvo pointed to its expert's testimony identifying specification passages that allegedly demonstrate possession of the invention. For example, the expert relied on the statement that "[t]he composition contains an acid inhibitor present in an amount effective to raise the gastric pH." The Generics disagreed that any passages relied on by Nuvo's expert were sufficient to satisfy the written description requirement since they merely discussed uncoated PPI dosage amounts and the use of it in a drug formulation, not its efficacy.

The Federal Circuit agreed with the Generics, holding that the specification passages relied on by the expert simply mirror the claim language and state that uncoated PPI may be effective. Although the court noted that the specification does not need to include experimental data demonstrating effectiveness or an explanation why the claimed composition would be effective, it must include "more than a mere wish or hope" that the invention works. In particular, since those of skill in the art would not have known that uncoated PPI would be effective, "[t]here must be some description, such as a constructive reduction to practice, establishing that the inventor 'was in possession of the . . . claimed invention'."

Second, Nuvo argued that since the specification teaches how to make and use the invention, this is enough to show written description support. It relied on this court's decision in *Alcon* to further bolster its view. The Generics disagreed and noted that not only are enablement and written description two separate and distinct inquiries, but *Alcon* is factually distinguishable.

The court again sided with the Generics stating that "[t]eaching how to make and use an invention does not necessarily satisfy the written description requirement," particularly since "[t]he purpose of the written description requirement is broader than to merely explain how to 'make and use' [the invention]." Since, contrary to *Alcon* where the patentees provided testing data, Nuvo's specification does not provide any data showing that uncoated PPI is effective in raising gastric pH, the court agreed with the Generics it did not apply.

Third, Nuvo argued that the claimed efficacy of uncoated PPI is necessarily inherent in the specification's disclosure of methods of making and using formulations containing uncoated PPI. To support its position, it relied on this court's decision in *Allergan* where it held that the specification's description of a formulation, its components, and how to make and use it was sufficient to demonstrate inherency of the claimed efficacy. The Federal Circuit agreed with the Generics that *Allergan* is factually distinguishable. It noted that, unlike in *Allergan* where the parties' agreed an inherent property existed, the parties here disputed whether uncoated PPI was inherently effective at raising gastric pH. Moreover, nothing in the record supported the inherency argument.

Thus, given the lack of support for the claim language requiring effectiveness of uncoated PPI, the Federal Circuit held the asserted patents invalid and reversed the district court's determination.

PATENTS / PLEADINGS

Kevin Shortsle

Only Basic Facts and Legal Conclusions Needed to Satisfy Pleading Standard in Hatch-Waxman Cases

Evaluating the sufficiency of pleading infringement in Hatch-Waxman cases, the US District Court for the District of Delaware held that a plaintiff receiving a Paragraph IV notice letter may state a claim for patent infringement by alleging (i) its ownership interest in the patent; (ii) its receipt of a Paragraph IV certification; (iii) the filing of an ANDA or 505(b)(2) application; and (iv) its contention that the defendant's proposed product will infringe. *Belcher Pharms. v. International Medication Systems*, Case No. 18-960 (D. Del. 2019) (Stark, C.J.).

Plaintiff Belcher Pharmaceuticals's (Belcher) complaint alleged that International Medication Systems (IMS) submitted an NDA under 21 USC § 355(b)(2) of the Hatch-Waxman Act (505(b)(2) application), sent a notice letter to Belcher that included a Paragraph IV certification of US Patent No. 9,283,197 (the '197 patent), and the manufacture of IMS's proposed product is covered by the '197 patent.

IMS filed a Rule 12(b)(6) motion to dismiss, arguing Belcher failed to allege facts setting forth a plausible case for patent infringement in violation of the *Iqbal* and *Twombly* pleading standards. IMS argued that Belcher's complaint should be treated like a typical complaint for patent infringement, which requires pleading facts with particularity to allow the court to reasonably infer the defendant is liable for infringement. The court denied IMS's motion, focusing its analysis on the artificial nature of an infringement case brought under 35 USC 271(e)(2) and the purpose of the Hatch-Waxman Act.

The court found that the purpose of the Act—to encourage new drugs to market quickly and cost-effectively—was advanced by allowing plaintiffs to plead the artificial act of infringement and develop particularized infringement theories during the litigation. The court noted that plaintiffs have an "extremely limited time, just 45 days" from receiving the defendant's notice letter to decide whether to bring a lawsuit. In many instances there are multiple defendants, each with their own ANDA or 505(b)(2) application, and much of the 45-day window is dedicated to negotiating confidentiality terms allowing plaintiffs access to the defendant's ANDA or 505(b)(2) application. Further, the court recognized the Act does not require plaintiffs get access to the defendant's application and, many times, they do not gain access during the 45-day period. In addition, plaintiffs are not able to purchase the accused product and test it, since the defendant's product by definition is not available for purchase. Lastly, given that defendant's action triggers the lawsuit, it should already know at least to some extent why it is plausible that plaintiffs believe its patent covers defendant's proposed product.

Based on these reasons, and that neither party cited a case saying what is required for **pleading** infringement in a Hatch-Waxman case is the same as any other patent infringement suit, the court concluded that Belcher's pleading complied with *Iqbal* and *Twombly* as applied to the Hatch-Waxman context.

PATENTS / MARKING

Zachary D. Miller

Orange Book Listing of Patents Does Not Satisfy Section 287 Marking Requirements

The US District Court for the District of Delaware dismissed two composition patents for failure to comply with the patent marking requirements of 35 USC § 287, and rejected the argument that listing the two patents in the FDA's Orange Book in connection with the unmarked product qualified as patent marking. *Horatio Washington Depot Techs. LLP v. Tolmar, Inc.*, Case No. 17-1086-LPS (D. Del. 2019) (Stark, C.J.).

In the 1990s, ALZA Corporation developed technology related to the use of implantable pumps containing an active ingredient, leuprolide acetate, and a solvent, DMSO, to treat prostate cancer. They filed several patents on the

technology, including the patents at issue in this case, and launched a product—Viadur—which used the technology. The patents at issue were listed in the FDA's Orange Book in connection with the Viadur product, but the Viadur product (or packaging) was not marked with the patents. Unfortunately, Viadur was not commercially successful and was discontinued around 2009. Subsequently, the patents at issue were sold, and were eventually acquired by Horatio after they expired in 2017. Shortly thereafter, Horatio sued Tolmar for infringement based on a competing product—Eligard—which had been on the market since 2002. In its complaint, Horatio alleged that Tolmar knew of the patents due to their presence in the Orange Book. Horatio, however, failed to allege that the Viadur product was marked—instead, alleging that no product was available to be marked during the six-year period for which they sought damages under 35 USC § 286. Since only past damages were at issue, Tolmar moved to dismiss the patents for ALZA's failure to mark Viadur.

In its briefing, Horatio argued: (i) that listing the patents in the Orange Book satisfied the purposes of the marking statute, so should qualify as patent marking; (ii) that Horatio, a good-faith purchaser of the patents, should not be held to ALZA's failure to mark because it had no connection to Viadur, and it would be unreasonable to require Horatio to discover the lack of marking; and (iii) that the marking requirement should be read in connection with Section 286's time limitation on damages, such that marking is only required for products sold during the damages window. The district court disagreed with Horatio's arguments and dismissed the patents.

Addressing Horatio's Orange Book listing argument, the court first noted that there are only two statutory alternatives permitted by the marking statute—constructive notice by marking or actual notice. The court evaluated the Orange Book listing under each statutory alternative. Constructive notice by marking requires the product itself, or its packaging, to have the patent number (or a website containing the patent number) listed directly on it. Simply put, the Orange Book did not qualify as physical marking. While the court acknowledged that the Orange Book might qualify as "constructive notice" in other instances, it found that the language of the statute controlled, and that it could not allow a "more lenient 'Orange Book' form of constructive notice."

The court once again looked to the language of the statute to evaluate Horatio's good-faith purchaser argument. Specifically, the court noted that the marking requirement applied to all patentees—which was defined as "not only the patentee to whom the patent was issued but also the successors in title to the patentee." As a successor in title, Horatio was required to comply with the marking statute. The court was not swayed by Horatio's argument that as a good-faith purchaser, it could not know whether prior owners had complied with the marking statute. Instead, the court found that this was common due diligence a purchaser could undertake during the purchasing process. Moreover, the court found compelling the argument that Horatio could not have purchased more rights to the patent than the original patentee—Alza—had owned. Thus, if Alza did not have the right to recover past damages due to the marking statute, the sale of the patent did not create those rights.

Finally, the court disagreed that the marking statute should be commensurate with Section 286's six-year limitation on damages. The court noted that Horatio provided no legal support for its argument, and that there is nothing in the statutes themselves to suggest such a connection. Accordingly, the court dismissed the patents for failure to comply with the marking requirements of Section 287.

PATENTS / CLAIM CONSTRUCTION

Brittany A. Washington

The Same Claim Term in Related Patents Carries the Same Construed Meaning

Following a Markman hearing, the US District Court for the District of New Jersey construed the claim term "reducing the likelihood" of chemotherapy-induced nausea and vomiting (CINV) to mean decreasing the probability of the condition, based in part on the Federal Circuit's interpretation of the claim term in a related patent. *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc. et al.*, Case No. 2-14-cv-04274 (D.N.J. 2018) (Chesler, S.)

Plaintiff Helsinn Healtchare S.A. owns a patent directed to a method for reducing CINV using Aloxi®, a palonosetron-based compound. Defendants Teva Pharmaceutical USA, Inc. and Teva Pharmaceutical Industries, Ltd. submitted an Abbreviated New Drug Application seeking approval to market a generic version of Aloxi. Helsinn sued Teva, alleging infringement of claims in the patent. The present case is part of a larger group of cases involving various palonosetron patents.

The parties disputed the construction of the claim term "reducing the likelihood" of CINV, as recited in the independent claim, and its parallel term "reduces the likelihood," as recited in a dependent claim. Neither the parties nor the court distinguished the two claim terms in analyzing the proposed constructions. Teva proposed that the claim term should mean "decreases the probability or makes it less probable that delayed CINV will occur." Helsinn sought to construe the term to mean "to prevent delayed nausea and vomiting in a statistically significant number of patients." In doing so, Helsinn argued that another district court adopted the same construction of the identical claim term in a case concerning the parent patent.

Before turning to its own analysis, the court noted that the district court construed the claim term without the benefit of the Federal Circuit's subsequent analysis of the term in

the parent patent. At issue before the Federal Circuit was whether the parent patent and three related patents were reduced to practice before the critical date. The Federal Circuit addressed if the term "reducing the likelihood" of CINV required preventing the condition from occurring and concluded that complete control of CINV was not a claim requirement. Because the disputed claim term was identical in the instant patent and its parent patent, the court presumed it carried the same construed meaning and, thus, adopted the same construction.

The court also rejected Helsinn's arguments that the patent specification, the drug's FDA approval, the patent prosecution history, and expert testimony supported its proposed construction. First, the court found the specification repeatedly and almost exclusively described the purpose of the invention as preventing or reducing CINV. Because the specification used two different terms, the court concluded that the terms "preventing" and "reducing" held different meanings. Next, the court declined to import the FDA's approval for the drug's CINV prevention indication into the claim limitation because the patent did not refer to the standards for FDA approval. The court then found that Helsinn's proposed construction was barred by prosecution history disclaimer. During the prosecution of the parent patent application, the patentee removed the limitation "preventing" CINV to overcome an enablement rejection, thus restricting the scope of the claims. The court explained that the prosecution history of a claim limitation in an earlier application applies with equal force to subsequently issued patents containing the same limitation. Therefore, Helsinn's proposed construction was barred by the patentee's surrender of "preventing" CINV in the parent application. Finally, the court rejected Helsinn's expert testimony, finding that the court need not look beyond intrinsic evidence to understand the meaning of the disputed claim term.

In light of the intrinsic record as well as the Federal Circuit's prior analysis of the same claim term, the court adopted Teva's proposed construction that the claim term "reducing the likelihood" of CINV means decreasing the probability of the condition, not preventing the condition.

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