

PHARMA REVIEW

Dear Readers:

Welcome to the third 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, and appellate and district court decisions in pharma-related antitrust litigations.

In this issue, we cover:

- The enforcement of antitrust claims related to claims of anticompetitive activity in foreign markets (*Biocad JSC v. F. Hoffman-La Roche, et al.*)
- The necessary evidence to demonstrate a reasonable expectation of success in proving obviousness of a method of treatment (*OSI Pharms., LLC v. Apotex Inc.*)
- The difficulty in alleging antitrust violations related to sham litigation based on likely invalidity of asserted patents (*Duke v. Akorn, Inc.*)
- The appropriate venue analysis for patent infringement claims based on the filing of an ANDA (*Valeant Pharms. N. Am. LLC v. Zydus Pharms. (USA) Inc.*)
- And more!

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

Happy holidays!

ISSUE 3

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ANTITRUST/FTAIA AND ANTITRUST INJURY

Zachary M. Johns

Second Circuit Upholds Dismissal of Antitrust Complaint Alleging Scheme to Block Competitor From Launching Biosimilar Cancer Treatments in the United States

The US Court of Appeals for the Second Circuit recently affirmed the dismissal of an antitrust complaint by Biocad JSC against Genentech, F. Hoffman-La Roche (Roche), and R-Pharm JSC. In doing so, the court clarified the reach of the “import exclusion” to the Foreign Trade Antitrust Improvements Act (FTAIA) and, in a concurring opinion, Judge Robert Katzmann provided guidance on the proper standard under which the antitrust injury element for nascent competitors should be analyzed. *Biocad JSC v. F. Hoffman-La Roche, et al.*, 942 F.3d 88 (2nd Cir. 2019) (Chin, J.)

Biocad, which is based in Russia, had announced that it planned to enter the United States with biosimilar products for three monoclonal antibodies currently sold by Roche when Roche’s exclusivity expired. According to Biocad, the defendants sought to extend Roche’s exclusivity in the United States beyond the expiration of applicable patents by engaging in a multifaceted antitrust campaign in Russia designed to financially cripple Biocad. The purported goal of defendants’ campaign in Russia was to prevent Biocad from eventually launching its biosimilar products in the United States. Biocad brought suit in the United States alleging antitrust violations based on Roche’s activities in Russia. The district court dismissed Biocad’s case for failure to state a claim.

The Second Circuit focused on the district court’s dismissal of Biocad’s antitrust claims under the Sherman Act and New York state law on the basis that they were beyond the reach of the Sherman Act under the FTAIA. The FTAIA is a “cumbersomely worded” statute that essentially excludes from the reach of the Sherman Act anticompetitive conduct that causes only foreign injury. There are two exceptions for conduct involving (1) imports and (2) domestic effects. Since Biocad waived its reliance on the domestic effects exception in the district court, the Second Circuit focused only on the import exclusion.

The import exclusion applies to “conduct involving . . . import trade or import commerce.” The question was whether defendants’ foreign conduct in Russia involved import trade or commerce where there was no effect in the United States, but where the defendant intended to impact import commerce in the future. Citing the statutory language, structure, and purpose of the FTAIA, the court concluded that the import exclusion applies only to where a defendant’s actions have a *direct* and *immediate* impact on the US import market. It is irrelevant whether a defendant subjectively

intended to affect import commerce in the future. Thus, while it appears that the defendants’ immediate objective was to impair Biocad’s ability to compete in Russian markets, the mere possibility that this would later prevent Biocad from entering the United States at some point is “too remote and speculative to plausibly affect imports into the United States.” As a result, the FTAIA barred Biocad’s antitrust claims.

Judge Katzmann wrote in a concurring opinion to express his view that the district court improperly required Biocad to allege a “probability of FDA approval” to satisfy the antitrust injury requirement at the motion-to-dismiss stage. Judge Katzmann observed that while the Second Circuit has held that a potential market entrant may show antitrust injury by alleging an intention and preparedness to engage in business, the court last wrote on this topic in 1909. Courts since then have identified four factors for preparedness that Judge Katzmann would be inclined to adopt in the appropriate case, including (1) the plaintiff’s background and experience in the prospective business, (2) the ability to finance entry, (3) consummation of contracts related to potential entry, and (4) other affirmative action by the plaintiff to engage in the proposed business. While the likelihood of FDA approval may be relevant, as some courts outside the Second Circuit have recognized, Judge Katzmann cautioned that courts should be wary of applying a rigid “probable FDA approval” requirement at the pleading stage.

Practice note: The FTAIA and its exclusions are nuanced and complicated, as the Second Circuit acknowledged. Businesses seeking to use the US antitrust laws to complain of anticompetitive conduct located outside the United States or to defend against such claims should consult experienced antitrust counsel. In addition, the Second Circuit has signaled a willingness to take a more flexible approach regarding what needs to be alleged to show antitrust injury for competitors who are seeking to enter a market. This could lead to a relaxation of the pleading burden for nascent competitors located in the Second Circuit who believe they may have been improperly foreclosed from entering a market by conduct of a future competitor.

PATENTS/OBVIOUSNESS

Krista Vink Venegas

Federal Circuit Reverses PTAB Finding of Unpatentability Due Obviousness Based on a Lack of Substantial Evidence Supporting Reasonable Expectation of Success

The Federal Circuit held patent claims for methods of treating non-small cell lung cancer were not unpatentable due to obviousness because the prong of reasonable expectation of success was not supported by substantial evidence. *OSI Pharms., LLC v. Apotex Inc.*, 939 F.3d 1375 (Fed. Cir. 2019) (Stoll, J.).

Erlotinib, an epidermal growth factor receptor (EGFR) inhibitor, is the active ingredient in OSI Pharmaceutical's TARCEVA product, indicated for uses including non-small cell lung cancer (NSCLC) with EGFR mutations. One of the Orange Book-listed patents was the subject of this IPR. The dependent claim at issue was essentially directed to a method for the treatment of a mammal with NSCLC (or other conditions), comprising administering a therapeutically effective amount of erlotinib. In 2000, the standard of care for NSCLC was chemotherapy, but research had begun on targeted therapies using EGFR inhibitors. Unfortunately, many agents that showed promise in vitro failed in clinical trials. Specifically, the record showed that from 1990 to 2005, only seven of 1,631 NSCLC treatments studied in Phase II trials were cleared by the FDA.

Apotex relied on three primary prior art references to demonstrate obviousness. The primary reference was a patent directed at a class of antiproliferative compounds that inhibit the erbB family receptors (including EGFR). Erlotinib was listed as one preferred compound among 105 specifically recited compounds for treating a variety of tumors (including lung tumors, but not specifically NSCLC). One secondary reference was a review article discussing tumor malignancy signaling mechanisms. The review surveyed about 30 studies and mentioned that erlotinib (and another compound) are competitive inhibitors of EGFR (referring to two cited studies), and the author of the review stated that "these compounds appear to have good anti-cancer activity in preclinical models, with an acceptable therapeutic index, particularly in patients with non-small cell lung cancer." However, in the IPR proceedings the author of the review article declared that neither of the two studies cited was directed to the effect of erlotinib on NSCLC. He further declared that at the time of writing the article (or since), he was not aware of any such study that was available as of the writing of the article (suggesting that the sentence in the review article included a drafting error). The alternative secondary reference was OSI's 10-K. Petitioners focused on the description of Product Development and Research Programs that disclosed that erlotinib targets a variety of cancers (including NSCLC), that OSI had completed a Phase I trial (evaluating safety, dosing, and side effects) and that a Phase II trial (evaluating clinical efficacy) had been initiated. However, the statement was nonspecific as to which indication(s) of use were included in the studies and included no statement confirming erlotinib's effect on NSCLC.

The Patent Trial and Appeal Board found the challenged claims obvious because one of skill combining the primary reference (disclosing all of the claimed elements, but for the treatment of NSCLC type of lung cancer) with one of the secondary references would have had a reasonable expectation of success of achieving the claimed invention. Specifically, the board determined that knowing OSI was focused on the use of erlotinib to treat NSCLC, and the disclosure of OSI's Phase II trial in its 10-K, were sufficient to

support a reasonable expectation of success because those of skill knew preclinical animal efficacy data must have been submitted in an Investigational New Drug application prior to the Phase I trial. Further, the board credited the statement in the review article about the preclinical models showing erlotinib's efficacy to treat NSCLC, although there was a declaration submitted by its author confirming there was no support for the statement in the review article.

The Federal Circuit reviewed the finding de novo and reversed due to a lack of substantial evidence of reasonable success. Specifically, the court found that the prior art did not include any information about erlotinib's effectiveness in treating NSCLC. The suggestive evidence of record was weighed against the high degree of unpredictability in the art and significant lack of success of other NSCLC drug candidates in Phase II trials.

ANTITRUST / SHAM LITIGATION & PATENT MISUSE

Kevin Shortle

Allergan Doesn't Bat an Eyelash and Wins Dismissal of Sham Litigation Counterclaims

The US District Court for the District of New Jersey dismissed defendant Akorn's antitrust and patent misuse counterclaims and related affirmative defenses because Akorn failed to meet the high pleading standard for the sham litigation exception to *Noerr-Pennington* antitrust immunity. *Duke v. Akorn, Inc.*, 2019 U.S. Dist. LEXIS 159314, 2019 WL 4410284 (D.N.J.) (Martinotti, J.).

The parties have a long litigation history over Akorn's ANDA for its generic version of Allergan's Latisse® (bimatoprost) product, indicated for eyelash growth. Allergan had previously sued Akorn three times under three sets of different patents (*Latisse I-III*). *Latisse I* ended with final judgment declaring the asserted patents invalid for obviousness after the Federal Circuit reversed the district court. Allergan filed *Latisse II* while *Latisse I* was pending at the district court. After the Federal Circuit's decision in *Latisse I*, the district court entered final judgment against Allergan finding (i) the asserted patents invalid as obvious for the same reasoning in *Latisse I* and (ii) that collateral estoppel prevented Allergan from contesting their invalidity. Allergan filed *Latisse III* several months after the Federal Circuit's decision in *Latisse I*. Like *Latisse II*, the district court entered final judgment finding collateral estoppel again prevented Allergan from asserting the third set of patents against Akorn because they were substantially similar to the patents asserted in *Latisse I* and *II*. In each case, the district court denied the defendants' motions for attorney fees under 35 U.S.C. § 285.

In the current litigation, *Latisse IV*, Duke and exclusive licensee Allergan sued Akorn for infringing US Patent No.

9,579,270 (the '270 patent). Akorn counterclaimed for sham litigation and attempted monopolization under 15 U.S.C. §2, conspiracy to monopolize under 15 U.S.C. § 1 and 2, patent misuse and similar affirmative defenses. Allergan and Duke moved to dismiss under FRCP 12(b)(6) arguing that Akorn failed to plead enough facts to meet the sham litigation exception to *Noerr-Pennington* immunity and failed to plead fraud or improper expansion of the '270 patent to support its patent misuse claim.

Noerr-Pennington immunity protects parties from antitrust liability whose purpose for petitioning the government or the courts is to restrain competition or monopolize commerce. To succeed with the sham litigation exception, litigants must show the lawsuit was objectively baseless, meaning no reasonable litigant could realistically expect success on the merits. Akorn responded by arguing that it pleaded sufficient facts to show sham litigations dating to *Latisse I* and made specific allegations about Duke's attempt to expand the scope of the '270 patent for patent misuse. The district court granted Allergan's motion to dismiss.

First, the court found that *Noerr-Pennington* immunity insulated plaintiffs from antitrust liability. Allergan had a reasonable basis to file the *Latisse I-III* cases and they were not objectively baseless **when filed**—an “essential” inquiry according to the court. *Latisse I* was a close case. Allergan had prevailed at the trial court, but the Federal Circuit reversed, finding the patents invalid for obviousness. Allergan filed *Latisse II* prior to the Federal Circuit's reversal in *Latisse I*. *Latisse III*, while filed after the Federal Circuit's decision, involved a patent not previously litigated in *Latisse I* or *II*, and that issued years after either case. The court abided by the principle that it is a rare case where a patentee facing an invalidity challenge will be found to have brought sham litigation because patents are given a presumption of validity.

It was also important to the district court that previous courts in *Latisse II* and *III* denied Akorn's and other co-defendants' motions for attorney fees. Since the exceptional case standard of 35 U.S.C. § 285 is less stringent than the sham litigation exception to the *Noerr-Pennington* doctrine, the district court concluded the previous cases were not objectively baseless and did not constitute sham litigation, and dismissed all of Akorn's sham litigation antitrust counterclaims.

Second, the district court dismissed Akorn's conspiracy-to-monopolize counterclaims based on the finding that Allergan had not brought sham litigation. The court also found no conspiracy between Duke and Allergan because of their patent owner-exclusive licensee relationship. The court agreed with other district courts that parties with unified interests are incapable of conspiring with one another for purposes of 15 U.S.C. § 1.

Lastly, the district court dismissed Akorn's patent misuse counterclaim. Akorn first failed to allege any fraud by Duke or Allergan in obtaining the patents. In addition, the court

held that precedent demonstrated that sham litigation cannot form the basis for a patent misuse claim as a matter of law. Finally, the court found that Akorn also failed to allege any facts to support its claim that Duke or Allergan impermissibly broadened the '270 patent's scope.

Practice note: When pleading sham litigation in patent infringement cases based on prior findings of invalidity, it will be difficult to meet the high pleading standard for the sham litigation exception to *Noerr-Pennington* immunity—i.e., that, when filed, the lawsuit was objectively baseless in that no reasonable litigant could realistically expect success on the merits—given the statutory presumption of validity set forth in 35 U.S.C. § 282(a).

PATENTS/INDEFINITENESS AND INDUCED INFRINGEMENT

Shon Lo

Federal Circuit Affirms Invalidity for Indefiniteness and No Induced Infringement

The Federal Circuit upheld a district court judgment of invalidity based on the indefiniteness of the term “consisting essentially of” and affirmed summary judgment of no induced infringement. *HZNP Medicines LLC, et al. v. Actavis Labs. UT, Inc.*, 940 F.3d 680 (Fed. Cir. 2019) (Reyna, J.).

Horizon Pharma USA, Inc. markets PENNSAID 2%, a twice-daily topical diclofenac sodium formulation for the treatment of pain of osteoarthritis of the knees. A prior art product, PENNSAID 1.5%, has a different formulation, and must be applied four times a day. Actavis filed an ANDA seeking to market a generic version of PENNSAID 2%. Horizon asserted 12 Orange Book-listed patents against Actavis in the US District Court for the District of New Jersey.

The asserted patents comprised a group of method-of-use patents and a group of formulation patents. The method claims are generally directed to methods for applying the inventive topical formulation comprising the steps of (1) applying the inventive topical diclofenac formulation; (2) waiting for the treated area to dry; and (3) subsequently applying a sunscreen, insect repellent, or second topical medication to the treated area. The formulation claims

are generally directed to topical formulations consisting essentially of a list of enumerated ingredients.

After holding a *Markman* hearing, the district court found three terms in the asserted claims of the formulation patents were indefinite. Specifically, the court found a person of ordinary skill in the art (POSA) would not have understood with reasonable certainty the meaning of the terms, (1) “the topical formulation produces less than 0.1% impurity A after 6 months at 25°C and 60% humidity” because the identity of “impurity A” is undefined and unknowable; (2) “the formulation degrades by less than 1% over 6 months”

Even for ANDA, Existing Infringement Dictates Venue

The District of New Jersey split from previous decisions interpreting the patent venue statute in the ANDA context and adopted a stricter reading considered more in line with Federal Circuit precedent. *Valeant Pharms. N. Am. LLC v. Zydus Pharms. (USA) Inc.*, Case No. 18-13635-PGS (D. N.J. 2019) (Sheridan, J.). Although venue is proper “where the defendant **has committed** acts of infringement and has a regular and established place of business,” 28 U.S.C. § 1400(b) (emphasis added), certain courts had previously found this past-tense language incongruent with the forward-looking ANDA framework.

As one court explained, “Congress” choice of verb tense in the patent venue statute creates an almost impenetrable problem in the particular context of Hatch-Waxman patent litigation. This is because the temporal focus of the Hatch-Waxman infringement analysis is the future, not—as is true in essentially all other patent infringement suits—the past, or even the present.” *Bristol-Myers Squibb Co. v. Mylan Pharm., Inc.*, Case No. 17-379 (D. Del. Sept. 11, 2017).

These courts had therefore decided that “an ANDA filer’s future, intended acts must be included as part of the ‘acts of infringement’ analysis for purposes of determining if venue is proper under the patent venue statute.”

The *Valeant* court instead adopted a stricter approach. “The Federal Circuit has cautioned against liberally construing the patent venue statute, and on its face, the patent venue statute states ‘a civil action for patent infringement may be brought **where** the defendant **has committed** acts of infringement.’” (emphasis theirs). In the court’s view, “*Bristol-Myers Squibb Co.*’s interpretation of that statute does not follow from a plain reading of the statute, which is clear: only where a defendant has committed an act of infringement may a party bring a patent suit.”

Applying this interpretation, the defendant’s only infringing act was filing its ANDA. And as the defendant had “submitted its ANDA application in West Virginia, to the FDA in Maryland,” this act undisputedly occurred outside New Jersey. The court therefore found venue improper for Valeant’s infringement claims.

Perhaps anticipating this outcome, Valeant attempted to hedge its bets by also asserting its infringement claims as declaratory judgment counts. It argued that even if venue was improper for the infringement claims under Section 1400(b), venue was nevertheless proper for the declaratory judgment counts that were subject to the general venue statute.

Again, the court disagreed. Noting that “Plaintiffs seek declaratory judgment that Defendants **infringed** on its patents” (emphasis theirs), the court saw no reason to

because neither the claims nor the specification disclose the means to evaluate degradation; and (3) “consisting essentially of” because the basic and novel properties of the invention were indefinite under the *Nautilus* standard.

The Federal Circuit affirmed. The specification did not define “impurity A,” and the court rejected Horizon’s argument that a POSA would understand the term to mean “USP Related Diclofenac Compound A.” Looking at the language of the claims, the court noted that the claim tied impurity A to the *formulation* rather than just diclofenac sodium. That, along with the absence of details on the HPLC conditions used in the sole example discussing impurity A undercut Horizon’s argument that a POSA would look to the pharmacopoeia to discern the identity of impurity A. The court further found that because the disputed “degrades by” term relies on “impurity A,” it too is indefinite.

The transition phrase “consisting essentially of” permits inclusion of components not listed in the claim, provided that they do not materially affect the basic and novel properties of the invention. Horizon argued that the *Nautilus* standard of indefiniteness applies to claims, and not to the basic and novel properties of the invention described in the specification. The Federal Circuit rejected this argument, stating that by using the phrase “consisting essentially of” in the claims, the inventor in this case incorporated into the scope of the claims an evaluation of the basic and novel properties described in the specification. The Federal Circuit was careful to note that the phrase does not render a claim indefinite per se, so long as the basic and novel properties provide clear notice of what is being claimed. In this case, the district court identified five basic and novel properties, one of which was better drying time. The specification provided two tests for measuring drying time. But the specification reported inconsistent results for the two tests. Thus, the Federal Circuit affirmed that a POSA would not know which one to use to evaluate better drying time, and the “consisting essentially of” claims are indefinite.

The district court granted summary judgment of no induced infringement of the method-of-use patents. Evaluating Actavis’s label, the court found that the label did not require or direct a subsequent application of sunscreen, insect repellent, or second medication. The Federal Circuit affirmed. The mere possibility that direct infringement might occur is not sufficient for inducement. Rather, the label instructions must reflect an affirmative or specific intent to induce infringement. Here, Actavis’s label only required application of the topical formulation and not the other two steps required by the claim.

Judge Pauline Newman, dissenting in part, argued that when the properties of a composition are described in the specification, the usage “consisting essentially of” the ingredients of the composition does not invalidate the claims when the properties are not repeated in the claims. Judge Newman also dissented from the panel’s finding of no induced infringement.

depart from “the Supreme Court’s holding in TC Heartland LLC, that 28 U.S.C. § 1400(b) is the ‘sole and exclusive provision controlling venue in patent infringement actions . . . and is not to be supplemented . . . by §1391(c).” It further explained that even if venue were proper, it would decline to exercise jurisdiction over the declaratory judgment counts. As a co-pending, largely identical case was filed in West Virginia, the New Jersey court’s exercise of jurisdiction over the declaratory judgment counts would only result in both courts “litigating and deciding the same issues.”

Practice note: Courts continue to interpret venue for patent infringement actions strictly after TC Heartland. Even here, where other legal frameworks involved suggested a more liberal approach may be merited, the court declined to depart from the generally strict approach taken by the Federal Circuit.

PATENTS / NONINFRINGEMENT

Zachary D. Miller

Plaintiff’s Failure to Amend Infringement Contentions to Advise of Narrowed Infringement Theory Results in Summary Judgment of Noninfringement

The Federal Circuit affirmed a district court’s decision to strike the infringement report submitted by Phigenix’s expert and grant summary judgment of noninfringement. *Phigenix, Inc. v. Genentech, Inc.*, Case No. 2017-2617, 2018-2042 (Fed. Cir. September 5, 2019) (Stoll, J.)

Phigenix sued Genentech, claiming that Genentech’s drug-resistant breast cancer medication, Kadcycla, infringed a Phigenix patent. Phigenix initially provided infringement contentions and an expert report setting forth a theory that patients who were prescribed Kadcycla after previously being treated with “trastuzumab and a taxane, separately or in combination” infringed the asserted patents. During an early summary judgment motion, the district court found that the asserted claims were *not* entitled to a 2005 priority date based on the filing date of a provisional application.

Following this decision, Phigenix adopted a new infringement position: only patients that had been treated with trastuzumab, a taxane “and nothing else” prior to Kadcycla were alleged to infringe. The new alleged infringing population constituted 4% of the originally accused infringers. However, instead of moving to amend infringement contentions during the course of fact discovery, Phigenix only informed Genentech of this narrower theory during the infringement expert’s deposition—after questioning by Genentech. After the deposition, Genentech moved to strike the infringement expert’s report. The district court agreed that Phigenix had failed to provide adequate notice of the new theory, struck the expert report, and granted summary judgment of noninfringement based on a resulting lack of evidence. Phigenix appealed, arguing that the district court abused its discretion.

While a narrowed infringement theory may not always require new infringement contentions, the Federal Circuit found that here, where Genentech could demonstrate legitimate prejudice, notice of the new theory was required. Accordingly, the Federal Circuit affirmed the district court’s decision to strike the expert report and grant summary judgment of noninfringement.

Practice note: Infringement and invalidity theories may change over the course of fact and expert discovery. Be careful to ensure that the local patent rules, including rules regarding amending contentions, are amended when new theories cause a change in the scope of arguments.

PATENTS / SUBJECT MATTER ELIGIBILITY

Jeffrey R. Gargano

Methods of Treatment Patents Requiring No Treatment of Specific Patients Found Ineligible Under Section 101

The Federal Circuit affirmed a district court’s finding that Ino Therapeutics’ patents for (i) a method of treating patients who are candidates for inhaled nitric oxide treatment were directed to ineligible subject matter under 35 U.S.C. §101, and (ii) an infrared delivery system that provides nitric oxide to patients via gas cylinders were not infringed. *Ino Therapeutics LLC v. Praxair Distribution Inc.* (Fed. Cir. August 27, 2019)

The court’s opinion largely addressed the issue of whether the claims of the first group of asserted patents were directed to patent eligible subject matter. The claims were based on a study that concluded infants with left ventricular dysfunction (LVD) were at an increased risk of pulmonary edema when treated with inhaled nitric oxide (iNO) gas. The claims were drawn to a method of treatment that excluded a patient from treatment with iNO based on the determination that the patient had LVD and was therefore at an increased risk of pulmonary edema.

The court applied the two-part test for patent eligible subject matter established under *Mayo* and *Alice*. Under the first step, the court concluded that the claims were “directed to” a natural phenomenon because they merely involved detecting the presence of LVD in a patient and then doing nothing but leaving the natural processes to take place in the body for this group of LVD patients. The court found the claims not to be focused on changing the physiological state of the patient to treat a disease, but instead focused on screening for a natural law, which is not patent eligible. Turning to the second step of the *Mayo/Alice* test, the court looked to the claims to determine whether they contained an inventive concept sufficient to transform the claimed naturally occurring phenomena into a patent-eligible application. Here, the court concluded that the steps in the claimed process (other than the natural law discovered by

the study, i.e., if a patient has LVD, iNO gas can induce the life-threatening event known as pulmonary edema) involved well known, routine, and conventional activity commonly engaged in by researchers in the field. Thus, the claims were ineligible under § 101.

Mayo/Alice

Step 1: The Claims Are Directed to a Natural Phenomenon

Laws of nature, natural phenomenon, and abstract ideas are not patentable. 35 U.S.C. § 101. Here, the court found the natural phenomenon undisputed. Praxair's expert, Dr. Lawson, testified that "the standard observation that a dysfunctional ventricle, in combination with increased blood flow, could cause a backup of venous blood, and in turn, edema is a phenomenon taught to first year medical students." This testimony went unchallenged. It was also undisputed that treatment of infants experiencing hypoxic respiratory failure with iNO gas existed for decades. The court concluded that the inventors merely observed an adverse event that iNO gas causes for patients suffering from LVD, and the claims did no more than add an instruction to withhold iNO treatment from patients with LVD. The exclusion step, the court reasoned, merely restates the natural law. The claims expressly recite "excluding the second patient from treatment with inhaled nitric oxide, based on the determination that the second patient has left ventricular dysfunction, so is at particular risk of increased PCWP leading to pulmonary edema upon treatment with inhaled nitric oxide. The claim did not recite giving any affirmative treatment for the iNO-excluded group. Thus, the court concluded that it covered a method in which, for the iNO-excluded patients, the body's natural processes were simply allowed to take place.

The court also distinguished the claims at issue here from the claims at issue in *Vanda Pharma Inc. v. West-Ward Pharma Int'l Ltd.* 887 F.3d 1117 (Fed. Cir. 2018). In *Vanda*, the court found the claims patentable because they recited a specific method of treating a disease using an improved set of specific doses in light of the discovery of a natural law. Here, the court distinguished the claims because they did not improve treatment of the underlying condition in question—pulmonary edema and hypoxic respiratory failure—by taking advantage of the body's natural process. Instead, the directive to exclude patients with LVD from iNO treatment and do nothing more for this class of patients (while continuing to treat other patients according to well-known procedures and doses), collapses the claims into the natural phenomenon.

Mayo/Alice

Step 2: The Claims Do Not Include Additional Limitations That Recite Inventive Concept and Transform the Claims Into a Patent-Eligible Application

A claim that recites an abstract idea, law of nature, or natural phenomenon must include additional features (i.e.,

the inventive concept) to ensure that the claim does more than monopolize the ineligible subject matter. Critically the inventive concept necessary at step two of the *Mayo/Alice* analysis cannot be furnished by the unpatentable law of nature (or natural phenomenon or abstract idea) itself. Here, Praxair argued that the additional claim limitations amount to nothing more than routine and conventional steps and a general instruction to apply the natural phenomenon. The court found that defendants did not meaningfully dispute the district court's findings that the steps (other than the exclusion step applying the natural phenomenon) of the claims were routine and conventional. The court found that the specification of the asserted patents made it clear that identifying candidates for treatment with 20 ppm iNO was routine and conventional in the art.

The claims also required two identifying steps: (i) identifying patients that do not have LVD, and (ii) identifying patients that have LVD. The district court found, and defendants conceded, that they did not invent a new way of detecting LVD and that identifying patients with pre-existing LVD was well known to those skilled in the medicinal arts. As the court found with respect to step one of the *Mayo/Alice* test, the final claimed step, i.e., to exclude a patient with LVD from iNO treatment merely embodies the natural phenomenon and cannot transform the claim into an application of that phenomenon. The court reasoned that "[t]his would be a quite different case if the inventors had invented a new way of titrating the dose, . . . [b]ut this claim, unaccompanied by a recitation of some affirmative treatment, is directed to the natural law."

PATENTS / PLEADINGS

Candace Polster

Delaware Rejects Strict Standard for Pleading Patent Infringement of Dependent Claims

The US District Court for the District of Delaware rejected a strict pleading standard that would require a plaintiff to precisely plead how an accused product infringes each dependent patent claim where there is a nexus between the independent and dependent claims. *Shire ViroPharma Inc. v. CSL Behring LLC*, Case No. 1:17-cv-00414 (D. Del. Aug. 5, 2019) (Goldberg, J.).

The plaintiff, Shire ViroPharma (Shire), has patents covering its marketed drugs that treat hereditary angioedema, which is a rare genetic disorder that prevents the natural production of C1 esterase inhibitor protein. Defendants, CSL Behring (Behring), obtained FDA approval and started selling its C1 esterase inhibitor protein treatment HAEGARDA®. As a result, Shire sued Behring for infringing each of its related patents. Behring filed a motion to dismiss, arguing that Shire failed to allege sufficient facts to state a claim for infringement of the dependent (but not independent) claims. To decide Behring's Rule 12(b)(6) motion, the district court

evaluated whether Shire's complaint was required to meet a stringent, limitation-by-limitation pleading standard for its assertion of both independent and dependent claims.

For pleading patent infringement, the US Court of Appeals for the Federal Circuit has previously held that the *Iqbal/Twombly* plausibility pleading standard requires the plaintiff only to provide fair notice by identifying the asserted patents and a general allegation that a defendant's product infringes the patents—specific facts are not necessary. Similarly, district courts have held that allegations establishing infringement of the independent claim are sufficient to encompass the dependent claim if the plaintiff pleads a nexus between the dependent and independent claims.

For each patent identified in its complaint against Behring, Shire provided the limitations of independent claim 1 and details about how HAEGARDA® infringes each limitation. The court found that Shire met the nexus requirement connecting the independent claim with the dependent claims by alleging that Behring infringed “one or more” claims of the asserted patents, which all depended on independent claim 1.

The court denied Behring's motion to dismiss Shire's asserted dependent claims, holding that specific facts related to the dependent claims were unnecessary for Shire to plead infringement. Moreover, the court found that a stricter pleading requirement for dependent claims would make the court's local patent rules—which require the plaintiff to serve infringement contentions including a claim chart relating each accused product to the asserted claims—superfluous.

PATENTS / CLAIM CONSTRUCTION

Richard W. Martin

Related Patents Sometimes Provide Guidance for Claim Construction

After a *Markman* hearing, a magistrate judge ruled against the patentee's proposed construction because it was inconsistent with a definition in the specification of a separate, albeit related, patent. However, the patentee was not able to rely on that same definition to argue the meaning of another disputed term. *Collegium Pharm., Inc. v. Teva Pharms. USA, Inc.*, Civil Action No. 18-300-LPS-CJB (D. Del., September 11, 2019) (Burke, J.).

Collegium asserted 13 patents against Teva's ANDA No. 209431, which seeks approval to market generic oxycodone extended release capsules. As relevant to claim construction, the parties disputed the meaning of the term “homogeneous single phase” in the asserted claims of US Patent No. 9,592,200, and the term “solidified solution” in the asserted claims of US Patent Nos. 8,557,291 and 9,248,195. In both cases, Collegium argued that the disputed terms should be

construed to require that the drug be “molecularly dispersed” within the homogenous single phase and solidified phase, respectively. The judge ruled against both constructions.

First, the judge considered the “homogeneous single phase” term. Finding against Collegium's “molecularly dispersed” construction, the opinion relied on a definition in another of the asserted patents, US Patent No. 8,840,928, where the patentee used “molecularly dispersed” to define a “solid solution” as a “matrix such that the system is chemically and physically uniform or homogenous throughout.” According to the opinion, this disclosure “thus provides evidence that when the patentee wished to make clear that a solution included a drug that was molecularly dispersed throughout, it knew how to do so and said so expressly.” Notably, the relationship between the '200 Patent and the '928 patent—specifically whether the latter is in the intrinsic record of the former—is not addressed.

The opinion also relied on admissions made during oral argument to find that the claims reciting “homogeneous single phase” are not limited to “molecularly dispersed” embodiments. In particular, the opinion notes that Collegium agreed that a “fully dissolved” solution is “molecularly dispersed,” whereas a “partially dissolved” solution is not. Thus, because the specification contemplates embodiments where the drug is partially dissolved, the judge found that the term “homogeneous single phase” does not require molecularly dispersed (i.e., fully dissolved) drug.

Turning to the other disputed term, Collegium cited the definition of “solid solution” in the '928 patent to argue that “solidified solution” should be construed to require “molecularly dispersed” drug. However, despite relying on this definition to rule against Collegium's construction of “homogeneous single phase,” the opinion found it unpersuasive when applied to construction of the “solidified solution” term. In particular, the Report and Recommendation states that “solidified” and “solid” are “two different terms [and] are thus generally presumed to have different meanings.” Furthermore, the specifications of the '291 and '195 patents do not themselves define “solidified.” In view of these findings, the opinion relied on claim differentiation, coupled with incompletely dissolved embodiments disclosed in the specification, to rule that “solidified solution” does not require molecularly dispersed drug.

Morgan Lewis

CONTACTS AND CONTRIBUTING AUTHORS

Jeffrey R. Gargano

Editor, *Pharma Review*

+1.312.324.1732

jeffrey.gargano@morganlewis.com

Zachary D. Miller

Editor, *Pharma Review*

+1.312.324.1706

zachary.miller@morganlewis.com

Michael J. Abernathy

+1.312.324.1447

mike.abernathy@morganlewis.com

Shon Lo

+1.312.324.1742

shon.lo@morganlewis.com

Kevin Shortsle

+1.312.324.1740

kevin.shortsle@morganlewis.com

John "Clay" Clayton Everett, Jr.

+1.202.739.5860

clay.everett@morganlewis.com

Stacey Anne Mahoney

+1.212.309.6930

stacey.mahoney@morganlewis.com

Michael T. Sikora

+1.312.324.1482

michael.sikora@morganlewis.com

R. Brendan Fee

+1.215.963.5136

brendan.fee@morganlewis.com

Richard W. Martin, Ph.D

+1.312.324.1730

richard.martin@morganlewis.com

Scott A. Stempel

+1.202.739.5211

scott.stempel@morganlewis.com

Zachary M. Johns

+1.215.963.5340

zachary.johns@morganlewis.com

Candace Polster

+1.312.324.1192

candace.polster@morganlewis.com

Krista Vink Venegas

+1.312.324.1736

krista.venegas@morganlewis.com

Eric Kraeutler

+1.215.963.4840

eric.kraeutler@morganlewis.com

Steven A. Reed

+1.215.963.5603

steven.reed@morganlewis.com

Connect with us     

www.morganlewis.com

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