



NGE IP FOCUS: Life Sciences

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As intellectual property practitioners working in the life sciences industry, we are positioned to engage with innovative scientific advances as well as emerging legal issues impacting the ability to secure and maintain patent protection for these advances. The legal issues encountered run the gamut from niche issues specific to the life sciences industry to intellectual property issues of general applicability across industries. In this issue of NGE IP Focus, we highlight some recent legal decisions in the life sciences industry that illustrate the depth and breadth of legal issues encountered in the field.

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While universities, start-ups, mid-size companies, and large multinational biopharmaceutical powerhouses occupy different positions in the life sciences industry, each confronts many of the same IP issues. Indeed, an entity desiring to partner with or be acquired by a larger company must be cognizant of the types of patent claims that can survive intense scrutiny in district court litigation and/or post-grant trials. This will maximize the value of its IP and the likelihood of an acquisition, merger, or investment.

By the time a patent dispute culminates in litigation – particularly in the life sciences industry – the underlying patent is often immutable. This means that keen attention to the current state of the law must be coupled with foresight to anticipate and, where possible, address future vulnerabilities. This is needed to strategically navigate the evolving legal landscape both during preparation and prosecution of patent applications and during investigation and due diligence on IP prior to licensing or acquisition.

In Touch with Kevin O'Connor

Kevin represents his clients in all aspects of patent law, including due diligence investigations for mergers and acquisitions, patent counseling and prosecution, strategic management of patent portfolios, and opinion preparation, focusing his practice primarily on the biotechnological, pharmaceutical, and medical device industries.

Kevin's work has encompassed a broad spectrum of technologies, including cellular therapies such as stem cells and CAR T-cells, biologics such as therapeutic antibodies and peptides, small molecules, and nucleic acids such as silencing RNAs; nutraceuticals; gene editing; molecular biology for next generation sequencing; temperature management devices; coronary stent systems; hematology analyzers and controls; and diabetes management devices.

Clients value Kevin's sophisticated business and communication skills that he puts into play to effectively advise them on the practical implications of their legal strategies. Kevin has assisted clients with multimillion-dollar acquisitions and collaborations, including due diligence and agreement drafting with various intellectual property, antitrust and corporate issues.

Kevin received his Ph.D. in Neuroscience from the University of Colorado, where his studies focused on interactions between the central nervous system and the immune system.

Kevin is the author of 21 peer-reviewed journal articles and has presented his work at various national and international scientific meetings.

After finishing his graduate work, Kevin joined the Molecular and Cellular Pathobiology Program at Children's Memorial Research Center in Chicago to study the pathophysiology of a pediatric inflammatory disease.

Kevin has been listed as a Rising Star in the 2016–2017 editions of *Illinois Super Lawyers*. In 2016, the Law Bulletin Publishing Company chose him as one of the "40 Illinois Attorneys Under 40 to Watch." Kevin has donated his time and energy to advocacy for blood cancer research and has served on the Leadership Board of the Illinois Chapter of the Leukemia & Lymphoma Society.



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NGE Focus seeks to inform clients of key trends and critical issues that arise in Intellectual Property practice. Authored in conjunction with the editors of Wolters Kluwer Legal & Regulatory, U.S., *Antitrust Law Daily* and *IP Law Daily*, the publication is not intended as legal advice; rather, it serves as a general overview of the key legal issues in this area of practice. We encourage you to consult with your Neal Gerber Eisenberg attorney about specific legal matters or if you have additional questions about the content provided here.

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Two of the most closely watched topics in the industry are obviousness-type double patenting and subject matter eligibility as the law in these areas is in a state of flux. Obviousness-type double patenting has received renewed attention as a tool for challenging patents since several patents have recently been held to be invalid on this ground. The subject matter eligibility boundaries set forth by the Supreme Court in *Mayo* and *Myriad* have given rise to a new wave of disputes borne out of the industry's reaction to these decisions. We explore these themes in the cases highlighted in this issue's articles.

The doctrine of obviousness-type double patenting is of particular interest in the life sciences industry because multiple patents often protect a prescription medicine and the final years of the patent term provide significant value to the patent holder.

In the first article, we see that a divided Federal Circuit panel applied traditional obviousness factors, including assessing predictability and a reasonable expectation of success, in finding that UCB's species claims covering the compound lacrosamide were not invalid for obviousness-type double patenting over its earlier-issued and earlier-expiring genus claims. Though defendant-appellant Accord's request for Supreme Court review was denied, several other defendant-appellants have independently petitioned for review of the panel majority's decision. In addition to seeking review of the obviousness-type double patenting determination, the petition sharply criticizes the panel majority's apparent adoption of the district court's "lead compound" analysis, which is an industry-specific test used to assess whether pharmaceutical compounds are obvious.

The next two articles, both involving Novartis, address the interplay between the judicially-created doctrine of obviousness-type double patenting and the statutes governing patent term. In *Novartis AG v. Ezra Ventures LLC*, a unanimous panel of Federal Circuit judges confirmed that obviousness-type double patenting does not invalidate a patent term extension that has been otherwise validly obtained under 35 USC § 156. In *Novartis Pharmaceuticals Corp. v. Breckenridge Pharmaceutical, Inc.*, another unanimous panel concluded that the correct patent term

statutory framework for assessing obviousness-type double patenting is the one that existed at the time the underlying application was filed – here, the framework prior to the Uruguay Round Agreements Act of 1994.

While subject matter eligibility is a topic of general interest to intellectual property practitioners regardless of technological field, the specific analysis in the context of life science-based claims is unique.

It has been widely believed that claims directed to a method for treating a disease where a diagnostic or prognostic step provides actionable information to inform the course of treatment were distinguishable from the claims that the Supreme Court struck down in *Mayo*. Indeed, since *Mayo*, the patent office has been granting such claims. In the fourth article, we see that a divided Federal Circuit panel agreed with this interpretation. The patent office believed the decision to be important enough to issue a memorandum instructing its examining corps that method of treatment claims that practically apply a natural relationship should be patent eligible irrespective of whether an unconventional step is present in the claims. The issue remains unsettled, however, as the defendant-appellant has recently filed a petition for Supreme Court review, criticizing the majority's decision as giving inappropriate weight to the "post-solution" treatment step.

The fifth article in this issue serves to remind us that such method of treatment claims should also be carefully crafted with an eye toward enforcement and, particularly, toward issues of indirect infringement and joint infringement. Pernix's claims were construed to require action of a healthcare provider *and* of a patient. The case underscores that infringement considerations for a method of treatment claim may involve assessment of the actions of the drug manufacturer (or ANDA filer), physician, diagnostic laboratory, and/or patient.

The sixth article relates to another type of technology that has triggered the subject matter eligibility analysis – testing of a biological sample. In this decision, the court elaborates on the eligibility of primer claims, which are the type of claim also at issue in *Myriad*. Here, primer claims are ineligible – despite reciting certain non-natural chemical modifications – if the recited nucleic acid sequence is identical to one found in nature. From this decision we also learn that method claims

directed to inferring the presence of a particular bacterium based on detection of signature nucleotides in a biological sample are ineligible.

Life sciences patent holders often also confront issues revolving around inventorship and subsequent ownership of IP, particularly when the IP originates with a non-commercializing entity. Assignment and license agreements should receive the same careful consideration as the

underlying IP asset to avoid situations like the one found in the final article, where the licensee, Gensetix, did not possess the right to bring an infringement suit in its name alone and could not force the university-licensor to join an infringement suit as an involuntary plaintiff.

In sum, IP portfolios require strategic management from the earliest stages, especially in the life sciences industry. We hope that you enjoy reading more in the pages that follow. ■

Vimpat® epilepsy drug patent survives double-patenting challenge

UCB, Inc., UCB BioPharma SPRL, Research Corp. Technologies, Inc., and Harris FRC Corp. (collectively, "UCB"), the owner/licensees of a patent covering lacosamide, an anti-epileptic drug marketed under the tradename Vimpat®, successfully resisted an appeal by generic manufacturers, as the U.S. Court of Appeals for the Federal Circuit found that the asserted claims were not invalid for obviousness-type double patenting, obviousness, or anticipation. Chief Judge Sharon Prost dissented, arguing that this was a case of double patenting (*UCB, Inc. v. Accord Healthcare, Inc.*, May 23, 2018, Stoll, K.).

that the claims were invalid for obviousness-type double patenting, obviousness, and anticipation. With respect to double patenting, the manufacturers pointed to two distinct patents through which the respondents had already obtained exclusive rights to lacosamide. Following a bench trial, the district court concluded that the asserted patent claims were not invalid. The petitioners appealed to the Federal Circuit, arguing that the district court misapplied the relevant legal standards. Finding no legal or factual error, the Federal Circuit affirmed the district court's no-invalidity determination.

In chemical cases, the double patenting inquiry is ... whether the later compound would have been an obvious or anticipated modification of the earlier compound.

The patent at issue, U.S. Patent No. RE38,551 (the '551 patent), discloses that lacosamide is the Renantiomer of N-benzyl-2-acetamido-3-methoxypropionamide. For its R, R1, and R3 positions, lacosamide has an unsubstituted benzyl at R, an unsubstituted methyl at R1, and a nonaromatic methoxymethyl at R3. The specification teaches that "the R stereoisomer is unexpectedly more potent than the corresponding S stereoisomer and the racemic mixture." To date, Vimpat® remains the only approved functionalized amino acid for the treatment of epilepsy.

UCB filed an infringement suit against petitioners Mylan Pharmaceuticals, Inc.; Mylan, Inc.; Alembic Pharmaceuticals Ltd.; Sun Pharma Global FZE; and Sun Pharmaceutical Industries, Ltd. after they filed Abbreviated New Drug Applications (ANDAs), seeking approval for generic versions of Vimpat®. The defendants stipulated to infringement of claims 9, 10, and 13 of the '551 patent but maintained

Obviousness-type double

patenting. By statute, only a single patent may issue for the same invention. Nonstatutory double patenting, however, is a

judicially-created doctrine, which "prohibits an inventor from obtaining a second patent for claims that are not patentably distinct from the claims of the first patent." In chemical cases, the double patenting inquiry is not whether a person of ordinary skill in the art would select the earlier compound as a lead compound, but rather whether the later compound would have been an obvious or anticipated modification of the earlier compound. The manufacturers relied on U.S. Patent No. 5,654,301 (the '301 patent) for their argument that the '551 patent is invalid for obviousness-type double patenting. Although lacosamide is not specifically disclosed in the '301 patent, it is undisputed that lacosamide falls within the broad genus of claim 39 of the '301 patent. The court agreed with the generic manufacturers that the obviousness-type double patenting inquiry requires consideration of the differences between the claims in the referenced '301 patent and the '551 patent. In this case, both claims recite a methoxymethyl group at R3. Thus, the double patenting analysis requires determining

whether the claims' differences, i.e., unsubstituted benzyl and methyl at R and R1, would have been obvious to one of skill in the art. The district court found that the differences between claim 45 of the '301 patent and the asserted claims of the '551 patent rendered the claims patentably distinct. The district court did not err by focusing its double patenting analysis on the claims' differences, as well as the claims as a whole.

Obviousness. The generic manufacturers asserted that claim 9 of the '551 patent would have been obvious based on disclosure of compound 107e as a racemic mixture in a thesis by graduate student Philippe LeGall (LeGall). Appellants further assert that LeGall alone, or in combination with other prior art references, render claim 9 obvious. The generic manufacturers also argued that the district court erred by using a lead compound analysis because this case involves purification, not structural modification, of a known compound. The Federal Circuit disagreed with the generic manufacturers. A lead compound analysis is not required in analyzing obviousness of a chemical compound when, in the inventing process, there was no lead compound. In any event, even if a lead compound analysis is required here, the court held that the district court did not clearly err in finding that a person of ordinary skill in the art would not have selected compound 107e as a lead compound. The court also evaluated the evidence before the district court. Based on this evidence, the Federal Circuit saw no clear error in the district court's fact findings and sustained its conclusion that the asserted claims of the '551 patent would not have been obvious.

Anticipation. Two generic manufacturers argued that because LeGall disclosed the chemical structure of the racemic compound 107e, it necessarily discloses the R-enantiomer (lacosamide) recited in claim 9 of the

'551 patent. The Federal Circuit disagreed and held that the district court did not clearly err in finding that LeGall does not anticipate claim 9 of the '551 patent.

Dissent. Chief Judge Sharon Prost dissented, opining that the district court clearly erred when it found there would not have been a reasonable expectation of success in selecting unsubstituted benzyl for R and unsubstituted methyl for R1. In Chief Judge Prost's view, the asserted claims of the '551 patent were not patentably distinct from the cited prior art.

Petition for certiorari. The generic manufacturers have asked the Supreme Court to review the Federal Circuit's decision. The manufacturers contend that the Federal Circuit improperly applied a restrictive, technology-specific threshold test in affirming the validity of the claims at issue. The manufacturers point out that, pursuant to 35 U.S.C. §103 and the Supreme Court's decision in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), the inquiry into the scope and content of the prior art, as well as the differences between the prior art and the claims at issue, is to be flexible, expansive, and technology-neutral. The petition for certiorari asks: (1) Whether, under this Court's well-settled precedent, a patentee may obtain a second patent on the same invention actually covered by a former patent to the same patentee; and (2) Whether, under 35 U.S.C. §103, a patent may be obtained when the differences between the claimed invention and the prior art were obvious to a person having ordinary skill in the art, but—before addressing the Graham factors—a judge decides that an undisputed prior-art reference does not meet the Federal Circuit's restrictive "lead compound test." The petition in *Mylan Pharmaceuticals Inc. v. UCB, Inc.*, Dkt. No. 18-692, was filed on November 21, 2018. ■

The consolidated case Nos. are [2016-2610](#), [2016-2683](#), [2016-2685](#), [2016-2698](#), [2016-2710](#), and [2017-1001](#).

Obviousness-type double patenting did not invalidate term extension for MS drug

A pharmaceutical company's patent term extension (PTE) relating to a drug for treatment of multiple sclerosis was not invalidated by obviousness-type double patenting, the U.S. Court of Appeals for the Federal Circuit has held. The PTE was validly obtained pursuant to Section 156 of the Hatch-Waxman Act, and did not run afoul of the obviousness-type

double patenting doctrine. Accordingly, the patent was valid, unexpired, and enforceable with the PTE (*Novartis AG v. Ezra Ventures LLC*, December 7, 2018, Chen, R.).

Novartis AG and Novartis Pharmaceuticals Corporation ("Novartis") held U.S. Patent No. 5,604,229 ("the

'229 patent") in relation to its multiple sclerosis drug, Gilenya®. Ezra Ventures LLC ("Ezra") filed an abbreviated New Drug Application (ANDA) relating to a generic version of Gilenya®.

The '229 patent, which claims a large group of compounds, including fingolimod, the active ingredient in Gilenya®, was filed before the effective date of the Uruguay Round Agreements Act of 1994 (URAA). Under the law in effect at that time, the '229 patent was set to expire on February 18, 2014, 17 years from issuance. Novartis secured a PTE of five years on the patent under Section 156, extending the expiration date to February 18, 2019. Section 156 allows a term extension of up to five years on a patent covering a product subject to regulatory review. Only one patent relating to a product may be extended, but the patent owner can choose among the product's qualifying patents. Novartis owned at least two patents covering Gilenya® that could qualify for PTE under Section 156: the '229 patent and U.S. Patent No. 6,004,565 ("the '565 patent") and chose to extend the term of the '229 patent. Because the '565 patent issued from a patent application filed after the effective date of the URAA, its term expired on September 23, 2017—20 years from its earliest effective filing date.

Section 156 patent extension. Ezra argued that the extension of the '229 patent's term beyond the life of the '565 patent was impermissible because it de facto also extended the life of the '565 patent, violating Section 156's

requirement that only one patent term can be extended. Ezra's argument was precluded under a plain reading of the statute. Only Novartis's '229 patent was legally extended with a certificate of extension, according to the Federal Circuit. As a consequence, the method of the '565 patent cannot be practiced during the '229 patent's extended term.

Obviousness-type double patenting. Ezra also contended that the '229 patent was invalid due to obviousness-type double patenting because the term extension it received caused the '229 patent to expire after Novartis's allegedly patentably indistinct '565 patent. The Federal Circuit disagreed. The court's ruling in *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317 (Fed. Cir. 2007)—holding that obviousness-type double patenting does not invalidate a validly obtained PTE—applied here. In *Merck*, the court concluded that a "straightforward reading" of Section 156 provides for a term extension if the other statutory requirements for a PTE are met. Ezra's argument that this case differed from *Merck* because it involves invalidity for obviousness-type double-patenting rather than statutory construction of Section 156 was incorrect, the court found, because the bulk of the *Merck* opinion relates to a statutory construction of Section 156, and its holding was directly relevant. The district court correctly found that the '565 patent is not a double patenting reference to the '229 patent and that the '229 patent is valid through the end of its PTE. ■

This case is [No. 2017-2284](#).

Gilead double patenting rule only applies to patents filed after URAA's effective date

The federal district court in Wilmington, Delaware, erred by finding that a patent owned by Novartis AG, filed after the June 8, 1995 effective date of the Uruguay Round Agreements Act (URAA), was an invalidating obviousness-type double patenting reference for a related patent which expired earlier, the U.S. Court of Appeals for the Federal Circuit has ruled. The court clarified that its prior opinion in *Gilead Sciences, Inc. v. Natco Pharma Ltd.*—holding that the expiration date is the benchmark of obviousness-type

double patenting—is limited to the context when both patents in question are *post*-URAA patents. This case involved one pre-URAA patent and one post-URAA patent governed by different patent term statutory regimes. Under the circumstances, the correct framework was to apply the traditional pre-URAA framework and look to issuance date as the reference point for obviousness-type double patenting (*Novartis Pharmaceuticals Corp. v. Breckenridge Pharmaceutical, Inc.*, December 7, 2018, Chen, R.).

Novartis AG owns U.S. Patent No. 5,665,772 (the '772 patent), titled "O-alkylated rapamycin derivatives and their use, particularly as immunosuppressants." The patent claims the compound 40-O-(2-hydroxyethyl)-rapamycin, also referred to as everolimus, a derivative of rapamycin. Everolimus is the active ingredient in Novartis's Zortress® and Afinitor® products used to treat certain cancers and prevent rejection in kidney and liver transplantations. Novartis AG and Novartis Pharmaceuticals Corporation (collectively, "Novartis") sued Breckenridge Pharmaceutical Inc., Par Pharmaceutical, Inc., and

Gilead decision is limited to the context in which both patents in question are post-URAA patents.

West-Ward Pharmaceuticals International Ltd. for infringing claims 1–3, 7, and 10 of the '772 patent after the defendants sought FDA approval to market generic versions of Zortress® and Afinitor®.

The district court held that asserted claims were invalid based on obviousness-type double patenting. The invalidating reference was Novartis's U.S. Patent No. 6,440,990 (the '990 patent). The '772 patent, which was filed on April 7, 1995, was set to expire on September 9, 2014, 17 years after the issuance date. Novartis later obtained a five-year patent term extension (PTE) under 35 U.S.C. § 156, thereby resetting the termination date to September 9, 2019. The '990 patent expired before the '772 patent because it was filed after the June 8, 1995 effective date of the Uruguay Round Agreements Act of 1994 (URAA). The URAA changed the term of a U.S. patent from 17 years from the issuance date to 20 years from the filing date of the earliest application (excluding provisionals) to which priority is claimed. The '990 patent expired on September 23, 2013, 20 years from its earliest effective filing date. Due to the intervening change in law through the implementation of the URAA, the lifespan of the '772 patent encompassed that of the '990 patent. The defendants appealed.

Application of *Gilead*. In finding that the '990 patent was a proper double patenting reference for the '772 patent, the district court relied on the Federal Circuit's decision in *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, which held that a later-filed but earlier-expiring patent can serve as a double patenting reference for an earlier-filed but later-expiring patent. 753 F.3d 1208, 1212 (Fed. Cir. 2014).

The Federal Circuit reversed, concluding that the '990 patent did not qualify as a double patenting reference for the '772 patent. The court said its opinion in *Gilead* "was limited to the context in which both patents in question are post-URAA patents." This case was distinguishable because it involved one pre-URAA patent (the '772 patent) and one post-URAA patent (the '990 patent), governed by different patent term statutory regimes.

The facts in this case also did not give rise to the type of patent prosecution gamesmanship present in *Gilead* because the '772 patent expired after the '990 patent "only due to happenstance of an intervening change in patent term law," the court noted. Novartis did not structure the priority claim of its '990 patent to capture additional patent term beyond the term it was granted for its '772 patent.

Pre-URAA framework. The court explained that under the present facts, the correct framework is to apply the traditional obviousness-type double patenting practices used in the pre-URAA era to the pre-URAA '772 patent and look to the '772 patent's issuance date as the reference point for obviousness-type double patenting. Under the traditional, pre-URAA framework, the '990 patent did not qualify as a proper double patenting reference for the '772 patent. The district court's decision was reversed. ■

The consolidated case Nos. are [2017-2173](#), [2017-2175](#), [2017-2176](#), [2017-2178](#), [2017-2179](#), [2017-2180](#), [2017-2182](#), [2017-2183](#), and [2017-2184](#).

Eleventh Amendment barred joinder of University of Texas to infringement suit

The Eleventh Amendment barred the joinder of The Board of Regents of the University of Texas System (UT) as an involuntary plaintiff to a patent infringement suit brought by Gensetix against Baylor College of Medicine and other defendants, the federal district court in Houston has decided. Furthermore, Gensetix, as the licensee of the asserted patents, did not have standing to assert infringement claims against the defendants without UT because UT retained substantial rights in the patents. In addition, joinder of UT was necessary under Rule 19. The court granted the defendants' motion to dismiss and declined to exercise supplemental jurisdiction over Gensetix's state law claims (*Gensetix, Inc. v. Baylor College of Medicine*, December 10, 2018, Hanen, A.).

Gensetix is the exclusive commercial licensee of two patents owned by UT—U.S. Patent Nos. 8,728,806 and 9,333,248, relating to methods of modifying patients' immune systems to kill cancer cells. Gensetix alleged that one of the named inventors of the patents, William K. Decker, who was previously employed by the University of Texas MD Anderson Cancer Center, continued to practice the patents at defendant Baylor College of Medicine (BCM). Gensetix also alleged that that Decker secretly interfered with negotiations between BCM and Gensetix to acquire intellectual property rights based on Decker's and BCM's improvements to the patented methods. BCM assigned those purported rights to Diakonos Research, Ltd.

Gensetix filed suit naming UT as an involuntary plaintiff. Gensetix asserted patent infringement and state law claims against BCM, Diakonos, and Decker. UT and the defendants filed separate motions to dismiss.

Eleventh Amendment. UT, as an arm of the State of Texas, argued that Eleventh Amendment immunity deprived the court of subject matter jurisdiction. The court explained that subject matter jurisdiction was not at issue; rather, the legal issue was whether the Eleventh Amendment prevented UT from being joined as an involuntary plaintiff in a patent suit.

Although there were currently no claims against UT, requiring joinder would, in effect, force UT to pursue claims against its will, the court said. Citing *Thomas v. FAG*, 50 F.3d 502 (8th Cir. 1995) and *Hartley Co. v. JF Acquisition, LLC*, 2017 WL 1628529 (S.D. Ohio 2017), the court explained that "[t]he purpose of the Eleventh Amendment is to prevent states from being 'compelled to litigate' (i.e., defend or pursue claims) in 'a lawsuit which it neither initiated nor agreed to participate in.'" Eleventh Amendment immunity includes immunity from suit and UT did not waive its immunity, initiate this suit, or agree to participate in this litigation.

Standing. Absent UT, Gensetix was required to independently have standing for the infringement claims to survive. The key factor in determining a licensee's standing to sue for patent infringement is whether the licensor has retained substantial rights to the patent-in-suit. See *Luminara Worldwide, LLC v. Liown Elecs. Co. Ltd.*, 814 F.3d 1343, 1350 (2016).

Here, the rights retained by UT weighed against a finding that the license agreement conveyed all substantial rights to Gensetix, according to the court. The license agreement between Gensetix and UT granted Gensetix exclusive rights to commercially exploit the patents and stated that Gensetix, at its own expense, must enforce the patents covered by the license and could retain recovery from such enforcement. However, UT retained the right to sue if Gensetix failed to do so. UT also retained the right to publish general findings, use licensed subject matter for research, teaching, or other academic purposes, and transfer rights to other research institutions for non-commercial research use. In addition, Gensetix's rights were subject to termination and the termination provisions ran for the life of the license. "Thus, Gensetix's right to license the patent was not truly exclusive," the court said. Because UT retained substantial rights in the patents-in-suit, Gensetix did not have standing to sue for infringement without joining UT as a party.

This case is *No. 4:17-cv-01025*.

Infringement finding, injunction affirmed in dispute over generic drug for treating schizophrenia

In a split decision, the U.S. Court of Appeals for the Federal Circuit affirmed a decision of the District of Delaware holding, after a bench trial, that West-Ward Pharmaceuticals International Ltd. and West-Ward Pharmaceuticals Corp. subsidiary (now known as Hikma Pharmaceuticals International Ltd. and Hikma Pharmaceuticals USA, Inc.) (collectively, “West-Ward” or “Hikma”) induced infringement of asserted claims of a patent for methods of treating schizophrenia. The appeals court also affirmed the district court’s determination that the patent-in-suit was not invalid, and its grant of injunctive relief to the patent’s

The claims of the ‘610 patent were eligible because they were not ‘directed to’ the recited natural relationship between iloperidone, the patient’s genotype, and the risk of QTc prolongation, but claimed an application of that relationship.

owner, Aventisub LLC, and its exclusive licensee, Vanda Pharmaceuticals Inc. (collectively, “Vanda”). Chief Judge Sharon Prost wrote in dissent, opining that the patent-in-suit was directed to an ineligible law of nature (*Vanda Pharmaceuticals, Inc. v. West-Ward Pharmaceuticals International Ltd.*, April 13, 2018, Sleet, G.).

Vanda asserted that West-Ward infringed U.S. Reissue Patent No. 39,198 (“the ‘198 patent”) and U.S. Patent No. 8,586,610 (“the ‘610 patent”). The ‘198 patent was not at issue on appeal. The ‘610 patent recited methods of treating schizophrenia patients with iloperidone (a drug known to cause QTc prolongation) wherein the dosage range is based on the results of a patient’s genotyping assay. The plaintiffs made and sold a brand-name iloperidone treatment, Fanapt®

Following a bench trial, the district court found that West-Ward’s proposed products induced infringement of the asserted claims of the ‘610 patent, but they did not contributorily infringe them. The court held that West-Ward’s submission of a Paragraph IV certification for the ‘610 patent was an act of infringement. The district court also held that the asserted claims were not invalid under Section 101 (patent- ineligible subject matter), Section 103 (obviousness),

or Section 112 (lack of written description). Finally, the district court enjoined West-Ward from making and selling its ANDA product prior to the expiration of the ‘610 patent.

Jurisdiction and infringement. West-Ward argued that 35 U.S.C. §271(e)(2) did not create a basis for subject matter jurisdiction over Vanda’s infringement claims because the ‘610 patent had not issued when the ANDA was filed by West-Ward’s predecessor. The Federal Circuit agreed with Vanda that the district court had jurisdiction over this case. The infringement analysis under Section 271(e)(2)(A) required consideration of

the amended ANDA, the court said, and amendments to an ANDA, including a Paragraph IV certification for a later-issued patent, can constitute an act of infringement under Section 271(e)(2)(A). Vanda’s complaint alleged that West-Ward infringed the

‘610 patent under 35 U.S.C. §271(e)(2)(A) by filing the ANDA. Nothing more was required to establish the district court’s subject matter jurisdiction pursuant to 28 U.S.C. §1338(a).

Inducement. Turning to the merits, the court concluded that the district court did not clearly err in finding induced infringement. According to the court, in a Hatch-Waxman case, the patent owner did not need to prove an actual past instance of direct infringement by a physician to establish infringement under 35 U.S.C. §271(e)(2)(A). Therefore, it was not necessary to show that West-Ward’s expert administered the infringing drug to a patient. Rather, Section 271(e)(2)(A) made it possible for the patent owner to have the court determine whether, if a particular drug were put on the market, it would infringe the relevant patent.

Subject-matter eligibility. West-Ward argued that the asserted claims are ineligible under 35 U.S.C. §101 because they were directed to a natural relationship between iloperidone, the metabolism of a gene known as CYP2D6, and prolongation of the time between the Q and T waves of the heart rhythm (“QTc prolongation”). The court disagreed, finding that the claims of the ‘610 were directed to a novel method of treating a disease, not to natural phenomena. The

Federal Circuit reasoned that the claims of the '610 patent were eligible because they were not "directed to" the recited natural relationship between iloperidone, the patient's genotype, and the risk of QTc prolongation, but claimed an application of that relationship. The claims here required a treating doctor to administer iloperidone in specific dosages, depending on the result of a genotyping assay. The specification further highlighted the significance of the specific dosages by explaining how certain ranges of administered iloperidone correlated with the risk of QTc prolongation. Thus, the court explained, the '610 patent claims described a new way of using an existing drug that was safer for patients because it reduced the risk of QTc prolongation. The court also stated that the claims did not carry a risk of preemption because they did not "tie up" the doctor's subsequent treatment decisions.

Written description. In the Federal Circuit's view, the district court did not clearly err in finding that the '610 patent contained adequate written description for the claimed "12 mg/day or less" dosage range for poor metabolizers. The patent reported relevant test results and explained that patients can be more safely treated with iloperidone if the dose of iloperidone is adjusted based on the CYP2D6 genotype of each patient. It also included examples of such doses. West-Ward waived its written description challenge with respect to non-poor metabolizers by failing to properly present it to the trial court.

Injunctive relief. The Federal Circuit also decided that 35 U.S.C. §271(e)(4) supported the injunctive relief granted by the district court. The district court properly held that Vanda had established infringement of the '610 patent under Section 271(e)(2). The injunction provisions of Section

271(e)(4) contained no carveout for patents that issued after the date of submission of the original ANDA. Although the district court erred in concluding that the remedies pursuant to Section 271(e)(4) were unavailable, the court granted Vanda injunctive relief consistent with those remedies.

Dissenting opinion. Chief Judge Sharon Prost filed a dissenting opinion, based on her view that the asserted claims were directed to a law of nature, namely, the natural relationship between the presence of the enzyme CYP2D6 and the likelihood that a dosage of iloperidone will cause QTc prolongation. Judge Prost opined that the majority ran afoul of the Supreme Court's decision in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012). The Chief Judge agreed with the district court's finding that the claims were directed to a law of nature at step two of the *Mayo* inquiry, but disagreed with its further finding that they recited an additional "inventive concept" that satisfied step two.

Supreme Court petition. West-Ward (now known as Hikma) has filed a [petition for certiorari](#) with the Supreme Court. West-Ward argues that the Federal Circuit "did exactly what *Mayo* forbids: it exempted all patent claims that are drafted as reciting a method of medically *treating* patients from this analysis." The question presented by Hikma's petition is: Whether patents that claim a method of medically treating a patient automatically satisfy Section 101 of the Patent Act, even if they apply a natural law using only routine and conventional steps. The petition in *Hikma Pharmaceuticals USA Inc. v. Vanda Pharmaceuticals USA Inc.* was filed on December 27, 2018. ■

The consolidated case Nos. are [16-2707](#) and [16-2708](#).

Opioid-treatment method claims satisfied Section 101

Patents that claim a method for treating patients with an opioid were, as a matter of law, not invalid under Section 101 because they were directed to a specific dosing regimen to treat a specific condition, the federal court in Wilmington, Delaware has ruled. The court rejected other summary judgment motions on grounds that material issues of disputed fact remained for trial as to prior art references and inducement for infringement. Finally, the court struck a late-disclosed infringement theory (*Pernix Ireland Pain DAC v. Alvogen Malta Operations Ltd.*, May 15, 2018, Bryson, W.).

Infringement claims brought by Pernix Ireland Pain DAC's and Pernix Therapeutics (collectively, "Pernix") were based on Alvogen Malta Operation Ltd.'s ("Alvogen") filing of its Abbreviated New Drug Application (ANDA) with the Food and Drug Administration (FDA), seeking authorization to sell hydrocodone bitartrate extended release capsules as generic versions of Pernix's hydrocodone formulation, which was sold under the name Zohydro.

Pernix asserted claims 1-4, 11, 12, 17 and 19 of U.S. Patent No. 9,265,760 ("the '760 patent") and claim 1 of U.S. Patent No.

9,339,499 (“the ‘499 patent”), both directed to methods of treating pain in patients with hepatic impairment, that is, compromised liver function. The patented invention claimed formulations of extended release hydrocodone where the starting dose did not need to be adjusted for a patient with hepatic impairment relative to one without hepatic impairment.

Claims directed to “a specific dosing regimen to treat a specific condition based on a patient’s medical status” are not patent-ineligible

The court first granted Alvogen’s motion to strike Pernix’s late-disclosed patient-only infringement theory as to claims 1-4 and 11 of the ‘760 patent and then addressed the parties’ motions for summary judgment.

Infringement. Pernix argued that there was no genuine dispute that patients and physicians would act as a single entity in directly infringing certain claims and that Alvogen would be liable for induced infringement because, if its ANDA product becomes commercially available, Alvogen will induce patients and physicians to engage in direct infringement, with the specific intent to do so. With regard to claims 12, 17, and 19 of the ‘760 patent and claim 1 of the ‘499 patent, Pernix argued that there was no genuine dispute that patients will directly infringe those claims when they self-administer the drug; and Alvogen will intentionally induce the patients to infringe those claims. The court denied Pernix’s motion for summary judgment of infringement because of unresolved factual issues. For example, the extent to which physician’s instructions to patients constitute “direction and control” of the patient’s infringing conduct turned on factual questions such as whether the physician conditions receipt of a benefit—continued treatment for chronic pain—on the patient’s performance of the administering step, i.e., administering the drug as prescribed. In addition, the court found that resolution of issues of specific intent must necessarily await trial.

Anticipation. The court refused to grant summary judgment on grounds of Section 102 anticipation over two prior art references, U.S. Patent Appl. No. 2006/0240105 (“Devane”) and U.S. Patent No. 8,808,740 (“Huang”). The court found that there were disputes of fact that precluded a determination as to whether the inventors reduced the

species disclosed in Huang to practice as of November 2, 2011, so as to preclude Huang from serving as prior art. The parties did not dispute that Devane was silent on the issue of treating

patients with hepatic impairment and Alvogen failed to show as a matter of law that Devane’s genus of treating patients for pain inherently anticipated the species of treating hepatically impaired patients for pain.

Eligibility. The parties filed cross-motions as to whether the patent claims asserted covered patent-ineligible subject matter under Section 101. Alvogen argued that they were not eligible because they were “premised on the relationship between [hepatic impairment] and the bioavailability of hydrocodone in the body after administration of Devane’s [extended release hydrocodone] prior art formulation—namely that the response of the human body to this formulation is similar in patients with and without mild or moderate [hepatic impairment].” Although the inventions recited in the asserted claims were based upon a natural law, namely the physiological response to hydrocodone in individuals with or without mild or moderate hepatic impairment, the claims did more than merely report those physiological responses. The claims asserted in this case described a specific dosing regimen to treat a specific condition based on a patient’s medical status. Therefore, the invention claimed patent-eligible subject matter. Accordingly, Pernix’s motion for summary judgment was granted and Alvogen’s motion was denied. ■

The case is [No. 1:16-cv-00139-WCB](#).

Patent for detecting tuberculosis bacteria ineligible as directed to natural phenomenon

Roche Molecular Systems, Inc.’s patent addressing methods for detecting the pathogenic bacterium *Mycobacterium tuberculosis*, a major cause of

tuberculosis, was directed to patent-ineligible subject matter, the Federal Circuit has held. Because the asserted claims were directed to a natural phenomenon and lacked

any inventive concept that transformed them into patent-eligible subject matter, the Federal Circuit affirmed a district court's judgment declaring the patent invalid. The Federal Circuit held that being the first to discover a previously unknown naturally occurring phenomenon or a law of nature alone was not enough to confer patent eligibility (*Roche Molecular Systems, Inc. v. Cepheid*, October 9, 2018, Reyna, J.).

Roche Molecular Systems, Inc. owns U.S. Patent No. 5,643,723 ("the '723 patent"), titled "Detection of a Genetic Locus Encoding Resistance to Rifampin in Microbacterial Cultures and in Clinical Specimens." Cepheid made and sold "Xpert MTB/RIF Assay," an assay that can detect MTB in a biological sample and can identify rifampin-resistant MTB. Roche asserted that Cepheid's product infringed the '723 patent. The federal district court in San Francisco decided that the asserted claims of the '723 patent were directed to patent-ineligible subject matter and were therefore invalid under 35 U.S.C. §101. Roche appealed to the Federal Circuit.

Primer claims. The appeals court first examined whether the primer claims in the patent covered patent eligible subject matter. Roche argued that at step one of the *Alice/Mayo* test, the primer claims were patent-eligible because they were directed to artificial, man-made primers that were different from naturally occurring DNA. The court recognized it was well established that primers were short, single stranded nucleic acid molecules that bind to their complementary nucleotide sequence. The Federal Circuit previously held that primers necessarily contain the identical sequence of the nucleotide sequence directly opposite to the DNA strand to which they are designed to bind. *In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755, 760 (Fed. Cir. 2014) ("*BRCA1*"). Here, the court found that the primers were indistinguishable from their corresponding nucleotide sequences on the naturally occurring DNA. Therefore, the primer claims were ineligible.

Method claims. The court then addressed whether the method claims of the '723 patent were patent eligible. At *Alice/Mayo* step one, the plain language of the asserted method claims, viewed in light of the written description, demonstrated that they were directed to naturally occurring

phenomena. The method claims disclosed a diagnostic test based on the observation that the presence of the 11 position-specific signature nucleotides of the naturally occurring MTB *rpoB* gene indicated the presence of MTB in a biological sample. The court held that the method claims did not contain an inventive concept that transformed the 11 position specific signature nucleotides of the MTB *rpoB* gene into patent-eligible subject matter. While it may be true that Roche inventors were the first to use PCR to detect MTB in a biological sample, being the first to discover a previously unknown naturally occurring phenomenon or a law of nature alone was not enough to confer patent eligibility. Many groundbreaking, innovative, and brilliant discoveries have been held patent-ineligible. Because the asserted method claims of the '723 patent were directed to a natural phenomenon and lacked any inventive concept that transformed them into patent-eligible subject matter, the court held that the method claims were ineligible.

Concurring opinion. While Circuit Judge Kathleen M. O'Malley agreed with the majority that the decision in *BRCA1* compelled the conclusion that the primer and method claims of the '723 patent were not eligible for patent protection, she wrote a concurring opinion arguing that the court should revisit the holding in *BRCA1*, at least with respect to the primer claims. Specifically, Judge O'Malley stated that the holding in *BRCA1* was unduly broad for two reasons: (1) the question raised in *BRCA1* was narrower than the holding in that case; and, (2) the court's interpretation of the nature and function of DNA primers lacked the benefit of certain arguments and evidence that the patent owner presents in the present case. Judge O'Malley recommended that the court engage in *en banc* review of *BRCA1*. ■

The case is [No. 2017-1690](#).

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