United States Court of Appeals for the Federal Circuit

UCB, INC., UCB MANUFACTURING IRELAND LIMITED, UCB PHARMA GMBH, LTS LOHMANN THERAPIE-SYSTEME AG,
Plaintiffs-Cross-Appellants

v.

WATSON LABORATORIES INC., ACTAVIS LABORATORIES UT, INC.,
Defendants-Appellants

2018-1397, 2018-1453

Appeals from the United States District Court for the District of Delaware in No. 1:14-cv-01083-LPS-SRF, Chief Judge Leonard P. Stark.

Decided: June 24, 2019

JACK B. BLUMENFELD, Morris, Nichols, Arsht & Tunnell LLP, Wilmington, DE, argued for plaintiffs-cross-appellants. Also represented by DEREK J. FAHNESTOCK, MARYELLEN NOREIKA; JAMES TRAINOR, ROBERT COUNIHAN, ADAM GAHTAN, KEVIN MCGANN, SILVIA MEDINA, Fenwick & West LLP, New York, NY.

JOHN C. O'QUINN, Kirkland & Ellis LLP, Washington, DC, argued for defendants-appellants. Also represented by

WILLIAM H. BURGESS, CALVIN ALEXANDER SHANK; LEORA BEN-AMI, THOMAS F. FLEMING, CHRISTOPHER T. JAGOE, New York, NY.

Before TARANTO, SCHALL, and CHEN, *Circuit Judges.*

CHEN, *Circuit Judge*.

This appeal concerns UCB, Inc., UCB Manufacturing Ireland Limited, UCB Pharma GmbH, and LTS Lohman Therapie-Systeme AG (UCB)'s U.S. Patent Nos. 6,884,434[1] and 8,232,414.[2] The '434 patent claims a transdermal therapeutic system comprising rotigotine, a drug used for the treatment of Parkinson's disease. The '414 patent claims a polymorph of rotigotine. The United States District Court for the District of Delaware found that Watson Laboratories Inc. and Actavis Laboratories UT, Inc. (Actavis)'s generic products infringed the '434 patent under the doctrine of equivalents. The district court also upheld the validity of the '434 patent over Actavis's obviousness and anticipation challenges. Actavis appeals the district court's infringement and validity judgments. UCB cross-appeals the district court's invalidation of the '414 patent under 35 U.S.C. § 102(a) as known and used by others in the United States before the date of invention. For the reasons articulated below, we affirm.

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[1] UCB Manufacturing Ireland Limited and LTS Lohman Therapie-Systeme AG are assignees of the '434 patent. UCB, Inc. is a party to this case because it holds the approved New Drug Application for brand name drug Neupro, under which the '434 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the Orange Book).

[2] UCB Pharma GmbH is an assignee of the '414 patent.

TECHNICAL BACKGROUND

The technology at issue relates to a transdermal (via the skin) form of delivering a drug that treats Parkinson's disease. Parkinson's is a degenerative neurological condition linked to reduced dopamine levels in the brain, caused by degeneration and death of "dopaminergic" neurons. The '434 and '414 patents relate to the compound rotigotine, a dopamine receptor stimulator, that has been used to treat Parkinson's since the 1990s. Rotigotine comes in two forms: free base form and hydrochloride salt form.

Cygnus Therapeutic Systems conducted early attempts at transdermal rotigotine formulation circa 1994. J.A. 118–19. Its system is described in patent application WO 94/07468 (Cygnus) and a 1995 article entitled "A Two-Phase Matrix for the Delivery of N-0923, a Dopamine Agonist" by Chiang et al. (Chiang). Rotigotine in the Cygnus system is present in the hydrochloride salt form, which is dissolved in water to create an aqueous phase in the patch's matrix. Preliminary clinical trials using patches manufactured by Cygnus demonstrated proof of concept that a sufficient amount of rotigotine can be transdermally delivered for treatment of Parkinson's. No commercial product resulted from Cygnus's work.

UCB developed a rotigotine transdermal patch without using water and filed the '434 patent to cover such a patch. The patent is entitled "Transdermal therapeutic system which contains a d2 agonist and which is provided for treating Parkinsonism, and a method for the production thereof." The only asserted independent claim reads:

> 1. A transdermal therapeutic system comprising a self-adhesive matrix layer containing the free base

> [rotigotine[3]] in an amount effective for the treatment of the symptoms of Parkinson's syndrome, wherein the matrix is based on [] an acrylate-based or silicone-based polymer adhesive system having a solubility of ≧5% (w/w) for the free base [rotigotine], all of said free base being present in the matrix *in the absence of water*; a backing layer inert to the components of the matrix layer; and a protective foil or sheet covering the matrix layer to be removed prior to use.

'434 patent, col. 7 ll. 55–67 (emphasis added). The claim covers administration of rotigotine through a transdermal patch made of three layers, the most relevant for this appeal being an adhesive layer in which an effective amount of the free base form of rotigotine is dissolved in an acrylate- or silicone-based polymer adhesive so that there is no water and at least 5% rotigotine by weight in the layer. Dependent claims cover use of polyvinylpyrrolidone (PVP), a solubility enhancer, as part of the adhesive system to achieve the claimed solubility.

The FDA approved UCB's rotigotine transdermal patches in May 2007, and UCB has been selling the product under the brand name Neupro since July 2007. Neupro's polymer adhesive system is silicone-based and contains PVP.

Relevant to the other UCB patent in this appeal—the '414 patent—in June and July 2007, batches of rotigotine patches were manufactured for distribution in the United

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[3] The claim covers the "S" enantiomer of rotigotine, with the chemical name "(–)-5,6,7,8-tetrahydro-6-[propyl-[2-(2-thienyl)ethyl]amino]-1-naphthalenol." '434 patent, col 7 ll. 62–63. Enantiomers are two non-superimposable, mirror-image, three-dimensional structural configurations of the same molecule.

States. Of particular relevance to the alleged public use of the '414 patented product before its date of invention, laminate lot 47808 was produced during this period.

Until August 2007, UCB manufactured Neupro patches by dissolving rotigotine in ethanol, among other steps, to create a rotigotine solution. It then prepared a coating mass from this solution and other components (including a silicone-based polymer), which, after drying, produced a matrix. The matrix did not contain crystalline rotigotine, and the rotigotine in the resulting patches, pre-distribution, was non-crystalline.

On August 7, 2007, an unknown solid precipitated during the dissolution step, causing UCB to halt manufacture of Neupro patches. Over the next few months, UCB investigated and determined that the solid was a polymorph of rotigotine, characterized by unique single-crystal X-ray diffraction parameters. Polymorphs are different three-dimensional, solid-state, crystalline structures of the same chemical compound.

UCB filed a patent application to cover the newly discovered Form II polymorph of rotigotine. This resulted in the '414 patent, entitled "Polymorphic form of rotigotine and process for production," with a priority date of November 28, 2007. The claims read:

> 1. A polymorphic form of rotigotine characterized by at least one parameter selected from the group consisting of:
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> > (a) a powder X-ray diffraction spectrum comprising at least one peak at the following °2θ angles (± 0.2): 12.04, 13.68, 17.72, and 19.01;
> >
> > (b) a Raman spectrum comprising at least one peak at the following (±3 cm^{-1}): 226.2, 297.0, 363.9, 737.3, 847.3, 1018.7, and 1354.3 cm^{-1}

> (c) a DSC peak with a T_{onset} at 97°C. ± 2°C. measured with a heating rate of 10°/min; and
>
> (d) a melting point of 97°C. ± 2°C.
>
> 2. The polymorphic form of rotigotine of claim 1, wherein the polymorphic form of rotigotine is characterized by at least the following powder X-ray diffraction peaks at °2θ angles (± 0.2): 12.04, 13.68, 17.72 and/or 19.01.
>
> 3. A polymorphic form of rotigotine having a powder X-ray diffraction spectrum substantially as shown in FIG. 1.

'414 patent, col. 8 ll. 48–64.

On November 12, 2007, UCB submitted a Field Alert Report to the FDA, alerting the FDA that "small crystalline structure (snowflakes)" had been observed on the active surface of Neupro patches that had already been manufactured and distributed. J.A. 4833–34. UCB informed the FDA that "testing confirmed on November 7, 2007 that the snowflakes contain crystalline structures of a polymorph variant (Form 2) of the active ingredient Rotigotine." J.A. 4833. According to its report, many of the examined patches contained snowflakes; of 29 batches of product, only one did not have any patches containing visible snowflakes. J.A. 4838. For batches manufactured for distribution in the United States, over 90% of the examined patches contained crystals by November 12, 2007. J.A. 6144.

On November 30, 2007, two days after the priority date of the '414 patent, a female patient experienced an adverse event while being treated with Neupro. J.A. 5965. An Alert Report submitted by UCB states that the patient received samples of Neupro in September 2007 and "responded well" to treatment. *Id.* In November 2007, she purchased Neupro patches that were from lot 47808. *Id.*

While using these patches, the patient began "clearly back-sliding, experiencing previous symptoms of losing mobility, shaking and freezing." J.A. 5966. The Report indicated that the patient used the lot 47808 patches for "one week," implying that she was using the patches before the '414 patent's priority date of November 28, 2007. After experiencing this back-sliding, the patient "was reverted to the samples of the newer lot number" and "an improvement in the patient was noted." *Id.*

PROCEDURAL HISTORY

Actavis filed an Abbreviated New Drug Application (ANDA) for generic versions of transdermal rotigotine patches, and UCB filed suit for infringement of the '434 and '414 patents under 35 U.S.C. § 271(e)(2). The case proceeded to a four-day bench trial on the validity and infringement of claims 1, 5, 7, and 14–15 of the '434 patent, and the validity of claims 1–3 of the '414 patent.[4]

The district court found infringement of all the asserted '434 patent claims by Actavis's ANDA products (the Accused Products) under the doctrine of equivalents. Actavis's products use a polyisobutylene adhesive, rather than the claimed acrylate-based or silicone-based polymer adhesives, but the district court found the adhesives in this context to be substantially similar and that nothing in this case barred application of the doctrine of equivalents. J.A. 138–54.

The district court then upheld the validity of claims 1, 5, 7, 14, and 15 of the '434 patent, rejecting, in relevant part, Actavis's arguments of anticipation under 35 U.S.C. § 102 by the Cygnus prior art reference and obviousness

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[4] Actavis stipulated to infringement of the '414 patent claims.

under 35 U.S.C. § 103 over Cygnus with Lipp[5] or Pfister,[6] and over Timmerman[7] with Miranda.[8] J.A. 154–62.

The district court also found the '414 patent claims invalid under § 102(a) because the Form II polymorph of rotigotine was used by others in the United States before the invention date—Neupro patches with Form II crystals were administered to at least one patient before November 28, 2007. J.A. 180–84.

Actavis appeals the district court's infringement and above-listed validity findings on the '434 patent. UCB cross-appeals the district court's invalidation of the '414 patent. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

A. Infringement of the '434 Patent

The only infringement issue relevant to this appeal is whether the Accused Products have a "matrix . . . based on []an acrylate-based or silicone-based polymer adhesive system." '434 patent, col. 7 ll. 59–61. Actavis does not dispute

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[5] Canadian Patent No. 2,120,599, entitled "Transdermal Therapeutic Systems Containing Crystallization Inhibitors," listing Ralph Lipp et al. as inventors.

[6] European Patent Application EP 0524776, entitled "Silicone pressure sensitive adhesive compositions for transdermal drug delivery devices and related medical devices," listing Willliam Richard Pfister et al. as inventors.

[7] A journal article published by Timmerman et al., entitled "Microdialysis and striatal dopamine release: stereoselective actions of the enantiomers of N-0437."

[8] International Patent Application WO 95/18603, entitled "Transdermal Device Containing Polyvinylpyrrolidone as Solubility Enhancer," listing Jesus Miranda as an inventor.

that its Accused Products literally meet every other element of the asserted claims. The Accused Products use a polyisobutylene adhesive, which is different from the claimed acrylate-based or silicone-based polymer adhesives. But UCB argued that, under the doctrine of equivalents, polyisobutylene-based adhesives are interchangeable with the claimed adhesives.

1. Limits to the Application of the Doctrine of Equivalents

First, we agree with the district court that UCB was not "barred" from asserting the doctrine of equivalents here because of prosecution history estoppel, intentional narrow claiming, vitiation, or ensnarement.

a. Prosecution History Estoppel

Prosecution history estoppel can limit application of the doctrine of equivalents because "[i]f a patentee surrenders certain subject matter during prosecution, the patentee is then barred from using the doctrine of equivalents to recover for infringement based on that same subject matter." *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 904 F.3d 965, 975 (Fed. Cir. 2018), *cert. denied*, 139 S. Ct. 1265 (2019).

The original patent application for the '434 patent had 17 claims, which were cancelled in a preliminary amendment prior to any Patent Office action. J.A. 5010. New claims 18–33 all included an "acrylate-based or silicone-based polymer adhesive system having a solubility of $\geq 5\%$ (w/w) for [rotigotine free base]." J.A. 5010–15. That claim language was never amended during prosecution. New claims 34–41 were generally directed to processes for preparing a transdermal therapeutic system that included "an adhesive," without specifying any particular adhesive. J.A. 5013–15.

The examiner then issued a restriction requirement, asking the applicant to elect to prosecute claims from

Group I (claims 18–33) or Group II (claims 34–41). J.A. 5160–62. The applicant elected Group I, but did so "with traverse," meaning that it disputed that any election was necessary. J.A. 5163–65. In response, the examiner explained the reason for restriction: Group II claims required use of PVP as a solubility enhancer, but PVP would only be required for a silicone-based polymer, not acrylate-based polymer, because rotigotine is soluble enough in the latter to not need an enhancer. J.A. 5160, 5206. So, "the process of group II [was] only applicable on silicone-based polymer and not on acrylate-based polymer," while "group I read[] on a matrix based on acrylate polymer or silicone polymer." J.A. 5206. Further, the examiner pointed out that "the product of group I requires the product to be substantially free from inorganic silicate, while the process of group II requires the inorganic silicate." *Id.* The examiner thus concluded that "the two groups do not have the same technical features," finalized the restriction requirement, and withdrew the Group II claims from further consideration. J.A. 5206–07.

Actavis argued that UCB's election of the Group I claims after the examiner issued a restriction requirement should prevent UCB from now asserting infringement under the doctrine of equivalents. The Group II claims were not limited to silicone- and acrylate-based polymer adhesive systems. In Actavis's view, because UCB withdrew those claims, it gave up claim scope of adhesives that are not silicates or acrylates and should not be allowed to recapture that subject matter through the doctrine of equivalents.

The district court disagreed with Actavis's reading of the prosecution history, and we do as well. J.A. 142–44. A restriction requirement does not necessarily invoke prosecution history estoppel. *See Bayer Aktiengesellschaft v. Duphar Int'l Research B.V.*, 738 F.2d 1237, 1243 (Fed. Cir. 1984). Whether a patentee's actions in the face of a restriction requirement give rise to estoppel must be judged

"from the viewpoint of a [skilled artisan], and when the issue includes consideration of formalities of patent practice, experience in patent law and procedures is presumed." *Merck & Co. v. Mylan Pharm., Inc.*, 190 F.3d 1335, 1340 (Fed. Cir. 1999). In *Merck,* this court determined that the patentee's decision to limit the claims to a certain subset—in response to the examiner's restriction requirement and obviousness rejection—"were primarily in consideration of the patentability rejection under § 103." *Id.* at 1340–41. Thus, this court concluded that Merck's actions gave rise to prosecution history estoppel.

Here, the examiner's restriction requirement did not relate to polyisobutylene, and the examiner was not communicating anything about the patentability of polyisobutylene-based adhesive systems. UCB never added a polyisobutylene-excluding limitation by amendment, and its election cannot be read as such. Moreover, even if UCB had claimed "an adhesive" in the elected claims, as Actavis argues it should have done in order to keep polyisobutylene within the claim scope, the technical differences that triggered the restriction requirement would still have remained and still would have required the same restriction: the Group II claims required inorganic silicate and applied only to a subset of adhesives that needed PVP, while Group I did not have those limitations. Thus, the restriction requirement here, and UCB's election in response, do not indicate a surrender of polyisobutylene as an equivalent. [9]

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[9] Actavis also cites to *Pacific Coast Marine Windshields Ltd. v. Malibu Boats, LLC*, where this court found that in the prosecution of a design patent on a marine windshield, "[b]y cancelling figures showing corner posts with two holes and no holes, the applicant surrendered such designs and conceded that the claim was limited to what the remaining figure showed—a windshield with four

Because we conclude that UCB did not make a narrowing amendment in respect to the restriction requirement, we reject Actavis's argument that UCB had the burden to show that a "narrowing amendment" was unrelated to patentability.

Accordingly, we find no good basis in the prosecution history here to bar the application of the doctrine of equivalents to polyisobutylene-based polymer adhesive systems.

b. Narrow Claiming

Relatedly, Actavis argued to the district court that UCB had chosen to draft narrow claims and should not be permitted to expand the scope of those claims through the doctrine of equivalents. Specifically, Actavis argued that Dr. Mueller, an inventor of the '434 patent, knew that polyisobutylene was a polymer that could be used in transdermal patches but chose not to prosecute a claim broad enough to cover polyisobutylene. J.A. 4219. On appeal, Actavis makes the broader argument that polyisobutylenes were generally known in the art, citing Dr. Mueller's knowledge as an example. The Cygnus prior art reference

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holes in the corner post—and colorable imitations thereof." 739 F.3d 694, 703 (Fed. Cir. 2014); Oral Arg. at 6:35–8:35. But due to the nature of design patents, the differences between the figures in that case made the claim scope of each figure, as to the relevant hole limitation, mutually exclusive. In contrast, as we explain, the inclusion of polyisobutylene under the adhesive claim limitations in the two groups of claims here is not so clearly mutually exclusive. In any event, we have never held that a restriction and election during prosecution of a utility patent application, without more, can constitute prosecution history estoppel for claim scope covered by the restricted and then cancelled claims, and we decline to do so here, given that there were other reasons for the restriction.

also mentions polyisobutylene as a possible adhesive for transdermal patches. J.A. 5705, 5708–09.

The district court disagreed with Actavis, citing this court's holding in *Ring & Pinion Service Inc. v. ARB Corp.* that "[t]here is not, nor has there ever been, a foreseeability limitation on the application of the doctrine of equivalents" as to claim limitations that have never been amended or relied on during prosecution, because "[e]xcluding equivalents that were foreseeable at the time of patenting would directly conflict with [prior Supreme Court and Federal Circuit case] holdings that 'known interchangeability' supports infringement under the doctrine of equivalents." J.A. 145; 743 F.3d 831, 834 (Fed. Cir. 2014) (citing *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.,* 520 U.S. 17, 36 (1997); *Graver Tank & Mfg. Co. v. Linde Air Products Co.,* 339 U.S. 605, 609 (1950); *Abraxis Bioscience, Inc. v. Mayne Pharma (USA) Inc.*, 467 F.3d 1370, 1382 (Fed. Cir. 2006); *Interactive Picture Corp. v. Infinite Pictures, Inc.*, 274 F.3d 1371, 1383 (Fed. Cir. 2001); and *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1261 (Fed. Cir. 1989)).

We understand *Ring & Pinion* to hold that foreseeability at the time of claim drafting is not a per se bar to the application of the doctrine of equivalents. But, at the same time, *Ring & Pinion* does not foreclose consideration of foreseeability of an asserted equivalent as one factor that may, in some cases, help show that the facts cannot support infringement under the doctrine of equivalents.

Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC is an example of such a case. 683 F.3d 1356, 1366 (Fed. Cir. 2012). There, Cadbury asserted infringement of U.S. Patent No. 5,009,893, which claimed a chewing gum that combined menthol with a coolant claimed as an "N-substituted-p-menthane-carboxamide of [a specific formula]." *Id.* at 1358. One such carboxamide was called "WS-3." *Id.* The accused infringing product used a coolant called "WS-23,"

which the parties, on appeal, agreed did not fall within the literal scope of the carboxamides claimed in the '893 patent. *Id.* at 1359, 1365. But the district court ruled on summary judgment that WS-23 was "not an equivalent of WS-3 for purposes of the '893 patent." *Id.* at 1365. This court affirmed, citing several reasons. First, the "disclosure of the '893 patent focuse[d] narrowly on N-substituted-p-menthane carboxamides, and not on carboxamides generally," because it focused on advantageous characteristics unique to N-substituted-p-menthane carboxamides such as its "unexpected[ly] heightened cooling sensation in edible products" and its structural similarity to menthol itself—characteristics not shared by WS-23. *Id.* at 1365–66. Second, the claim was drafted to cover only a subset of N-substituted-p-menthane-carboxamides, indicating a narrowing even beyond the specification. *Id.* at 1366. Third, there was clear evidence in the record that the inventors of the '893 patent were introduced to WS–3 and WS–23 by a salesman for the distributor of the compounds during the same sales call, where they were told that the two compounds were appropriate for the same uses, and yet, the inventors still drafted their claims narrowly to recite certain N-substituted-p-menthane carboxamides, as opposed to a broader category of carboxamides that would include WS–23. *Id.*

The facts are different here. *Wrigley* does not support treating the present facts as precluding a finding of equivalence.

Actavis does not argue that the '434 patent's specification relies on any unique characteristics of acrylate or silicone-based polymer adhesive systems that would not be present in a polyisobutylene-based system. The language in the Summary of the Invention stating that the claimed system "is essentially characterized by a matrix on the basis of an acrylate-based or silicone-based non-aqueous polymer adhesive system having a solubility for [rotigotine free base] of >5% (w/w), which matrix is substantially free

of inorganic silicate particulates," is just a recitation of the qualities of the matrix; the passage does not identify unique characteristics of acrylate or silicone-based polymer adhesive systems to the exclusion of other systems. '434 patent, col. 2 ll. 35–40. And the fact that the specification repeatedly recites acrylate- and silicone-based polymers is irrelevant to the issue of whether it describes those polymers in a manner that would suggest to a skilled artisan that polyisobutylene is not an equivalent. For this inquiry, the specification states that the "adhesive's dissolving capacity for the active substance is an important parameter for the development of matrix systems, just as the mobility of the active substance in the matrix, and its transfer via the contact surface to the skin." *Id.* at col. 3 ll. 15–18. As explained in detail below, the district court found record evidence that there was no substantial difference between the claimed adhesive systems and polyisobutylene-based polymer adhesive systems for these parameters.

Furthermore, the claims also correspond directly to the specification by reciting all acrylate-based or silicone-based polymer adhesive systems, without narrowing to a subset as in *Wrigley*.

Finally, the evidence of the inventor's knowledge here at the time of filing is not as clear as in *Wrigley*. Actavis points to a feasibility study done by the inventors in January 1996. J.A. 5913–43. The document describes that "[f]or the formulation of matrix systems with a self-adhesive matrix formulation the following adhesives are most commonly used: silicone based adhesive[,] polyacryl resin based adhesives[,] *polyisobutylene based adhesives*[, and] adhesives on the basis of styrene/ isoprene A-8-A blockpolymers." J.A. 5916 (emphasis added). The inventors explained that "the suitability of silicone based matrix formulation was already demonstrated by Cygnus," so they chose to concentrate on "polyacrylic resins and styrene/isoprene/styrene blockpolymers." *Id.* No reason was given for not testing polyisobutylene-based adhesives. Further, one

inventor testified that he had "limited experience" with polyisobutylene as a liquid but was "not so familiar" with its polymer form. J.A. 4219.

Thus, in contrast to *Wrigley*, there is not enough indication from the patent specification, claims, or the record evidence of the inventor's knowledge here to conclude that UCB surrendered polyisobutylene as a possible equivalent. In the absence of such facts, we agree with the district court that UCB's claiming of acrylates and silicates does not bar treating polyisobutylenes as an equivalent for infringement purposes. J.A. 146–48.[10]

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[10] Actavis cites two additional cases for this issue: *Carnegie Mellon University v. Hoffmann-La Roche Inc.*, 541 F.3d 1115 (Fed. Cir. 2008), and *Tanabe Seiyaku Co. v. International Trade Commission*, 109 F.3d 726 (Fed. Cir. 1997). Appellants' Op. Br. at 48–49. *Carnegie Mellon* was decided under the vitiation doctrine, which we address separately herein. In *Tanabe*, the applicant "chose to define its invention in terms of specific base-solvent combinations, rather than in terms of categories of bases and solvents," but also proceeded to define the success of its invention "in terms of the exact base-solvent combinations" during prosecution such that "a review of the prosecution history by a competitor would reinforce the suggestion in the claim language and specification that using other ketone solvents . . . is not an insubstantial change [and would suggest] that other ketone solvents may result in lower yields than the claimed solvents." 109 F.3d at 732. In affirming the International Trade Commission's finding of no infringement under the doctrine of equivalents, the *Tanabe* court largely relied on the interchangeability/substantial differences doctrine and evidence that butanone was not as successful as the claimed acetone. 109 F.3d at 732–34. Prosecution

Further, we note as a policy matter that the patent system should not incentivize inventors to claim equivalents that they had not invented or tested, just because they know of the possibility of an equivalent, and also should not force inventors to delay filing for a patent on what they have invented while testing all known possible equivalents for fear of being unable to assert infringement under the doctrine of equivalents in the future.

c. Vitiation

"Under the doctrine of equivalents, an infringement theory . . . fails if it renders a claim limitation inconsequential or ineffective." *Akzo Nobel Coatings, Inc. v. Dow Chem. Co.,* 811 F.3d 1334, 1342 (Fed. Cir. 2016). This vitiation doctrine ensures that "the application of the doctrine [of equivalents] . . . is not allowed such broad play as to effectively eliminate that element in its entirety." *Warner-Jenkinson*, 520 U.S. at 29. Vitiation "is not an exception or threshold determination that forecloses resort to the doctrine of equivalents, but is instead a legal conclusion of a lack of equivalence based on the evidence presented and the theory of equivalence asserted." *Cadence Pharm. Inc. v. Exela PharmSci Inc.*, 780 F.3d 1364, 1371 (Fed. Cir. 2015). For example, in *Carnegie Mellon University v. Hoffmann-La Roche Inc.*, this court concluded that finding *Taq* bacteria equivalent to *E. coli* bacteria would essentially render the "bacterial source [is] *E. coli*" claim limitation meaningless and would thus vitiate that limitation of the

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history was a factor in the court's analysis, but not one that by itself barred consideration of infringement under the doctrine of equivalents. Thus, *Tanabe* does not bar consideration of the doctrine here, even if the prosecution history was as suggestive in the instant case (which as explained above, it is not).

claims. 541 F.3d 1115, 1129 (Fed. Cir. 2008) (affirming summary judgment of noninfringement).

Here, Actavis argues that UCB's doctrine of equivalents infringement theory should fail because it vitiates the "acrylate-based or silicone-base polymer adhesive system" limitation of claim 1. We do not agree that finding polyisobutylene to be an equivalent gives the element "an acrylate-based or silicone-based polymer adhesive system" such broad play that the element would disappear entirely. *See Warner-Jenkinson*, 520 U.S. at 29. The district court did not broaden the right to exclude so widely as to cover all adhesive systems and vitiate the "acrylate-based or silicone-based" claim language. As explained below, the district court here conducted a specific analysis as to whether polyisobutylene would be covered, and it had adequate reasons for why a skilled would understand that polyisobutylene, specifically, would work just as well as acrylate or silicone for the claimed transdermal patch. Accordingly, we agree with the district court that vitiation does not bar application of the doctrine of equivalents here. J.A. 146–47.

d. Ensnarement

Actavis also contends that UCB's infringement theory is improper because it "ensnares" the prior art. *See Intendis GMBH v. Glenmark Pharm. Inc., USA*, 822 F.3d 1355, 1363 (Fed. Cir. 2016) ("A patentee may not assert 'a scope of equivalency that would encompass, or ensnare, the prior art.'") (quoting *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1322 (Fed. Cir. 2009)). "A helpful first step in an ensnarement analysis is to construct a hypothetical claim that literally covers the accused device." *DePuy Spine*, 567 F.3d at 1324. "Next, the district court must assess the prior art introduced by the accused infringer and determine whether the patentee has carried its burden of persuading the court that the hypothetical claim is patentable over the prior art." *Id.* at 1325. "In short,

[the court] ask[s] if a hypothetical claim can be crafted, which contains both the literal claim scope and the accused device, without ensnaring the prior art." *Intendis*, 822 F.3d at 1363.

Actavis argues that a hypothetical claim including polyisobutylene-based polymers would ensnare the prior art. But the prior art that Actavis points to covers silicone and acrylate polymers as well; its theory, if correct, would thus invalidate both the actual and hypothetically broader claims. Actavis offers no examples of prior art that would be ensnared by the addition of polyisobutylene to the claim, in contrast to the claim as is.

The district court "disagree[d]" with Actavis's contention that there is an ensnarement issue here and found that "*UCB*'s equivalence theory does not ensnare the prior art." J.A. 147–48 (emphasis added). We concur and do not find that the district court erroneously placed the burden on Actavis to prove ensnarement. Actavis's ensnarement argument is substantively a patent invalidity challenge, which we address later in this opinion. *See Jang v. Boston Sci. Corp.*, 872 F.3d 1275, 1288–89 (Fed. Cir. 2017) (explaining that ensnarement and validity are "two different concepts").

2. Merits

Second, we find no clear error with the district court's substantive application of the doctrine of equivalents.

Infringement under the doctrine of equivalents is a factual question, *VirnetX, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1322–23 (Fed. Cir. 2014), which we review for clear error on appeal from a bench trial. *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1359 (Fed. Cir. 2007).

The Supreme Court has set out two frameworks for evaluating equivalency. *Warner-Jenkinson*, 520 U.S. at 39–40. The relevant framework here, which the district court applied, is the (in)substantial differences test, under

which"[a]n element in the accused device is equivalent to a claim limitation if the only differences between the two are insubstantial." *Voda v. Cordis Corp.*, 536 F.3d 1311, 1326 (Fed. Cir. 2008). This court has explained that "the substantial differences test may be more suitable . . . for determining equivalence in the chemical arts," and identified "structural equivalen[cy]" as particularly relevant when comparing chemical equivalents. *Mylan Institutional LLC v. Aurobindo Pharma Ltd.,* 857 F.3d 858, 869 (Fed. Cir. 2017).

The purpose of the adhesive polymer in the disputed claim element is to act as a scaffold for the drug and to provide adhesion to a patient's skin for the transdermal patch. The district court found that, at the time the '434 patent was filed, silicates, acrylates, and polyisobutylenes were the most commonly used pressure-sensitive adhesives in transdermal patches. J.A. 127. The district court then identified a set of properties that silicates, acrylates, and polyisobutylenes share: they are pressure-sensitive, adhesive, biologically inert, non-irritating, and non-toxic. J.A. 121–28. Thus, the district court found that a skilled artisan "would recognize that polyisobutylene is not substantially different from the classes of adhesives literally within the scope of the claims." *Id.* at 128.

The district court also made fact findings as to the differences between polyisobutylene and silicates/acrylates. "Polyisobutylene is an organic polymer, consisting exclusively of carbon and hydrogen atoms, forming a non-polar backbone, without any functional groups," and accordingly is non-polar and hydrophobic. *Id.* Silicates and polyacrylates, unlike polyisobutylene, may contain functional groups that may be polar and/or reactive. So, due to differences in polarity, polyisobutylene has different adhesiveness compared to acrylate- and silicone-based adhesives. *Id.* Further, polyisobutylene, unlike silicone- or acrylate-based polymers, does not allow for crosslinking agents to be used to increase adhesion or reduce cold-flow. Finally,

rotigotine contains atoms that can interact with certain functional groups that can be present in silicone- and acrylate-based polymers, but rotigotine does not interact significantly with polyisobutylene. *Id.*

The district court explained that these differences do not matter for how the claimed invention works, as evidenced by the comparative results between UCB's Neupro product and the Accused Products, called PIB Neupro (Neupro with polyisobutylene substituted for silicone). The district court noted that permeation results for Neupro and PIB Neupro were comparable in terms of transdermal delivery of rotigotine at the intended wear time of 24 hours, and that Actavis chose polyisobutylene because it worked just as well as silicone. J.A. 129. The district concluded that "[t]hese results show that the polyisobutylene-based polymer adhesive system did not alter the way rotigotine is transdermally delivered compared to a silicone-based polymer adhesive system," nor did it "alter rotigotine transdermal delivery rates," showing that "polyisobutylene is interchangeable with silicone in the claimed polymer adhesive system." *Id.* Accordingly, the district court concluded that "[t]he polyisobutylene-based adhesive system is an insubstantial modification of the claimed invention." *Id.*

As for the dependent claims, which recite the use of PVP as a solubility enhancer, the district court found that the Accused Products use PVP as a solubility enhancer for rotigotine—in the same way as the claimed silicone-based polymer adhesive system. J.A. 130. The district court cited Actavis's stability testing (1) confirming that PVP was necessary in the polyisobutylene-based polymer adhesive system to fully dissolve the necessary amount of free base and prevent crystallization and (2) disclosing that this amount was within the range of PVP claimed in the '434 patent. *Id.* Further, both a polyisobutylene-based polymer adhesive system and the claimed silicone-based polymer adhesive system use a hydrophobic adhesive with inherently low solubility for rotigotine free base in which rotigotine-PVP

complexes are dispersed. *Id.* So, the district court reasoned that just because "polyisobutylene has some different properties (e.g., lack of heteroatoms and functional groups, different polarity, etc.)," this "does not change how the polymer adhesive system works": "the polymer functions as a scaffold for the drug," and "[r]otigotine-PVP complexes form in both silicone polymers and polyisobutylene to increase drug solubility and allow for drug mobility." J.A. 131.

The district court thus concluded that "[p]olyisobutylene is interchangeable with silicone in the claimed polymer adhesive system, resulting in an insubstantially different system that also uses dispersed rotigotine-PVP to effect ≥5% solubility." J.A. 132.

On appeal, Actavis argues that the district court erroneously relied on evidence comparing UCB's branded Neupro product with (a) Actavis's ANDA product and (b) PIB Neupro. Appellants' Op. Br. at 57. The crux of Actavis's argument is that Neupro is not equivalent to the asserted claims because it undisputedly contains 5 molecules of water for every 7 molecules of rotigotine. *Id.* at 74 (citing J.A. 4620:23–28:12 (testimony by UCB's expert); J.A. 5946, 5951–52 (Neupro validation document disclosing ratio and stating that Neupro patches have final "water content" of 0.3%)). Actavis argues that because it has water, Neupro does not have free base rotigotine in the patch's matrix "*in the absence of water*" as required by '434 patent claim 1. Since it is not equivalent to the claims, Actavis argues that any comparison between it and the Accused Products is a legally erroneous basis for infringement.

But the district court explicitly stated whether Neupro is or is not an embodiment of the claims is not dispositive of the infringement question because "infringement requires a comparison of the accused product (the ANDA product) and the claims." J.A. 149 n.6.

And the district court only relied on Neupro and PIB Neupro for points unrelated to water content. The district court observed that "[b]oth Neupro itself and the '434 patent in exemplary embodiments use silicone adhesives . . . that have a solubility for rotigotine of less than 0.1%" to make the point that the low solubility of polyisobutylene was not a concern that would differentiate it from silicates. J.A. 151. The district court also pointed out that Actavis started with Neupro and substituted polyisobutylene for silicone to make PIB Neupro because it viewed the two as interchangeable. J.A. 129. And the district court cited the comparative permeation studies because they showed no statistical difference in the amount of rotigotine delivered between the two adhesives. J.A. 152. It is not clear how any of these conclusions are affected by the water content of Neupro. Regardless, as summarized above, the district court had many non-Neupro-related reasons for finding substantial similarity here.

We do not find clear error in any of the district court's fact findings as to polyisobutylene's characteristics as compared to silicates and acrylates. We also do not find clear error in the district court's fact findings as to what a skilled artisan would have known about the interchangeability of polyisobutylene-based adhesives and silicone-based adhesives (i.e., why the similarities matter more than the differences for the claimed system). Giving credit to those fact findings, we affirm the district court's conclusion that the Accused Products infringe the claims under the doctrine of equivalents.

B. Validity of the '434 Patent

This court reviews legal conclusions from a bench trial *de novo* and factual findings for clear error. *Pfizer*, 480 at 1359. Anticipation is a factual question that we review for clear error; we review the legal conclusion of obviousness *de novo* and the underlying fact findings for clear error. *Genetics Inst., LLC v. Novartis Vaccines & Diagnostics, Inc.*,

655 F.3d 1291, 1302 (Fed. Cir. 2011) (citations omitted). Actavis appeals the district court's rejection of three of its proposed invalidity grounds: (1) anticipation by Cygnus, (2) obviousness over Cygnus in combination with Lipp or Pfister, and (3) obviousness over the combination of Timmerman and Miranda.

1. Cygnus-Based Anticipation and Obviousness

The Cygnus prior art patent application generally discloses controlled-release drug formulations that can be used with transdermal patches. J.A. 5704. The application describes "a novel matrix composed of a continuous hydrophobic domain and a dispersed particulate hydrated silicate domain," "which may be used to administer hydrophilic drugs in a sustained manner." J.A. 5706. Rotigotine is listed as an exemplary hydrophilic drug in Example 15. J.A. 5717–18. In that example, skin flux (rate of absorption) studies are presented of patches containing, in relevant part: rotigotine, a phosphate buffer (which is a water-based solution), and a silicone-based adhesive. *Id.* Example 15's patches are further described in Chiang. J.A. 155, 4827–28.

The district court found that Cygnus did not disclose a crucial element of claim 1: a patch containing rotigotine in free base form. J.A. 157–58. Cygnus states the chemical name of rotigotine free base: S(-)-2-(N-propyl-N-2-thienylethylamine)-5-hydroxytetralin. J.A. 5717. Rotigotine, however, can exist in free base form or in salt form. J.A. 157. Actavis presented Example 15 of Cygnus as evidence that Cygnus teaches a free base form existing in a patch. J.A. 158. In that example, rotigotine is present as a salt in a phosphate buffer water solution, where most of the rotigotine would be in charged salt form and only 1.28% could be present in neutral free base form. *Id.*

On appeal, Actavis points to Cygnus's Example 15 as teaching a patch with some rotigotine in free base form. But Actavis's argument has a fatal flaw: there is nothing

in Cygnus that teaches a *water-free* patch with rotigotine in free base form. All the patches in Cygnus's examples—including those with rotigotine—contain significant amounts of water (10–15% w/w) such that even the 1.28% of rotigotine present in free base form in Example 15 would necessarily be in the presence of water because of the phosphate buffer.[11] Accordingly, it was not clearly erroneous for the district court to find that "merely providing the chemical name [in the specification] for the rotigotine free base" was not enough to disclose that the base was present in the absence of water. J.A. 158.

Thus, we agree with the district court's conclusion that Actavis did not present "sufficient evidence that rotigotine free base is present in a patch that is water-free" in Cygnus. *Id.*

Neither Lipp nor Pfister fills this gap. Both disclose transdermal patches containing PVP, but neither discloses any anti-Parkinson's drugs, much less rotigotine free base in the absence of water.[12]

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[11] Actavis contended at Oral Argument that Cygnus discloses substituting other solvents for water: "Other hydrophilic polar solvents such as ethanol, propylene glycol, low molecular weight (200 to 400 mw) polyethylene glycol, isopropyl alcohol, N-butanediol, m-pyrol and benzyl alcohol may be substituted for water or included in the hydrophilic domain of the matrix." Oral Arg. at 3:07 (citing J.A.5209). But the district court found that "Actavis [] presented no evidence" that use of such solvents would actually result in rotigotine free base in a water-free patch. J.A. 158. Actavis does not show on appeal that the district court erred in that finding.

[12] Actavis also argues that all of the asserted '434 patent claims are "obvious as claiming well-known

2. Obviousness over Timmerman and Miranda

The district court also rejected Actavis's argument that the asserted claims of the '434 patent would have been obvious in light of Miranda combined with Timmerman. Miranda describes (1) transdermal patches based on silicone or polyacrylate-based polymer adhesives, (2) PVP as a solubility enhancing agent, (3) an active ingredient present in concentrations between 3% and 10%, and (4) solvents that are not water. J.A. 5780, 5787, 5788, 5808–09. Miranda does not specifically name rotigotine as a suitable drug for its patches, but it does include a list of other drugs that are used to treat Parkinson's disease. J.A. 5797. Timmerman is a 1988 study in which rats were treated transdermally on the skin of their necks with a solution containing rotigotine free base. J.A. 4811–18. Timmerman deduced that transdermal application of rotigotine was superior to oral administration because it induced a much longer duration of action of the drug (13 hours) in comparison with the oral mode (5 hours). J.A. 4811, 4816. Timmerman concluded that "transdermal administration . . . may provide a most useful way of administering the drug for therapeutic use." J.A. 4817.

The district court found that Actavis did not provide an adequate rationale for combining the references' teachings, noting that Actavis did "not explain why a [skilled artisan] would have been motivated to start from the patches taught by Miranda." J.A. 161–62. The district court then found that it was not persuaded that a skilled artisan

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components." Appellants' Op. Br. at 72. But Actavis does not explain in any detail how a skilled artisan would understand or combine such evidence to arrive at the claimed invention. Actavis did not meaningfully develop this argument below or on appeal, and we do not find it sufficient to render any of the asserted '434 patent claims obvious.

would have reasonably expected the combination to be successful because: (1) the transdermal patch field was a relatively sparse one at the pertinent date (only 8 transdermal patches were available at the time of the invention of the '434 patent in 1998, and even now, only 20 drugs are available in patch form), and (2) of the drugs available as patches, rotigotine is the only active ingredient that was introduced as a patch without first being available in a different type of formulation. J.A. 162. So, even accepting Actavis's contention that Miranda provides a "recipe" or "check list" for making transdermal patches, the district court reasoned that a skilled artisan "would have confronted a significant challenge to create a patch that was successful at treating Parkinson's disease," especially in light of Chiang's teaching that path formulation can have a dramatic effect on observed rate of absorption through the skin (skin flux). *Id.* Ultimately, the district court was not persuaded that the claimed invention would have been, at the time of the invention, "as trivial and straightforward as simply combining rotigotine free base of Timmerman with the patch recipe of Miranda." *Id.*

On appeal, Actavis argues that the district court failed to find obviousness over this combination only because it applied an "unduly rigid" analysis in concluding that Actavis had not shown a motivation to combine or reasonable expectation of success. Appellants' Op. Br. at 62 (citing *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007)). Actavis argues that the district court's concern over why a skilled artisan would have been motivated to start with Miranda is misplaced because starting with Miranda was not part of its obviousness theory. As a threshold matter, we agree with Actavis that, under the flexible framework of *KSR*, it should not matter whether a proposed obviousness combination starts with Timmerman or Miranda. But even accepting Actavis's argument that a skilled artisan would start with Timmerman, there is still an evidentiary gap as to why a skilled artisan would think of using a

transdermal patch, as taught in Miranda, based on Timmerman's "transdermal administration" disclosure of applying a liquid dose of the drug on the hairless skin on the neck of a rat.

As to lack of reasonable expectation of success, we affirm the district court's finding. Miranda discloses thousands of combinations for making transdermal patches. First, it discloses huge ranges for the percent by weight of the rubber, polyacrylate, PVP, co-solvents, and drugs in the patches. J.A. 5806. Second, it discloses hundreds of drugs, of which anti-Parkinson drugs are just a small category and where that category does not even list rotigotine. J.A. 5789–802, 5797. Third, Miranda lists ethanol as just one of many possible solvents. J.A. 5808. Finally, it teaches that "[t]he amount of drug to be incorporated in the composition varies depending on the particular drug, the desired therapeutic effect, and the time span for which the device is to provide therapy." J.A. 5803.

Based on the above, it was reasonable to conclude that Miranda is less of a "recipe" for the claimed rotigotine transdermal patch and more of a list of thousands of possibilities out of which a skilled artisan would have to select the claimed combination as one to try. Miranda does not provide a reasonable expectation of success for making a transdermal patch of rotigotine without undue experimentation, and Timmerman cannot fill in this gap, as it does not contemplate using a patch to administer rotigotine transdermally. Chiang's disclosure that "[o]ne of the major obstacles for developing a transdermal delivery system is to deliver sufficient amounts of the drug through the skin," J.A. 4827–28, and its conclusion, as summarized by the district court, that "path formulation can have a dramatic effect on observed skin flux," J.A. 162, further suggest that transdermal drug administration is not a straightforward task such that narrowing down Miranda's teachings to the claimed invention could be achieved via routine experimentation. J.A. 4827–28. And the district court found that the

transdermal patch field was not a common, widespread one during the relevant time, and that of the drugs available as patches, rotigotine was the only active ingredient that was introduced as a patch without first being available in a different type of formulation. J.A. 162. All of these facts support the district court's conclusion that a skilled artisan would not have had a reasonable expectation of success in combining Miranda and Timmerman, even if there was a motivation to do so.

Since we find no reversible error in the findings by the district court about the prior art we have already discussed, we do not reach Actavis's arguments challenging additional findings regarding secondary considerations. Those considerations are unnecessary here, as they can only further support the rejection of the obviousness challenge.

Accordingly, we affirm the district court's findings upholding the validity of the asserted '434 patent claims.

C. Invalidity of the '414 Patent

On cross-appeal, UCB asks this court to reverse the district court's invalidation of the asserted '414 patent claims due to prior public use under § 102(a) because the record evidence allegedly did not support the district court's inferences as to how UCB's Form II invention was in actual use before the correct invention date. Cross-Appellants' Op. Br. at 62–63.

A patent may be found invalid if "the invention was known or used by others in this country" before invention by the applicant. 35 U.S.C. § 102(a) (pre-AIA).[13] This is

[13] The Leahy-Smith America Invents Act (AIA) changed 35 U.S.C. § 102. Pub. L. No. 112-29, § 3(b), 125 Stat. 284, 285–86 (2011). However, because the

because "[i]f the invention was known to or used by others in this country before the date of the patentee's invention, the later inventor has not contributed to the store of knowledge, and has no entitlement to a patent." *Woodland Tr. v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998). "For prior art to anticipate because it has been 'used,' the use must be accessible to the public." *Minnesota Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1301 (Fed. Cir. 2002). "[P]rior knowledge and use by a single person is sufficient." *Coffin v. Ogden*, 85 U.S. 120, 124 (1873).

The district court reasonably found that a patient in the United States used Neupro patches that contained Form II rotigotine before November 28, 2007—the '414 patent's filing date—and that therefore, the '414 patent claims were invalid under § 102(a).[14] J.A. 183. A female

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application from which the '414 patent issued has never contained a claim having an effective filing date on or after March 16, 2013, or a reference under 35 U.S.C. §§ 120, 121, or 365(c) to any patent or application that ever contained such a claim, the pre-AIA § 102(a) applies. *Id.* § 3(n)(1), 125 Stat. at 293.

[14] UCB disputes whether November 28, 2007 is the appropriate date of invention for the '414 patent. Generally, "the date of invention [is] presumed to be the filing date of the application until an earlier date is proved." *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 449 (Fed. Cir. 1986). It is the patentee's burden to present evidence of an earlier invention date. *See Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1576–78 (Fed. Cir. 1996). UCB assumed November 28, 2007 as the date of invention for its arguments against derivation (not on appeal), was on notice of Actavis's reliance on the date for § 102(a) purposes at least as of the district court's pre-trial

patient had received samples of Neupro in September 2007 and "responded well" to treatment. J.A. 5965. In November 2007, however, this patient purchased Neupro patches that were from lot 47808—one of the lots later discovered to have contained Form II rotigotine. *Id.*; J.A. 181–82. While using these lot 47808 patches, the patient began "clearly back-sliding, experiencing previous [Parkinson's] symptoms of losing mobility, shaking and freezing." J.A. 5966. The patient experienced the adverse event two days after the priority date of the '414 patent, but she had been using the patches for "one week," necessarily implying that she was using the patches before the '414 patent's priority date of November 28, 2007. *Id.* After experiencing this back-sliding, the patient "was reverted to the samples of the newer lot number" and "an improvement in the patient was noted." *Id.*

The district court found that Form II rotigotine was used in the United States before the November 28, 2007 priority date of the '414 patent based on (1) record evidence that most, if not all, of lot 47808's patches sent to the United States contained Form II rotigotine, and (2) the patient's back-sliding with the lot 47808 patches and subsequent improvement on different patches.

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order**,** and failed to raise any issue with the invention date until post-trial briefing. Under these circumstances, we find that the district court did not abuse its discretion in finding that UCB waived any argument of a date of invention earlier than November 28, 2007. *Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1376 (Fed. Cir. 2005) (Unless a procedural ruling raises issues unique to patent law, we apply the law of the appropriate regional circuit.); *Springer v. Henry*, 435 F.3d 268, 275 n.4 (3d Cir. 2006) (The Third Circuit reviews a district court's decision that a party has waived an issue for trial for abuse of discretion.).

On appeal, UCB first argues that there is insufficient evidence that there were Form II crystals in the patient's Neupro patches before the '414 patent's filing date. But the district court explained that the patient's patches were from lot 47808 and concluded that the whole batch had Form II crystal because so many of the retained and later tested samples from that lot contained Form II. J.A. 181–82. The district court also pointed to the patient's "back-sliding" symptoms as indicative of the Form II crystals' presence. J.A. 183. To argue that the patches used by the patient may not have contained Form II crystals, UCB points to a report showing that out of the twenty patches tested in that lot, nine of them did not have crystals initially. J.A. 4853. But that same report shows that all had crystals within a month of storage. *Id.* The patches used by the patient were stored for far longer than that; they were made in June/July 2007 and used in November 2007. J.A. 181; J.A. 5966. UCB further argues that the crystals observed on the patches may not have necessarily been Form II, as apparently it is impossible to distinguish Form I from Form II by sight. Cross Appellants' Op. Br. at 69 (citing J.A. 4838; J.A. 4282–83). But in this record, all lots where crystals were observed were confirmed to contain Form II. J.A. 4852–53.

Second, UCB argues that the patient's "back-sliding" symptoms are not necessarily evidence of Form II use. Cross-Appellants' Op. Br. at 69–70. UCB argues that the patient's other health issues might have contributed to those symptoms, citing record evidence that "[t]he impact of crystals on product efficacy in patients depends on the extent of drug release, variability at the level of the patient and product, and psychological patient factors." J.A. 4850. We understand this statement to suggest that the "back-sliding" is different from patient to patient. But it is not relevant, where, as here, the baseline for the "back-sliding" is the patient's own responsiveness to patches she took before and after the patches likely containing Form II. UCB

also points out that the patient's physician suspected different causes for the backsliding because the patient was "checked for co-morbidity, suspecting a cold or lung problems due to wildfires," the patient suffered from conditions other than Parkinson's, she was on several other medications, and her improvement after the switch to patches from a different lot number was temporary, with her conditioning declining again thereafter. J.A. 5966. Finally, UCB argues that a document the district court relied on actually shows that there was not enough Form II on the patches to cause back-sliding. Cross-Appellants' Op. Br. at 70–71. That document explains that ~one-third of a patch's surface area needs to be covered in Form II crystals to cause back-sliding, and many of the tested samples from the affected batches had an affected surface area of < 30%. J.A. 4850. But another report in the record shows affected areas >40%. J.A. 4848. That there might have been other causes for the back-sliding or that there may not have been enough crystals on the patches to cause back-sliding are speculative facts that are reasonably outweighed by other evidence in the record.

Third, UCB argues that Form II cannot penetrate the skin, so it has no therapeutic function in a patch, and therefore, the patches administered to the patient in November 2007 do not count as "use" of the '414 patent's invention under § 102. Cross-Appellants' Op. Br. at 62–63. But the '414 patent claims simply cover Form II rotigotine, without any limitations as to its use. If it was present in the patches that were administered to the patient, § 102(a) does not require that the invention be used for a particular purpose. The case cited by UCB, *3M v. Chemque*, 303 F.3d 1294, 1306–07 (Fed. Cir. 2002), stands for the inapposite proposition that evidence of product samples being sent to third parties is not sufficient to show that those samples were actually used by the third parties. The case here is different; there is evidence that patient actually used the patches with Form II rotigotine crystals in it. The patient's

use of the patches fairly counts as public use under § 102(a).

Anticipation under § 102(a) is an issue of fact reviewed for clear error. *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1367 (Fed. Cir. 2000). There is plenty of evidence that most, if not all, of the patches in lot 47808 contained crystals, and that those crystals contained Form II. There is also evidence that the patient, who reported backsliding only after one week of using lot 47808 patches and who reported improvement (even if short-lived) when a new set of patches was used thereafter, used patches with Form II and that her symptoms matched up with use of Form II. J.A. 5966. We do not find clear error in the district court's finding that Actavis presented clear and convincing evidence of public use before the date of invention under § 102(a). Accordingly, we affirm the district court's invalidation of the asserted '414 patent claims.

CONCLUSION

We affirm the district court's judgment of infringement and validity of the asserted '434 patent claims, as well as invalidity of the asserted '414 patent claims.

AFFIRMED

COSTS

No costs.