

**United States Court of Appeals  
for the Federal Circuit**

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**KAKEN PHARMACEUTICAL CO., LTD., BAUSCH  
HEALTH COMPANIES INC.,**  
*Appellants*

v.

**ANDREI IANCU, UNDER SECRETARY OF  
COMMERCE FOR INTELLECTUAL PROPERTY  
AND DIRECTOR OF THE UNITED STATES  
PATENT AND TRADEMARK OFFICE,**  
*Intervenor*

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2018-2232

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Appeal from the United States Patent and Trademark  
Office, Patent Trial and Appeal Board in Nos. IPR2017-  
00190, IPR2017-01429.

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Decided: March 13, 2020

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JOHN D. LIVINGSTONE, Finnegan, Henderson, Farabow,  
Garrett & Dunner, LLP, Atlanta, GA, argued for appel-  
lants. Also represented by JEFFREY JACOBSTEIN, Boston,  
MA; SAMHITHA MEDATIA, ANTHONY A. HARTMANN, CORA  
RENAE HOLT, BARBARA RUDOLPH, Washington, DC.

NICHOLAS THEODORE MATICH, IV, Office of the Solicitor,  
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VA, argued for intervenor. Also represented by THOMAS W. KRAUSE, WILLIAM LAMARCA, ROBERT J. MCMANUS, BRIAN RACILLA, FARHEENA YASMEEN RASHEED.

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Before NEWMAN, O'MALLEY, and TARANTO, *Circuit Judges*.  
TARANTO, *Circuit Judge*.

U.S. Patent No. 7,214,506 describes and claims methods for topically treating fungal infections in human nails. The parties here treat Kaken Pharmaceutical Co. and Bausch Health Companies Inc. (together, Kaken) as the patent owner. Acrux Limited and Acrux DDS Pty. Ltd. (together, Acrux), which no longer are parties to this proceeding, successfully sought an inter partes review of all claims of the '506 patent under 35 U.S.C. § 311–319. The Patent Trial and Appeal Board of the Patent and Trademark Office ultimately determined that all claims of the '506 patent are unpatentable for obviousness. *Acrux DDS Pty. Ltd. v. Kaken Pharm. Co., Ltd.*, No. IPR2017-00190, 2018 WL 2761408 (P.T.A.B. June 6, 2018).

Kaken appeals. The Director of the Patent and Trademark Office, who intervened after Acrux withdrew, defends the Board's decision. We agree with Kaken on its principal contention—that the Board erred in its claim construction of one claim limitation. Because the Board's obviousness analysis materially relied on its erroneous claim construction, we cannot affirm the Board's unpatentability determination. We reverse the claim construction, vacate the Board's decision, and remand the matter to the Board.

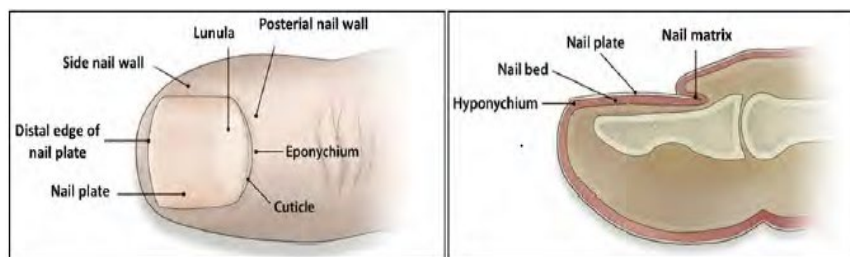
I

A

The '506 patent, titled “Method For Treating Onychomycosis,” provides a series of interlocking definitions. The patent states that “[o]nychomycosis” is a class of “superficial mycosis” that affects the “nail of [a] human or an

animal.” ’506 patent, col. 9, lines 32–35. The umbrella term, “superficial mycosis,” encompasses infections that attack tissues of the “skin or visible mucosa.” *Id.*, col. 5, lines 20–26. According to the patent, “skin” is “a tissue including the three layers being epidermis, de[r]mis and subcutaneous tissue, accompanied by pilus (hair), nail, [and various glandulae] as appendages.” *Id.*, col. 4, lines 54–57. In turn, the “term ‘nail’ includes nail plate, nail bed, nail matrix, further side nail wall, posterial nail wall, eponychium and hyponychium which make up a tissue around thereof.” *Id.*, col. 4, lines 65–67.

Each of these structures is labeled in the following diagram:



J.A. 2435. Although the patent contains its own definitions, including of “nail” and of “skin” (the latter including “nail”), evidence before the Board explained that common usage differs from the patent’s definitions. The “nail plate” is the “horny appendage of the skin that is composed mainly of keratin” and is “commonly called the nail.” J.A. 1236. By contrast, the “eponychium and hyponychium” are the “skin structures surrounding the nail.” J.A. 1276.

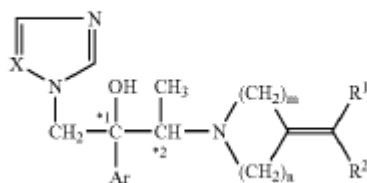
One specific form of onychomycosis is “tinea unguium,” which is caused by fungi of the *Trichophyton* species. ’506 patent, col. 9, lines 40–45. Two types of *Trichophyton* fungi, *Trichophyton rubrum* and *Trichophyton mentagrophytes*, are the most common causes of onychomycosis in humans. ’506 patent, col. 9, lines 35–38. Accordingly,

the patent refers to “onychomycosis” and “tinea unguium” interchangeably. *E.g.*, *id.*, col. 3, lines 41–45, col. 14, lines 60–63.

Traditionally, onychomycosis was treated with oral medications. *Id.*, col. 2, lines 25–27. Because those oral medications required long treatment periods and could cause gastrointestinal disorders, it was “desired to develop a topical preparation.” *Id.*, col. 2, lines 27–39. Topical treatments, however, were largely ineffective—most treatments “could not sufficiently permeate the thick keratin in [the] nail plate.” *Id.*, col. 2, lines 40–45. It is a stated object of the patent to provide a topical treatment that is effective more quickly than oral medications “due to good permeability, good retention capacity and conservation of high activity in nail plate as well as . . . potent antifungal activity.” *Id.*, col. 3, lines 42–47.

The ’506 patent teaches a method of topically treating onychomycosis with efinaconazole, also referred to as “KP-103,” which is a specific kind of azole compound. *See id.*, col. 3, line 52 through col. 4, line 6; *id.*, col. 8, line 23 through col. 9, line 17. Claim 1, the only independent claim, recites:

1. A method for treating a subject having onychomycosis wherein the method comprises topically administering to a nail of said subject having onychomycosis a therapeutically effective amount of an antifungal compound represented by the following formula:



wherein, Ar is a non-substituted phenyl group or a phenyl group substituted with 1 to 3 substituents selected from a halogen atom and trifluoromethyl group,

R<sup>1</sup> and R<sup>2</sup> are the same or different and are hydrogen atom, C<sub>1-6</sub> alkyl group, a non-substituted aryl group, an aryl group substituted with 1 to 3 substituents selected from a halogen atom, trifluoromethyl group, nitro group and C<sub>1-16</sub> alkyl group, C<sub>2-8</sub> alkenyl group, C<sub>2-6</sub> alkynyl group, or C<sub>7-12</sub> aralkyl group,

m is 2 or 3,

n is 1 or 2,

X is nitrogen atom or CH, and

\*1 and \*2 mean an asymmetric carbon atom.

*Id.*, col. 17, line 33 through col. 18, line 28. The two possibilities covered by the language “X is [a] nitrogen atom or CH” are, respectively, a triazole or an imidazole. Claim 2, which depends on claim 1, requires that the “compound represented by the formula (II)” is KP-103, which is the triazole version. *Id.*, col. 18, lines 29–32; *see id.*, col. 9, lines 15–17. The patent states that the “effectiveness of the KP-103 used as an antifungal in the present invention for onychomycosis has not been confirmed, but its antifungal activity has been already known.” *Id.*, col. 9, lines 22–25.

## B

In November 2016, Acrux petitioned for an inter partes review of claims 1 and 2 of the '506 patent, relying on two sets of references. The first set consists of three references: Japanese Patent Application No. 10-226639 (JP '639); U.S. Patent No. 5,391,367; and R.J. Hay et al., *Tioconazole nail solution—an open study of its efficacy in onychomycosis*, 10 CLINICAL AND EXPERIMENTAL DERMATOLOGY 111 (1985)

(Hay). Acrux argued that each of those references independently teaches a method of topically treating onychomycosis with various azole compounds. The second set of references consists of two references: H. Ogura et al., *Synthesis and Antifungal Activities of (2R,3R)-2-Aryl-1-azoly-3-(substituted amino)-2-butanol Derivatives and Topical Antifungal Agents*, 47 CHEM. PHARM. BULL. 1417 (1999) (Ogura); and *Abstracts F78, F79, and F80*, 36 INTERSCIENCE CONFERENCE ON ANTIMICROBIAL AGENTS AND CHEMOTHERAPY 113 (1996) (Kaken Abstracts). Acrux argued that both of those references disclose KP-103 as an effective antifungal agent.

Acrux challenged both claims of the '506 patent as unpatentable for obviousness, stating six (related) grounds, each one drawing a reference from the first set and a reference from the second set. Specifically, Acrux argued obviousness over JP '639 in combination with Ogura or the Kaken Abstracts, obviousness over the '367 patent in combination with Ogura or the Kaken Abstracts, and obviousness over Hay in combination with Ogura or the Kaken Abstracts. In its final written decision, the Board held claims 1 and 2 unpatentable for obviousness over JP '639, the '367 patent, and Hay, each in combination with the Kaken Abstracts. *Acrux*, 2018 WL 2761408, at \*12–26.

During the inter partes review, Kaken proposed that the phrase “treating a subject having onychomycosis” means “treating the infection at least where it primarily resides in the keratinized nail plate and underlying nail bed.” *Id.* at \*4. The Board rejected Kaken’s construction as too narrow, concluding that “the express definition of onychomycosis includes superficial mycosis, which in turn is expressly defined as a disease that lies in the *skin or visible mucosa*.” *Id.* at \*5. The Board also found significant that the express definition of “nail includes the tissue or skin around the nail plate, nail bed, and nail matrix.” *Id.* Accordingly, the Board concluded, “treating onychomycosis”

includes treating “superficial mycosis that involves disease of the skin or visible mucosa.” *Id.* at \*6. Applying that construction, the Board determined that a skilled artisan would have been motivated to combine the cited references and that Kaken’s objective indicia of non-obviousness deserved little weight. *Id.* at \*20–26.

Kaken timely appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

## II

Kaken challenges the Board’s construction of “treating a subject having onychomycosis.” According to Kaken, the Board’s construction ignores the ’506 patent’s core innovation—a topical treatment that can easily penetrate the tough keratin in the nail plate. Kaken asks us to reverse the claim construction and either to reverse the obviousness determination or to vacate it and remand for application of the proper construction.

## A

We review the Board’s claim construction de novo and any underlying factual findings for substantial evidence. *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 840–41 (2015); *Wasica Finance GmbH v. Continental Automotive Systems, Inc.*, 853 F.3d 1272, 1278 (Fed. Cir. 2017). The parties accept that, in this matter, the claims must be given their broadest reasonable interpretation. We hold, in light of the specification and prosecution history, that the Board’s claim construction is unreasonable. The broadest reasonable interpretation of “treating a subject having onychomycosis,” consistent with Kaken’s construction, is penetrating the nail plate to treat a fungal infection inside the nail plate or in the nail bed under it.

The '506 patent's specification characterizes "onychomycosis" in a way that links to three other crucial passages in the specification—two that provide express definitions of other terms and one that characterizes another term. Thus, after defining the terms "skin" and "nail," and characterizing "superficial mycosis," the specification declares that "onychomycosis" is "a kind of the above-mentioned superficial mycosis, in the other word a disease which is caused by invading and proliferating in the nail of human or an animal." '506 patent, col. 9, lines 32–35. This assertion about onychomycosis conveys that the disease covered by the term has two basic features: (1) it is a disease of the "nail" and (2) it is a kind of superficial mycosis. Contrary to the Board's conclusion, however, that characterization, when coupled with the other three linked specification passages, does not compel the conclusion that "onychomycosis" reasonably is understood to involve invasion of *any* part of what is defined as the "nail," including parts other than the nail plate or nail bed, such as skin in its ordinary sense.

More specifically, the Board relied on the '506 patent's definition of "nail": the "term 'nail' includes nail plate, nail bed, nail matrix, further side nail wall, posterial nail wall, eponychium and hyponychium which make up a tissue around thereof." *Id.*, col. 4, lines 65–67; *see Acrux*, 2018 WL 2761408, at \*5. That definition includes skin structures surrounding the nail plate. But the Board drew an unwarranted inference from that broad definition. As a matter of ordinary meaning, a statement that a particular disease invades the body would not imply that it can invade any part of the body. So too, when the specification says that "onychomycosis" is a disease involving invasion of the "nail," it does not compel the conclusion that the disease can invade any part of the defined "nail." A disease that invades the nail plate or bed only is still a disease that



invades the “nail” as defined. Thus, this language alone does not support the Board’s conclusion that an infection of any individual structure of the nail constitutes onychomycosis.

The Board also relied on the specification’s characterization of “superficial mycosis.” The specification says that superficial mycosis is a kind of mycosis in which “[a] seat of the disease lie[s] in the skin or visible mucosa,” *id.*, col. 5, lines 23–24, in contrast to deep mycosis, which lies “in viscus, central nervous system, subcutaneous tissue, muscle, [h]orn or articulation,” *id.*, col. 5, lines 24–26. The Board concluded that, because onychomycosis is stated to be a type of superficial mycosis, “which in turn is expressly defined as a disease that lies in the *skin or visible mucosa*,” onychomycosis “includes infections of skin contrary to [Kaken’s] interpretation of this term to require infection of the nail plate and nail bed.” *Acrux*, 2018 WL 2761408, at \*5.<sup>1</sup>

The “superficial mycosis” characterization is no more decisive in supporting the Board’s conclusion than is the “nail” definition. Specifically, the Board’s inference runs counter to the specification’s capacious definition of “skin” as including “nail”: “a tissue including the three layers being epidermis, de[r]mis and subcutaneous tissue, accompanied by pilus (hair), *nail*, [and certain glandulae] as appendages.” ’506 patent, col. 4, lines 54–57 (emphasis added). Because of that definition, the assertion that onychomycosis is a type of disease that lies in the “skin” in no way excludes onychomycosis from being limited to the

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<sup>1</sup> We understand the Board’s statement that “the express definition of onychomycosis includes superficial mycosis,” *Acrux*, 2018 WL 2761408, at \*5, to mean simply that the specification characterizes onychomycosis as a type of superficial mycosis.

“nail.” The characterization of “superficial mycosis” allows that possibility and does not mean that every type of superficial mycosis affects every type of “skin” structure.

The Board did not draw any inference specifically from the contrast with “deep mycosis.” The specification describes deep mycosis as affecting “subcutaneous tissue,” but the patent also defines “skin” as including “subcutaneous tissue.” *Compare id.*, col. 5, lines 23–26 *with id.*, col. 4, lines 54–57. The overlap reinforces the general lesson that the specification passages on which the Board relied do not provide clarity about the reasonable bounds of the class of structures that must be infected for a disease to constitute “onychomycosis.”

Other parts of the specification, which explain that an effective topical treatment would need to penetrate the nail plate, support Kaken’s construction. A patent’s statement of the described invention’s purpose informs the proper construction of claim terms, including when the task is to identify the broadest reasonable interpretation. *See In re Power Integrations, Inc.*, 884 F.3d 1370, 1376–77 (Fed. Cir. 2018) (the patent at issue “strives to eliminate unnecessary components,” so it would be unreasonable to construe a claim term to include a “bulky [component]”). The ’506 patent briefly describes topical treatments known in the prior art. It notes that those treatments were largely ineffective because they “could not sufficiently permeate the thick keratin in [the] nail plate.” ’506 patent, col. 2, lines 40–44. Accordingly, the ’506 patent explains, an effective topical treatment must have “good permeability, good retention capacity and conservation of high activity in [the] nail plate.” *Id.*, col. 3, lines 40–48. That discussion, in stating the “object of [the] present invention” relevant to the claims at issue, *id.*, col. 3, lines 40–41, supports Kaken’s construction. Treating an infection of the skin surrounding the nail plate alone would not require all those properties,

including “high activity *in* [the] nail plate.” *Id.*, col. 3, lines 40–48 (emphasis added).

The Board discounted that evidence based on a flawed understanding of the relationship between onychomycosis and tinea unguium. The Board reasoned that the patent’s description of an effective topical treatment is unhelpful because it is preceded by the phrase “a therapeutic agent for onychomycosis which exhibits the effect on tinea unguium by topical application” and tinea unguium “is included in the definition of onychomycosis, but is not co-extensive with it.” *Acrux*, 2018 WL 2761408, at \*6 (citing ’506 patent, col. 3, lines 41–45). Although the Board is correct that onychomycosis is broader than tinea unguium, it is not broader in a way that is significant for this analysis. The patent explains that tinea unguium is onychomycosis “caused by [the] *Trichophyton* species” of fungus and contrasts tinea unguium with “[o]nychocandidadis caused by [the] *Candida* species or onychomycosis (*sensu stricto*) caused by the other fungus.” ’506 patent, col. 9, lines 40–44. That onychomycosis can be caused by fungi other than the *Trichophyton* species does not decrease the probative value, for determining the *location* of the infection, of the patent’s description of an effective topical treatment for tinea unguium.

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The prosecution history—which includes, specifically, statements made by Kaken to overcome a rejection and the examiner’s statements explaining withdrawal of the rejection based on those statements—provides decisive support for limiting the claim phrase at issue to a plate-penetrating treatment of an infection inside or under the nail plate. A patent’s prosecution history can “inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim

scope narrower than it would otherwise be.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005); *see also Hynix Semiconductor Inc. v. Rambus Inc.*, 645 F.3d 1336, 1350 (Fed. Cir. 2011) (prosecution history is strong evidence of what a skilled artisan “would have understood disputed claim language to mean”). Particularly useful are “express representations made by or on behalf of the applicant to the examiner to induce a patent grant,” which include “arguments made to convince the examiner that the claimed invention meets the statutory requirements of novelty, utility, and nonobviousness.” *Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 452 (Fed. Cir. 1985). Prosecution history plays this role in applying the broadest-reasonable-interpretation standard. *See Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015), *overruled on other grounds by Aqua Prods., Inc. v. Matal*, 872 F.3d 1290 (Fed. Cir. 2017) (en banc). In this case, Kaken’s statements during prosecution, followed by the examiner’s statements, make clear the limits on a reasonable understanding of what Kaken was claiming.

The ’506 patent issued from a divisional application of U.S. Patent Application No. 10/031,929, which originally had seventeen claims. Divisional dated Oct. 14, 2003, at 35–39, in Appl. No. 10/685,266. When Kaken submitted its divisional application (the ’266 application), it included a preliminary amendment that reduced the number of claims to four: claims 2–17 were cancelled and claims 18–20 were added. Preliminary Amendment dated Oct. 14, 2003, at 3–4, in Appl. No. 10/685,266. Independent claim 18 described a “method for treating [a] subject having onychomycosis” using a compound having “formula (I).” Preliminary Amendment dated Oct. 14, 2003, at 3; *see* ’506 patent, col. 3, lines 54–63. Claim 19, which depended on claim 18, required a compound having “formula (II).” Preliminary

Amendment dated Oct. 14, 2003, at 3; *see* '506 patent, col. 8, lines 28–39.

The examiner, believing that claims 18–20 were directed to a method of treating general mycosis, initially rejected Kaken's application for obviousness-type double patenting over claims 9–12 of U.S. Patent No. 5,620,994. The '994 patent describes a "fungicide" containing the same compound described by formula (II) of the '506 patent. '994 patent, Abstract; *see* '506 patent, col. 8, lines 28–39. While independent claim 1 of the '994 patent claims that compound, '994 patent, col. 17, line 51, through col. 18, line 19, claim 9 of the '994 patent claims a "process for treating mycosis" using the compound of claim 1, *id.*, col. 18, lines 46–48. The examiner first explained that the "formula presented in instantly claimed Claim 19 [of the '266 application] is exactly the same as that in Claim [1] of [the '994] patent." Non-Final Rejection dated June 14, 2006, at 4, in Appl. No. 10/685,266; J.A. 1571. The examiner added that claims 18–20 were not "patentably distinct" from claims 9–12 of the '994 patent because "[c]laims 9–12 . . . claim a process to treat mycosis which again is a generic terminology for 'onychomycosis' via administering the compound of formula in Claim 1." Non-Final Rejection dated June 14, 2006, at 4; J.A. 1571.

Kaken responded by submitting an amendment that cancelled claim 1, clarified the wording of claim 18, and asserted the important difference between mycosis and onychomycosis. Noting that the "[t]reatment of onychomycosis significantly differs from the general treatment of mycoses claimed in '994," Kaken explained that "[o]nychomycosis is a condition that *specifically affects the nail plate.*" Amendment filed Sept. 14, 2006, at 10, in Appl. No. 10/685,266 (emphasis added); J.A. 1589. Kaken further argued that the "present invention shows the unexpected ability of an azolylamine derivate *to penetrate nail and be retained by the nail.*" Amendment filed Sept. 14, 2006, at 10 (emphasis

added); J.A. 1589. Accordingly, Kaken concluded, the rejection should be withdrawn.

The examiner credited Kaken's explanation and withdrew the rejection. In allowing the claims, the examiner stated, under the heading "Examiner's Reasons for Allowance," that "unexpectedly and in contrast to previously evaluated compositions/methods, the instantly claimed method cures the onychomycosis because the medicament upon direct administration to the nail, *penetrates through the nail plate and eradicates the infection at the site.*" Notice of Allowability dated Dec. 26, 2006, at 5, in Appl. No. 10/685,266 (emphasis added); J.A. 1608. The examiner also suggested that Kaken cancel claim 18 and make claim 19 independent, which Kaken did, and the resulting claims 19 and 20 became claims 1 and 2 of the issued '506 patent. *Compare* Notice of Allowability dated Dec. 26, 2006, at 3–4 *with* '506 patent, col. 17, line 34 through col. 18, line 32.

This exchange would leave a skilled artisan with no reasonable uncertainty about the scope of the claim language in the respect at issue here. Kaken is bound by its arguments made to convince the examiner that claims 1 and 2 are patentable. *See Standard Oil*, 774 F.2d at 452. Thus, Kaken's unambiguous statement that onychomycosis affects the nail plate, and the examiner's concomitant action based on this statement, make clear that "treating onychomycosis" requires penetrating the nail plate to treat an infection inside the nail plate or in the nail bed under it.<sup>2</sup>

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<sup>2</sup> The intrinsic evidence in this case is decisive, making it unnecessary to review the expert evidence. *See SIPCO, LLC v. Emerson Electric Co.*, 939 F.3d 1301, 1307 (Fed. Cir. 2019) ("To the extent the Board considered extrinsic evidence when construing the claims, we need not consider the Board's findings on the evidence because the

Accordingly, we reverse the Board's claim construction.

## B

The Board relied on its erroneous claim construction throughout its consideration of facts that were part of its obviousness analysis. For example, in determining that a skilled artisan would have been motivated to combine JP '639, the '367 patent, or Hay with the Kaken Abstracts, the Board rejected Kaken's primary argument as inconsistent with the Board's claim construction. Before the Board, Kaken argued that because the Kaken Abstracts document experiments testing KP-103 *in vitro* and in skin (in the ordinary, not patent-defined sense), a skilled artisan would not have been motivated to use KP-103 to treat onychomycosis. *See Acrux*, 2018 WL 2761408, at \*20. The Board concluded that this argument "relies upon an improperly narrow interpretation of the claim terms 'nail' and 'onychomycosis'" and "hinge[s] on a requirement that is not in the challenged claims, treatment of onychomycosis in the nail plate or nail bed." *Id.* Accordingly, the Board dismissed Kaken's arguments as "misdirected." *Id.*

Similarly, the Board rejected Kaken's objective indicia of non-obviousness because it concluded, relying on the claim construction we have concluded is erroneous, that there is no nexus between the objective indicia and the challenged claims. In its Patent Owner's response, Kaken

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intrinsic record is clear."); *Eidos Display, LLC v. AU Optonics Corp.*, 779 F.3d 1360, 1365 (Fed. Cir. 2015). With one possible exception, the evidence on both sides is uniform about the nail-penetrating character of onychomycosis addressed by the patent. The one possible exception involves an entirely superficial, on-the-nail fungus that commonly can be just scraped off. *See Acrux*, 2018 WL 2761408, at \*5. The intrinsic evidence is inconsistent with including treatment of that fungus within the claim scope.

identified KP-103 as the “active pharmaceutical ingredient in Jublia<sup>®</sup>, the first FDA-approved monotherapy for the topical treatment of onychomycosis.” J.A. 1121. Kaken made several objective-indicia arguments based on Jublia<sup>®</sup>: that Jublia<sup>®</sup> produced unexpected results; that Jublia<sup>®</sup> has had significant commercial success; that Jublia<sup>®</sup> received industry praise; and that Jublia<sup>®</sup> fulfilled a long-felt, but unmet need. *See Acrux*, 2018 WL 2761408, at \*22–26. But before considering any of those arguments, the Board pointed to evidence that the FDA approved Jublia<sup>®</sup> as a “topical treatment of onychomycosis of the toenails,” and Jublia<sup>®</sup>’s label directs the user to “apply Jublia<sup>®</sup> to affected toenails once daily.” J.A. 1809; *see Acrux*, 2018 WL 2761408, at \*23. Because “Jublia<sup>®</sup> is directed to treatment of specific fungal infections in toenails, and not to a ‘nail’ or to treat ‘onychomycosis,’” the Board explained, the “method for Jublia<sup>®</sup>’s use is not reasonably commensurate with the [scope] of the challenged claims.” *Acrux*, 2018 WL 2761408, at \*23. Thus, the Board concluded, the objective indicia presented by Kaken “do not weigh in favor of a finding that the subject matter of the claims would not have been obvious.” *Id.* at \*24.

The foregoing determinations are infected by the erroneous claim construction. In this court, the Director has sought to support the Board’s factual findings with little or no reliance on the claim construction we have held to be erroneous. But that effort is more a reconstruction of the Board’s analysis than a description of the Board’s actual reasoning. We conclude that the appropriate course in this case, as in so many others involving a reversal of a Board claim construction, is to vacate the Board’s decision and remand the matter. *See, e.g., Arista Networks, Inc. v. Cisco Sys., Inc.*, 908 F.3d 792, 798 (Fed. Cir. 2018); *Dell Inc. v. Accelaron, LLC*, 818 F.3d 1293, 1300 (Fed. Cir. 2016). We do not prejudge whether the correct claim construction permits the same factual findings or obviousness conclusion,



KAKEN PHARMACEUTICAL CO., LTD. v. IANCU

17

let alone what factual findings should be made on the evidence when the correct claim construction is used. Nor do we prejudge what effect the withdrawal of Acrux has on how the Board should proceed on remand.

### III

For the foregoing reasons, we reverse the Board's claim construction, vacate the Board's final written decision, and remand the matter to the Board.

Costs awarded to appellants.

**REVERSED IN PART, VACATED, AND REMANDED**