United States Court of Appeals for the Federal Circuit

JAZZ PHARMACEUTICALS, INC.,
Appellant

v.

AMNEAL PHARMACEUTICALS, LLC,
Appellee

2017-1671, 2017-1673, 2017-1674, 2017-1675, 2017-1676, 2017-1677, 2017-2075

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2015-00545, IPR2015-00546, IPR2015-00547, IPR2015-00548, IPR2015-00551, IPR2015-00554, IPR2015-01903.

Decided: July 13, 2018

KATHLEEN M. SULLIVAN, Quinn Emanuel Urquhart & Sullivan, LLP, New York, NY, argued for appellant. Also represented by F. DOMINIC CERRITO, GABRIEL P. BRIER, FRANK CHARLES CALVOSA, EVANGELINE SHIH, ERIC C. STOPS; DAVID B. COCHRAN, Jones Day, Cleveland, OH.

STEVEN ARTHUR MADDOX, Maddox Edwards, PLLC, Washington, DC, argued for appellee Also represented by MATTHEW C. RUEDY.

Before NEWMAN, LOURIE, and REYNA, *Circuit Judges.*

LOURIE, *Circuit Judge.*

Jazz Pharmaceuticals, Inc. ("Jazz") appeals from six *inter partes* review ("IPR") decisions of the United States Patent and Trademark Office Patent Trial and Appeal Board (the "Board").[1] Collectively, the decisions held certain claims of Jazz's U.S. Patents 7,668,730 ("'730 patent"), 7,765,106, 7,765,107, 7,895,059, 8,589,182, 8,457,988 ("'988 patent"), and 8,731,963 ("'963 patent") (together, the "patents in suit") invalid as obvious. Because the Board did not err in its conclusions of obviousness, we affirm.

BACKGROUND

The patents in suit are members of a family of patents owned by Jazz relating to a drug distribution system for tracking prescriptions of a "sensitive drug." '730 patent

---

[1] *Amneal Pharm., LLC v. Jazz Pharm., Inc.*, No. IPR2015-01903, 2017 WL 1096638 (P.T.A.B. Mar. 22, 2017) ("*'963 Decision*"); *Amneal Pharm., LLC v. Jazz Pharm., Inc.*, No. IPR2015-00545, 2016 WL 7985452 (P.T.A.B. Dec. 22, 2016); *Par Pharm., Inc. v. Jazz Pharm., Inc.*, No. IPR2015-00546, 2016 WL 7985429 (P.T.A.B. Dec. 22, 2016); *Par Pharm., Inc. v. Jazz Pharm., Inc.*, No. IPR2015-00547, 2016 WL 7985454 (P.T.A.B. Dec. 22, 2016); *Par Pharm., Inc. v. Jazz Pharm., Inc.*, No. IPR2015-00548, 2016 WL 7985430 (P.T.A.B. Dec. 22, 2016); *Par Pharm., Inc. v. Jazz Pharm., Inc.*, Nos. IPR2015-00551, IPR2015-00554, 2016 WL 7985458 (P.T.A.B. July 27, 2016) ("*'730/'988 Decision*").

Abstract.[2] "A sensitive drug is one which can be abused, or has addiction properties or other properties that render the drug sensitive." '730 patent col. 3 ll. 14–16.

One such sensitive drug is Xyrem®. Jazz exclusively markets Xyrem®, which the U.S. Food and Drug Administration ("FDA") has approved to treat symptoms associated with narcolepsy. However, the active ingredient in Xyrem®, gamma-hydroxybutyrate ("GHB"), may also be illicitly used as a "date-rape drug." *See* Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000, Pub. L. No. 106-172, 114 Stat. 7 (2000). Accordingly, under the Controlled Substances Act any approved drug product containing GHB is classified as a Schedule III depressant. 21 C.F.R. § 1308.13. Because of its potential for abuse, the FDA approved Xyrem® under "restricted distribution regulations contained in [21 C.F.R. § 314.500] (Subpart H) to assure safe use of the product." J.A. 11055; *see* 21 C.F.R. § 314.520.

During the regulatory review process for Xyrem®, the FDA scheduled an advisory committee meeting for June 6, 2001. The meeting was announced in a May 14, 2001 Federal Register Notice, which stated that the meeting was open to the public and that "[a] main focus of the deliberations will be on risk management issues" associated with Xyrem®. Meeting Notice, 66 Fed. Reg. 24,391 (May 14, 2001) ("Notice"). The Notice also provided a hyperlink to an FDA website where background material would be posted before the meeting, and the meeting minutes, transcript, and slides would be posted after the meeting. *Id.* Collectively, the Board referred to the background materials and the meeting minutes, transcript, and slides on the FDA website as the Advisory

---

[2] As the patents in suit share a substantially identical specification, for ease of reference we cite only the '730 patent.

Committee Art ("ACA materials"). Each of the Board's obviousness determinations relied on the ACA materials as prior art. The primary issue on appeal is whether the ACA materials were sufficiently accessible to the public to constitute prior art.

I

The claimed invention of the patents in suit involves tracking prescriptions of a sensitive drug through a database. '730 patent Abstract. Claim 1 of the '730 patent is illustrative, and recites:

> 1. A computerized method of distributing a prescription drug under exclusive control of an exclusive central pharmacy, the method comprising:
>
> receiving in a computer processor all prescription requests, for any and all patients being prescribed the prescription drug, only at the exclusive central pharmacy from any and all medical doctors allowed to prescribe the prescription drug, *the prescription requests containing information identifying patients, the prescription drug, and various credentials of the any and all medical doctors*;
>
> *requiring entering of the information into an exclusive computer database* associated with the exclusive central pharmacy for analysis of potential abuse situations, such that all prescriptions for the prescription drug are processed only by the exclusive central pharmacy using only the exclusive computer database;
>
> checking with the computer processor the credentials of the any and all doctors to determine the eligibility of the doctors to prescribe the prescription drug;

> confirming with a patient that educational material has been read prior to shipping the prescription drug;
>
> checking the exclusive computer database for potential abuse of the prescription drug;
>
> mailing the prescription drug to the patient only if no potential abuse is found by the patient to whom the prescription drug is prescribed and the doctor prescribing the prescription drug;
>
> confirming receipt by the patient of the prescription drug; and
>
> generating with the computer processor *periodic reports via the exclusive computer database to evaluate potential diversion patterns*.

Id. col. 8 l. 37–col. 9 l. 3 (emphases added).

Of particular relevance to this appeal are the "exclusive computer database," "information identifying," and "periodic reports" terms, italicized above. The specification describes an "exclusive central database" as including all data relevant to distribution of a sensitive drug, "including patient, physician and prescription information." *Id.* col. 2 ll. 10–12. Several types of such information are listed in the description of figure 2. "The prescriber information contains standard contact information as well as license number, DEA number and physician specialty. Patient and prescription information includes name, social security number, date of birth, gender, contact information, drug identification, patient's appropriate dosage, and number of refills allowed . . . ." *Id.* col. 4 ll. 18–23.

Reports may be run against information in the database to "reveal potential abuse of the sensitive drug, such as early refills." *Id.* col. 2 ll. 14–15. An early refill report is made when a specific event occurs: a patient requests a

prescription refill prior to the scheduled refill date. *Id.* col. 6 ll. 36–42. If the physician does not approve the early refill, the patient must wait until the next scheduled refill date. *Id.* col. 6 ll. 43–44. Other types of reports are created at set time points, for example, at "a predetermined number of days or product remaining." *Id.* col. 6 ll. 12–13. Likewise, the specification discusses "sample reports" that have "an associated frequency or frequencies." *Id.* col. 8 ll. 22–29. While claim 1 refers to "periodic reports," that specific term does not appear elsewhere in the written description.

II

Amneal Pharmaceuticals, LLC ("Amneal") petitioned for IPR of the seven patents in suit.[3] The Board instituted review of all petitioned claims for each patent except for the '963 patent, where the Board partially instituted review of a subset of the petitioned claims, *see Amneal Pharm., LLC v. Jazz Pharm., Inc.*, IPR2015-01903, slip op. at 2 (P.T.A.B. Mar. 25, 2016), Paper No. 10. Also, in several of its institution decisions, the Board instituted review on fewer than all grounds raised in the petition. *E.g.*, *Amneal Pharm., LLC v. Jazz Pharm., Inc.*, IPR2015-00551, IPR2015-00554, slip op. at 42 (P.T.A.B. July 28, 2015), Paper No. 20.

---

[3] Amneal filed several of its petitions for IPR jointly with Par Pharmaceutical, Inc. ("Par"). Jazz and Par reached a settlement during the pendency of this appeal, and accordingly Par is no longer a party. *See Jazz Pharm., Inc. v. Amneal Pharm., LLC*, No. 17-1671 (Fed. Cir. Jan. 19, 2018), ECF No. 51. In discussing the proceedings before the Board, we refer to the petitioners collectively as "Amneal."

The Board issued six final written decisions regarding the patents in suit.[4] The parties' current dispute centers on the Board's determination that the ACA materials were publicly accessible. The ACA materials consist of four documents associated with the public meeting held by the Xyrem® advisory committee: (1) the FDA advisory committee meeting transcript and slides; (2) an FDA preliminary clinical safety review of Xyrem®; (3) a Xyrem® briefing booklet; and (4) a video and transcript regarding a proposed distribution system for Xyrem®. *'730/'988 Decision*, 2016 WL 7985458, at *2; Appellant Br. 9. The Board determined that the ACA materials were publicly accessible on an FDA website listed in the Notice no later than October 4, 2001, over two months prior to the critical date of December 17, 2001. *'730/'988 Decision*, 2016 WL 7985458, at *11, *14.

Next, the Board turned to whether a person of ordinary skill exercising reasonable diligence would have been able to locate the ACA materials. *Id.* at *14–16. It found that a person of ordinary skill in the art was a pharmacist or computer scientist having familiarity with computerized drug distribution procedures. *Id.* at *4–5. Furthermore, the Board agreed with Amneal that a person of ordinary skill "would have been familiar with the Federal Register and motivated to look for notices related to drug distribution, safety, or abuse prevention," and that a skilled artisan would have known that Xyrem® contained an active ingredient susceptible to abuse. *Id.*; *see also id.* at *15. According to the Board, this provided a person of ordinary skill with "sufficient motivation to have located the Federal Register Notice and FDA web-

[4] For simplicity, unless otherwise noted we cite only the Board's final written decision concerning the '730 and '988 patents, which is representative of the other decisions on appeal. *See* Appellant Br. 9 n.5.

site for Xyrem." *Id.* at *15. Given that motivation, the Board found that a person of ordinary skill would have been capable of locating the Notice, as the Notice expressly stated that a "main focus of the deliberations will be on risk management issues" related to Xyrem®, and the basic purpose of the Federal Register is to provide "notice to interested individuals of the actions of federal agencies." *Id.* (internal quotation marks omitted).

The parties also dispute two of the Board's claim constructions and its obviousness analysis. First, the Board construed "periodic reports" to "refer to reports that are generated at regular intervals or intermittently," *id.* at *8, rejecting Jazz's argument that the term only included reports generated at regular frequencies, *id.* at *7. Second, the Board construed "information identifying patients" as "information identifying a patient," and not limited to the information listed in the specification or requiring all listed types of information. *Id.* at *8. Similarly, the Board construed "information identifying . . . various credentials of the any and all medical doctors" as "information identifying various credentials, i.e., at least two different types of credentials, of the prescribing doctor," and not limited to the information listed in the specification or requiring all listed types of information. *Id.* at *9.

Applying the above constructions, the Board held all instituted claims of the patents in suit unpatentable as obvious over the ACA materials alone or in combination with Robert R. Korfhage, *Information Storage and Retrieval* (1997) ("Korfhage"). The Board found that a person of ordinary skill would have been motivated to combine the ACA materials, *id.* at *16, and that the ACA materials collectively taught or suggested all limitations of the claims, *e.g.*, *id.* at *22, except for claims 2 and 10 of the '988 patent and claims 24, 26, and 27 of the '963 patent. The Board held those latter five claims obvious

over the ACA materials and Korfhage. *Id.* at *25; *'963 Decision*, 2017 WL 1096638, at *12, *14.

Claims 2 and 10 of the '988 patent depend from independent claims 1 and 9, respectively, and recite an exclusive central database "distributed over multiple computers, and wherein a query operates over all data in all the distributed databases relating to the prescriptions, the doctors, and the narcoleptic patients." '988 patent col. 9 ll. 14–16. The Board found that Korfhage disclosed a database that can be distributed over multiple computers for cost and efficiency reasons, and that a person of ordinary skill "would have been motivated to modify the [ACA] distribution system to include multiple computers in a distributed database system for reasons of cost, efficiency, and the anticipated volume of prescription-related information to be received, entered, and queried." *'730/'988 Decision*, 2016 WL 7985458, at *24. The Board credited Amneal's expert's testimony that distributed systems "were well-known in the art and that information systems were being driven toward distributed databases." *Id.* Accordingly, the Board held claims 2 and 10 unpatentable as obvious because implementing a database system on multiple computers "would have been a predictable use of a known distributed data system according to its established function." *Id.* at *25 (citing *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007)).

The Board conducted a similar obviousness analysis with respect to claims 24, 26, and 27 of the '963 patent. These claims also recite a "central computer database being distributed over multiple computers." '963 patent col. 11 ll. 19–20; *id.* col. 12 ll. 23–24. Again, the Board found that a person of ordinary skill "would have been motivated to distribute the ACA's single, centralized computer database over multiple computers, for reasons of cost, efficiency, and the anticipated volume of prescription-related information to be received, entered, and queried." *'963 Decision*, 2017 WL 1096638, at *9. The

Board later noted that the ACA materials disclose "a single, centralized database for controlling distribution of Xyrem." *Id.* at *12. It did so in the context of rejecting Jazz's argument that Korfhage emphasized systems having multiple databases. Crediting Amneal's expert, the Board explained that Korfhage also disclosed single database systems, consistent with the ACA system. *Id.* As with the other instituted claims of the patents in suit, the Board held claims 24, 26, and 27 unpatentable as obvious. *Id.* at *12, *14.

Jazz appealed, challenging the Board's holding that the ACA materials are prior art and its claim constructions and obviousness analysis. We consider each issue in turn.

DISCUSSION

I. Jurisdiction

We must first address whether we have jurisdiction over the entirety of Jazz's appeal. The Supreme Court recently decided that 35 U.S.C. § 318(a) prohibits the Board from instituting IPR of fewer than all claims challenged in a petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1353 (2018) ("The agency cannot curate the claims at issue but must decide them all."). However, following its pre-*SAS* regulation, *see* 37 C.F.R. § 42.108(a), the Board here did partially institute IPR. For the '963 patent, the Board instituted review of fewer than all claims challenged in the petition. And for several of the other patents, the Board did not institute review of each ground asserted in the petition. *See PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) ("Equal treatment of claims and grounds for institution purposes has pervasive support in *SAS*."). Nonetheless, on appeal neither party has requested a remand for the Board to consider non-instituted claims or grounds, or any other *SAS*-based relief.

We recently addressed a similar scenario in *PGS*. In *PGS*, the Board had instituted IPR of only some of the claims and grounds raised by the petitioner. *Id.* at 1358. But neither party on appeal "ask[ed] for any *SAS*-based action." *Id.* at 1359. Despite the Board's partial institution, we held that: (1) "the combination of the non-institution decisions and the final written decisions on the instituted claims and grounds 'terminated the IPR proceeding[s]'" so as to satisfy the finality requirement that this court has read to be incorporated in 28 U.S.C. § 1295(a)(4)(A), *id.* at 1361 (alteration in original) (quoting *Arthrex, Inc. v. Smith & Nephew, Inc.*, 880 F.3d 1345, 1348 (Fed. Cir. 2018)); and (2) any error committed by the Board under the Administrative Procedure Act in partially instituting IPR was waivable, so we could decide the appeal from the Board's final written decision absent a request by a party for *SAS*-based relief, *id.* at 1362–63.

Confronted with indistinguishable partially instituted IPRs and a lack of any request by either party for *SAS*-based action, we conclude that *PGS* controls this case. Under *PGS*, we have jurisdiction over Jazz's appeal under 28 U.S.C. § 1295(a)(4)(A) and are not obliged to reopen non-instituted claims or grounds. *Id.* at 1362. And we likewise see no reason to exercise any discretion to remand the non-instituted claims or grounds *sua sponte*. *See id.* at 1362–63.

II. Public Accessibility of the ACA Materials

Having concluded that we have jurisdiction over Jazz's appeal, we turn to the merits. We review the Board's legal determinations *de novo*, *In re Elsner*, 381 F.3d 1125, 1127 (Fed. Cir. 2004), but we review the Board's factual findings underlying those determinations for substantial evidence, *In re Gartside*, 203 F.3d 1305, 1316 (Fed. Cir. 2000). A finding is supported by substantial evidence if a reasonable mind might accept the evi-

dence as adequate to support the finding. *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938).

Jazz principally argues on appeal that the ACA materials are not prior art, so all of the Board's decisions relying on the ACA materials should be reversed. According to Jazz, the Board erred in concluding otherwise "by equating the constructive notice provided by the Federal Register with the law governing public accessibility of prior art." Appellant Br. 17. Emphasizing the substantial length of the annual Federal Register, Jazz asserts that the Board failed to make the requisite finding that a person of ordinary skill exercising reasonable diligence could have located the ACA materials. *Id.* Nor could the Board have made such a finding, Jazz contends, as under the facts of this case "searchability or indexing [is] required to conclude that the ACA [m]aterials are prior art," Reply Br. 10, and Amneal failed to submit any evidence of searchability or indexing.

Amneal responds that the ACA materials were widely disseminated, and that substantial evidence supports the Board's finding that a person of ordinary skill would have been motivated to find the ACA materials. Amneal further argues that neither indexing nor searchability is required under relevant case law.

This court and its predecessor have interpreted the "printed publication" provision of 35 U.S.C. § 102(b) (2006)[5] in light of its purpose "to prevent withdrawal by an inventor . . . of that which was already in the possession of the public." *Medtronic, Inc. v. Barry*, 891 F.3d

---

[5] Because the applications for each of the patents in suit were filed before March 16, 2013, the pre-Leahy-Smith America Invents Act version of § 102 applies. *See* Pub L. No. 112-29, 125 Stat. 284 (2011); 35 U.S.C. § 102 (2006).

1368, 1380 (Fed. Cir. 2018) (alteration in original) (quoting *In re Wyer*, 655 F.2d 221, 226 (CCPA 1981)). "Because there are many ways in which a reference may be disseminated to the interested public, 'public accessibility' has been called the touchstone in determining whether a reference constitutes a 'printed publication' . . . ." *In re Hall*, 781 F.2d 897, 898–99 (Fed. Cir. 1986). A reference is considered publicly accessible "upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it." *Wyer*, 665 F.2d at 226. "If accessibility is proved, there is no requirement to show that particular members of the public actually received the information." *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1569 (Fed. Cir. 1988).

Whether a reference qualifies as a "printed publication" under § 102(b) is a legal conclusion based on underlying factual findings. *E.g.*, *Suffolk Techs., LLC v. AOL Inc.*, 752 F.3d 1358, 1364 (Fed. Cir. 2014). As relevant to this issue, Jazz appeals only from the Board's underlying determination that the ACA materials were publicly accessible. Public accessibility is a question of fact that we review for substantial evidence. *In re NTP, Inc.*, 654 F.3d 1279, 1296 (Fed. Cir. 2011). As the IPR petitioner, Amneal had the burden to prove that a particular reference is a printed publication. *Medtronic*, 891 F.3d at 1380.

We agree with Amneal that substantial evidence supports the Board's finding that the ACA materials were publicly accessible. At the outset, we note that whether a reference is a "printed publication" is a "case-by-case inquiry into the facts and circumstances surrounding the reference's disclosure to members of the public." *In re Klopfenstein*, 380 F.3d 1345, 1350 (Fed. Cir. 2004). We thus review the pertinent facts here.

On May 14, 2001, the FDA announced a meeting of the Peripheral and Central Nervous System Drugs Advisory Committee through the Notice in the Federal Register. Notice, 66 Fed. Reg. 24,391 (May 14, 2001). The Notice stated that the meeting would be about "the safety and efficacy of . . . Xyrem," and that "[a] main focus of the deliberations will be on risk management issues." *Id.* The meeting would be "open to the public," and permit interested persons to "present data, information, or views, orally or in writing, on issues pending before the committee." *Id.*

The Notice also included a hyperlink to an FDA website where background material from the drug sponsor and the FDA would be posted before the meeting, and the meeting minutes, transcript, and slides would be posted after the meeting. *Id.* Furthermore, the Notice provided specific instructions on how to access the meeting materials on the FDA website: "Click on the year 2001 and scroll down to the Peripheral and Central Nervous Systems Drugs meetings." *Id.* Consistent with the guidance provided in the Notice, the Board found that the ACA materials were accessible on the hyperlinked public FDA website no later than October 4, 2001, over two months prior to the critical date of the patents in suit. *'730/'988 Decision*, 2016 WL 7985458, at *9, *11, *14. Jazz does not challenge that finding on appeal.

This is not the first time we have considered whether materials disclosed in association with meetings or conferences were "printed publications." In *Massachusetts Institute of Technology v. AB Fortia ("MIT")*, the reference at issue was a paper orally presented at a scientific conference attended by between 50 and 500 cell culturists. 774 F.2d 1104, 1108 (Fed. Cir. 1985). A copy of the paper was given to the head of the conference and to no more than six other persons, without restrictions, who requested the paper. *Id.* at 1108–09. We held that the paper was prior art because "between 50 and 500 persons interested

and of ordinary skill in the subject matter were actually told of the existence of the paper and informed of its contents by the oral presentation, and the document itself was actually disseminated without restriction to at least six persons." *Id.* at 1109.

Similarly, in *Klopfenstein*, several researchers presented slides at two scientific meetings for a total of approximately three days. 380 F.3d at 1347, 1350. At the meetings "[t]he reference was shown to a wide variety of viewers, a large subsection of whom possessed ordinary skill in the art." *Id.* at 1350. As in *MIT*, the slides were presented "with no stated expectation that the information would not be copied or reproduced by those viewing it." *Id.* After considering multiple factors, including the length of the display, the expertise of the intended audience, whether the presenters had a reasonable expectation that the materials would not be copied, and the ease or simplicity of copying the materials, we held that the slide presentation was sufficiently publicly accessible to count as a printed publication. *Id.* at 1350–52. We so held even though the slides were never distributed to the public and never indexed. *Id.* at 1350.

In *Cordis Corp. v. Boston Scientific Corp.*, a medical resident presented a scientific monograph to several physicians and other colleagues, and gave copies of the paper to approximately six of his teachers. 561 F.3d 1319, 1333 (Fed. Cir. 2009). Unlike in *MIT* and *Klopfenstein*, "[t]he record . . . contain[ed] clear evidence that . . . academic norms gave rise to an expectation that disclosures will remain confidential." *Id.* at 1334. Accordingly, in the context of a "distribution to a limited number of entities," we held that the resident's distribution of his monograph to academic and research colleagues did not make the monograph a prior art printed publication. *Id.*

Most recently, in *Medtronic* we considered whether distribution of a video and slides at several scientific

meetings on spinal surgery were prior art printed publications. *Medtronic*, 891 F.3d at 1379. A CD containing the video was distributed at three meetings, and the slides at two of those meetings. *Id.* As in *Klopfenstein*, there was no evidence that either the video or the slides were stored for public access after the meetings. *Id.* at 1381. The first meeting was limited to members of a certain professional organization, but the second and third meetings were open to other surgeons. *Id.* at 1379. Roughly 20 and 55 surgeons attended the second and third meetings, respectively. *Id.* The Board had held that the video and slides were not prior art, but neither distinguished the limited from the open meetings, nor addressed whether the video and slides were distributed with a reasonable expectation that they would remain confidential. *Id.* at 1382. As "the size and nature of the meetings[,] . . . whether they are open to people interested in the subject matter[,]" and "whether there is an expectation of confidentiality between the distributor and the recipients of the materials" are important factors in assessing public accessibility, we vacated the Board's finding that the video and slides were not prior art and remanded for further considerations. *Id.* at 1382–83.

Comparing the facts of this case to those in *MIT*, *Klopfenstein*, and *Medtronic* confirms that the ACA materials were disseminated more broadly and for a longer duration to persons of ordinary skill than the materials disclosed at individual meetings in those cases. In addition, unlike in *Cordis*, disclosure through public domain sources such as the Federal Register and a public federal agency website plainly indicates that there was no reasonable expectation that the ACA materials would remain confidential. As we explain below, each of these factors supports the Board's finding that the ACA materials were publicly accessible printed publications.

First, the breadth of the dissemination here to persons of ordinary skill is significant. "[A] printed publica-

tion need not be easily searchable after publication if it was sufficiently disseminated at the time of its publication." *Suffolk*, 752 F.3d at 1365. Unlike meetings of at most several hundred persons as in the cases above,[6] the Notice in the Federal Register widely disseminated the ACA materials through a hyperlink to a public FDA website where the ACA materials could be accessed. The Notice explained what materials were located on the FDA website, approximately when they would be available, and how to navigate to them.

Whether the disseminated material is addressed to or of interest to persons of ordinary skill is also relevant to the public accessibility inquiry. *See, e.g.*, *Klopfenstein*, 380 F.3d at 1351 (considering whether the reference "goes direct to those whose interests make them likely to observe and remember whatever it may contain that is new and useful") (internal quotation marks omitted)). The Board found, unchallenged on appeal, that a person of ordinary skill "would have been familiar with the Federal Register and motivated to look for notices related to drug distribution, safety, or abuse prevention." *'730/'988 Decision*, 2016 WL 7985458, at *4–5; *see also id.* at *15. In making that finding, the Board credited Amneal's expert, *id.* at *5, *15, and found that Jazz's expert's testimony was not to the contrary under the proper standard for a person of ordinary skill in the art, *id.* at

---

[6] The record in this case lacks any details regarding the FDA meeting itself—who attended and whether they were persons of ordinary skill, how long the meeting lasted, and whether copies of the ACA materials were distributed. Consequently, the Board did not address whether any potential distribution of the ACA materials at the meeting alone satisfied the "public accessibility" standard, and we do not address that possibility here in the first instance.

*15. As relevant here, wide dissemination of a reference through a publication like the Federal Register that those of ordinary skill would be motivated to examine is a factor strongly favoring public accessibility. *See Suffolk*, 752 F.3d at 1365; *Cordis*, 561 F.3d at 1333 (distinguishing case from situations involving "widespread distribution so that the public could easily obtain copies of the publication"); *see also Klopfenstein*, 380 F.3d at 1348 ("[A] public billboard targeted to those of ordinary skill in the art that describes all of the limitations of an invention and that is on display for the public for months may be neither 'distributed' nor 'indexed'—but it most surely is 'sufficiently accessible to the public interested in the art' and therefore . . . a 'printed publication.'").

Second, the ACA materials were available online for a substantial time before the critical date of the patents in suit. "[T]he longer a reference is displayed, the more likely it is to be considered a 'printed publication.'" *Klopfenstein*, 380 F.3d at 1351. In *Klopfenstein*, three days of slide presentations between two scientific meetings were enough. *Id.* at 1351–52. Here, the ACA materials were available on a public FDA website for at least two months before the critical date of the patents in suit. As with the breadth of dissemination, the length of time the ACA materials were available supports the Board's public accessibility finding.

Third, the ACA materials were distributed via public domain sources with no possible expectation that the materials would remain confidential or not be copied. We have consistently emphasized the importance of such expectations in determining whether a reference is publicly accessible. *See Medtronic*, 891 F.3d at 1382; *Cordis*, 561 F.3d at 1333–34; *Klopfenstein*, 380 F.3d at 1351; *MIT*, 774 F.2d at 1108–09. There can be no dispute that materials disclosed in the Federal Register and available online on a public FDA website have no expectation of confidentiality. This case bears no resemblance to *Cordis*,

where "academic norms gave rise to an expectation that disclosures will remain confidential." 561 F.3d at 1334. Like the factors considered above, the FDA's and drug sponsor's lack of any reasonable expectations of confidentiality support the Board's finding of public accessibility.

In sum, after considering the relevant factors identified in our public accessibility cases, the record here demonstrates that the ACA materials were widely disseminated to persons of ordinary skill for a substantial time with no reasonable expectation of confidentiality. They were "in the possession of the public," *Wyer*, 655 F.2d at 226, and cannot be withdrawn from it.

Jazz asserts that the Board's finding of public accessibility must be reversed because evidence of "searchability or indexing [is] required to conclude that the ACA [m]aterials are prior art," Reply Br. 10, and Amneal did not submit such evidence. Because neither indexing nor searchability was required, we reject Jazz's argument.

We have consistently held that indexing or searchability is unnecessary for a reference to be a printed publication under § 102(b). *Medtronic*, 891 F.3d at 1381 ("We have stated that a printed publication 'need not be easily searchable after publication if it was sufficiently disseminated at the time of its publication.'" (quoting *Suffolk*, 752 F.3d at 1365)); *Klopfenstein*, 380 F.3d at 1350 ("[D]istribution and indexing are not the only factors to be considered in a § 102(b) 'printed publication' inquiry."); *accord MIT*, 774 F.2d at 1108–09 (holding paper distributed at conference publicly accessible without considering indexing). Jazz has presented no persuasive argument for us to impose an indexing or searchability requirement here. Following our precedent, we decline to do so.

Moreover, even assuming that indexing is relevant to this case, the Federal Register was meaningfully in-

dexed.[7] The Notice was published on May 14, 2001, in issue 93 of the 66th annual volume of the Federal Register. 66 Fed. Reg., No. 93 (May 14, 2001). Consistent with its governing regulation, 1 C.F.R. § 6.1 ("Each daily issue of the Federal Register shall be appropriately indexed."), issue 93 included a five-page table of contents organized alphabetically by agency; each agency's rules, proposed rules, and notices are then listed in that order. Table of Contents, 66 Fed. Reg., No. 93, at III (May 14, 2001). FDA notices appear on the third page, with three entries in total. *Id.* at V. The last entry refers to the Notice at issue in this case. It includes the title of the Notice, "Meetings: Peripheral and Central Nervous Systems Drugs Advisory Committee," and provides the page number. *Id.*

Accepting the Board's unchallenged findings that a person of ordinary skill has a degree in either pharmacy or computer science, "was interested in drug distribution, safety, and abuse," and "would have had reason to look to the Federal Register and FDA Advisory Committee meeting notices," *'730/'988 Decision*, 2016 WL 7985458, at *4–5, *15, we are unpersuaded by Jazz's argument that the 2001 Federal Register "could be reviewed only page-by-page in paper format," Reply Br. 12, because the Federal Register was indexed with a table of contents organizing notices by agency. Thus, considering the multiple factors discussed above favoring public accessibility, Jazz's emphasis that the annual edition of the 2001 Federal Register was a lengthy 67,702 pages does not demonstrate the Board erred in finding that the ACA materials were publicly accessible.

Jazz also argues that the Board erred by "equating the constructive notice provided by the Federal Register

---

[7] "The contents of the Federal Register shall be judicially noticed . . . ." 44 U.S.C. § 1507 (2012).

with the legal standard for prior art." Appellant Br. 21. We disagree. In response to Jazz's argument that a person of ordinary skill would have been incapable of finding the Notice, the Board observed that "[t]he Federal Register provides notice to interested individuals of the actions of federal agencies," and that a skilled artisan would have been motivated to seek out FDA meeting notices regarding drug abuse. *'730/'988 Decision*, 2016 WL 7985458, at *15 (citing *Aris Gloves, Inc. v. United States*, 154 F. Supp. 203, 209 (Cust. Ct. 1957) ("[C]ongress, by statutory enactment, has designated the 'Federal Register' as the official publication in which notices by departments of the Federal Government shall appear . . . ."). We do not interpret the Board's decision as applying a *per se* rule that every notice in the Federal Register satisfies the requirements for prior art, nor do we endorse such a rule that would supplant the case-by-case inquiry consistently applied throughout our case law. Nor do we discern any error in the Board's sensible observation that the purpose of the Federal Register is to provide notice of government action such as the advisory committee meeting here.

However, we do reiterate that "[i]f accessibility is proved, there is no requirement to show that particular members of the public actually received the information." *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1569 (Fed. Cir. 1988); *see also In re Lister*, 583 F.3d 1307, 1313–14 (Fed. Cir. 2009) ("[O]nce accessibility is shown, it is unnecessary to show that anyone actually inspected the reference."). As we have explained, the ACA materials were publicly accessible because they were broadly disseminated to interested persons of ordinary skill for a substantial time with no expectations of confidentiality. The Board did not need to find that specific persons actually received or examined the materials.

For the foregoing reasons, we hold that substantial evidence supports the Board's finding that the ACA

materials were publicly accessible to persons of ordinary skill exercising reasonable diligence before the critical date of the patents in suit. Hence, they qualify as printed publications under § 102(b).

III. Claim Construction

We now turn to Jazz's claim construction arguments. Claim construction is a question of law that may involve underlying factual inquiries. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). We review the Board's claim construction based solely on intrinsic evidence *de novo*, while we review subsidiary factual findings regarding extrinsic evidence for substantial evidence. *HTC Corp. v. Cellular Commc'ns Equip., LLC*, 877 F.3d 1361, 1367 (Fed. Cir. 2017). The Board construed the claims on appeal according to their "broadest reasonable interpretation in light of the patent specification." *E.g.*, *'730/'988 Decision*, 2016 WL 2985458, at *5 (citing *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016)).

A. "periodic reports"

Jazz asserts that the Board erred in construing "periodic reports," as recited in claim 1 of the '730 patent, among others. According to Jazz, "periodic" as used in the claims means at regular frequencies, Appellant Br. 18, and the Board's construction renders the word superfluous.

Amneal responds that the Board properly construed "periodic reports" as including reports generated at irregular frequencies, and Jazz's proposed construction improperly adds limitations without support in the intrinsic or extrinsic evidence.

We agree with Amneal that the Board did not err in construing "periodic reports" to encompass reports generated at both regular and irregular intervals. *'730/'988 Decision*, 2016 WL 7985458, at *8. We begin with the

language of the claim itself. The claim does not define the word "periodic," nor does the written description ever use it. The Board considered dictionary definitions, some of which indicated "periodic" required regular intervals, while others suggested broader meanings of "repeated," "intermittent," or "occurring repeatedly from time to time." *Id.* at *7. While not decisive, the ordinary meaning of "periodic reports" is consistent with reports generated at irregular intervals. And although the meaning of "periodic" is broad, the word is not superfluous; a report that by its nature could only be generated once would not be "periodic."

We also look to the specification in interpreting the claims. The disclosure of the patents in suit further supports the Board's construction. The specification discloses two types of reports: reports made in response to a specific event that may occur at irregular intervals, such as early refill requests, '730 patent fig. 4B; *id.* col. 2 ll. 14–15; *id.* col. 6 ll. 33–37, and reports generated at regular frequencies, *id.* col. 6 ll. 12–13. Jazz argues that "periodic reports" refers only to the latter, and that the former reports are unclaimed embodiments. Appellant Br. 34. But Jazz provides no persuasive support in either the plain meaning of "periodic" or in the written description to exclude an embodiment repeatedly highlighted in the specification.

In addition, the prosecution history supports the Board's construction. During prosecution, the patent applicant pointed to several parts of the specification as providing written description support for the claim limitation "generating periodic reports via the exclusive computer database to evaluate potential diversion patterns." J.A. 14966. The cited disclosures referred specifically to early refill reports, J.A. 14993, and to the procedure for early refill requests, J.A. 15000, but not to reports generated at regular intervals. By indicating that the specification's disclosure of early refill reports provides written

description support for the "periodic reports" term, the prosecution history lends further support to the Board's construction that does not exclude reports generated at irregular frequencies from the scope of the claims.

Because the totality of the evidence supports the Board's construction of "periodic reports" but not Jazz's, we affirm the Board's construction.

B. "information identifying"

Jazz also argues that the Board erred in construing the various terms reciting "information identifying" patients and physicians, as recited in claim 1 of the '730 patent, among others. Contrary to the Board's construction, Jazz contends that the specification identified examples of such information, and those examples set forth the minimum content needed to satisfy the "information identifying" term because the specification uses the words "contains" and "includes." Appellant Br. 43.

Amneal responds that the Board properly construed the "information identifying" claim terms as potentially including the types of information listed in the specification, but not limited to those types of information and not requiring all types of that information. Again, Amneal argues that Jazz's construction improperly imports limitations from the specification into the claims.

We agree with Amneal that the Board did not err in rejecting Jazz's request to read into the claims a minimum set of identifying information. The claim language simply refers to "prescription requests containing *information identifying* patients, the prescription drug, and various credentials of the any and all medical doctors." *E.g.*, '730 patent col. 8 ll. 45–48 (emphasis added). It recites no specific types of identifying information. The specification does list various kinds of identifying information in discussing figure 2, *id.* col. 4 ll. 18–25, but never indicates that such information must be included in

the claimed "information identifying" a patient or physician. We decline to read such limitations into the broad claim language based on the specification's use of the word "contains" or "includes" in the context of describing a certain embodiment. Jazz cites no authority persuading us to do so. Thus, we affirm the Board's constructions of the claim terms reciting "information identifying."

IV. Obviousness

We finally consider Jazz's challenge to the Board's obviousness analysis. Obviousness is a question of law with underlying factual issues, including the scope and content of the prior art, differences between the prior art and the claims at issue, the level of ordinary skill, and relevant evidence of secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). Whether a skilled artisan would have been motivated to combine references is a question of fact. *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1051 (Fed. Cir. 2016) (en banc).

Jazz argues that the Board's finding that a person of ordinary skill would have been motivated to modify the ACA materials with the distributed system disclosed in Korfhage lacks substantial evidence with respect to claims 2 and 10 of the '988 patent and claims 24, 26, and 27 of the '963 patent. First, Jazz argues that the Board's decisions regarding the '963 and '988 patents are contradictory, so both cannot be right. Appellant Br. 47–48. Second, Jazz asserts that the Supreme Court's decision in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), requires that every finding of a motivation to combine be premised on subsidiary findings of "(1) whether there was a problem to be solved; and (2) whether there were a finite universe of possible options." Appellant Br. 49. Jazz contends that the Board failed to make such findings, so its decisions must be reversed.

Amneal responds that the Board's decisions are not contradictory, and that Jazz's reading of *KSR* would

impose "the exact sort of 'rigid preventative [rule] that [denies] factfinders recourse to common sense' the Court rejected." Appellee Br. 41 (alteration in original) (quoting *KSR*, 550 U.S. at 421).

We agree with Amneal that the Board's decisions are consistent. The Board made the same essential finding in both decisions that a person of ordinary skill would have been motivated to run the ACA materials' distribution system over multiple computers, as taught in Korfhage. *Compare '730/'988 Decision*, 2016 WL 7985458, at *24 ("[O]ne of ordinary skill would have been motivated to modify the [ACA materials'] distribution system to include multiple computers in a distributed database system for reasons of cost, efficiency, and the anticipated volume of prescription-related information to be received, entered, and queried."), *with '963 Decision*, 2017 WL 1096638, at *9 ("[A] [person of ordinary skill] would have been motivated to distribute the ACA's single, centralized computer database over multiple computers, for reasons of cost, efficiency, and the anticipated volume of prescription-related information to be received, entered, and queried."). When the Board discussed a "distributed database system" or "distributed databases," we understand it to have referred to a database implemented over multiple computers, consistent with the '988 patent itself, *see* '988 patent col. 10 ll. 29–34 (reciting "an exclusive central database . . . distributed over multiple computers," then referring to that system as "distributed databases").

We also agree with Amneal that Jazz misinterprets both the Supreme Court's decision in *KSR* and this court's obviousness precedent. *KSR* did not impose a rigid requirement to identify both a problem to be solved in the art and a finite universe of potential options. Rather, the Supreme Court rejected the teaching, suggestion, or motivation test, because the Court considered that the test was a "[r]igid, preventative rule[] that den[ies] factfinders recourse to common sense." *KSR*, 550 U.S. at 421.

Furthermore, the Supreme Court also rejected the "assumption that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem." *Id.* at 420. We have similarly recognized that persons of ordinary skill have diverse motivations, including "[t]he normal desire . . . to improve upon what is already generally known." *In re Ethicon, Inc.*, 844 F.3d 1344, 1351 (Fed. Cir. 2017); *see also Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1291 (Fed. Cir. 2012) ("New compounds may be created from theoretical considerations rather than from attempts to improve on prior art compounds.").

KSR did state that "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp." *KSR*, 550 U.S. at 421. But it did not set forth such factors as part of a mandatory formula. To treat them as such would be inconsistent with *KSR*'s holding and our own case law. Thus, the Board did not err in concluding that implementing the ACA materials' centralized database system on multiple computers "would have been a predictable use of a known distributed data system according to its established function." *'730/'988 Decision*, 2016 WL 7985458, at *25 (citing *KSR*, 550 U.S. at 417). As Jazz has presented no other arguments challenging the Board's finding of a motivation to modify, we affirm its holdings with respect to claims 2 and 10 of the '988 patent and claims 24, 26, and 27 of the '963 patent.

CONCLUSION

We have considered Jazz's remaining arguments, and find them unpersuasive. For the foregoing reasons, we affirm the Board's decisions.

AFFIRMED