UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/054,899	02/26/2016	Karine Deffez	298046-19	5327

3705 7590 01/30/2020

ECKERT SEAMANS CHERIN & MELLOTT LLC
U.S. Steel Tower
600 Grant Street, 44th Floor
Pittsburgh, PA 15219

EXAMINER	
YOUNG, MICAH PAUL	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
01/30/2020	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipmail@eckertseamans.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte KARINE DEFFEZ and JEAN-PIERRE CASSIERE

Appeal 2019-004972
Application 15/054,899
Technology Center 1600

Before ERIC B. GRIMES, ULRIKE W. JENKS, and
RACHEL H. TOWNSEND, *Administrative Patent Judges.*

GRIMES, *Administrative Patent Judge.*

DECISION ON REQUEST FOR REHEARING

Appellant requests rehearing of the Decision entered November 7, 2019 ("Decision"). The request for rehearing is denied.

Appellant argues that the Decision improperly interprets the claim language as being open to a swellable clay disintegrant, in addition to one or more of the disintegrants expressly recited in the claims. Req. Reh'g 2. Appellant argues that

> [t]he prosecution history shows that through the series of amendments, Appellant limited the scope of the claims to exclude any disintegrant beyond those specifically recited in the claims. Specifically, . . . Appellant amended claim 16 to recite "consisting of" with reference to the closed Markush group of disintegrants. Appellant's prosecuting attorney advised the examiner that the amendment expressly distinguished the cited reference by stating, "[i]n contrast to the subject matter of the

> instant claims, Patel '221 teaches a particularly soluble CNS compound and requires swellable clay as a disintegrating agent."

Id. at 4 (footnotes omitted). Appellant asserts that "[**t**]**he prosecution record clearly and unambiguously illustrates the fact that Appellant's claims expressly exclude swellable clay as a disintegrant**." *Id*. at 5.

This argument is unpersuasive. "[T]he PTO gives a disputed claim term its broadest reasonable interpretation during patent prosecution." *In re Bigio*, 381 F.3d 1320, 1324 (Fed. Cir. 2004). "Absent claim language carrying a narrow meaning, the PTO should only limit the claim based on the specification or prosecution history when those sources expressly disclaim the broader definition." *Id*. at 1325.

Here, the statement made during prosecution and cited by Appellant simply notes that Patel's composition differs from the claimed tablets in two respects: (a) it has a different active agent and (b) it includes a swellable clay disintegrant. *See* Req. Reh'g 4. The statement does not expressly disclaim compositions comprising a swellable clay disintegrant or, more broadly, compositions comprising any disintegrant that is not expressly recited in the claims.

"The 'broadest reasonable interpretation' rule recognizes that 'before a patent is granted the claims are readily amended as part of the examination process.' Thus, a patent applicant has the opportunity and responsibility to remove any ambiguity in claim term meaning by amending the application." *In re Bigio*, 381 F.3d at 1324 (citation omitted). Appellant retains the ability to amend the claims to unambiguously limit their scope, if that is desired.

Appellant also argues that a narrow interpretation of the claims is supported by *Shire Development LLC v. Watson Pharms. Inc.*, 848 F.3d 981 (Fed. Cir. 2017). Req. Reh'g 5. According to Appellant, claim 16 on appeal is directly analogous to the claims at issue in *Shire*, in which

> [t]he Federal Circuit held that, "[h]ere, claim 1's (a) and (b) limitations use the phrase "consisting of," or "consists of," to characterize the matrix, and "consisting of" to define the groups, which "creates a very strong presumption that that claim element is 'closed' and therefore 'exclude[s] any elements, steps, or ingredients not specified in the claim." Overcoming this presumption requires "the specification and prosecution history" to "unmistakably manifest an alternative meaning," such as when the patentee acts as its own lexicographer.

Id. at 7.

We disagree that *Shire* supports interpreting the claims to exclude disintegrants other than those expressly recited. In *Shire*, the relevant limitations recited "a) an inner lipophilic matrix consisting of substances selected from the group consisting of" certain compounds, and "b) an outer hydrophilic matrix wherein the lipophilic matrix is dispersed, and said outer hydrophilic matrix consists of compounds selected from the group consisting of" certain polymers. *Shire*, 848 F.3d at 983 (emphasis omitted).

The court noted that "claim 1's (a) and (b) limitations *use the phrase 'consisting of,' or 'consists of,' to characterize the matrix*, and 'consisting of' to define the groups." *Id*. at 984 (emphasis added). Appellant's claims, by contrast, do not use "consisting of" to characterize either the claimed tablet or a specific structural component that would be comparable to the matrices in Shire's composition. Thus, the *Shire* court's claim interpretation does not apply here.

The court recently considered claims that are similar to Appellant's in *Amgen Inc. v. Amneal Pharms. LLC*, 2020 WL 62012 (Fed. Cir. Jan. 7, 2020). Claim 1 in that case recited "[a] pharmaceutical composition comprising . . . (d) from about 1% to 10% by weight of at least one disintegrant selected from the group consisting of crospovid[o]ne, sodium starch glycolate, croscarmellose sodium, and mixtures thereof." *Id*. at *1–2.

The court considered the argument that *Shire* required interpreting the claim language to exclude any unrecited disintegrants, but concluded that the argument "read more into . . . *Shire* than is properly found there." *Id*. at *6. In *Shire*, "the issue presented to and decided . . . was framed solely in terms of interpreting element (b) [the outer matrix], without any reliance on the 'comprising' language of the general transition phrase of claim 1." *Id*. at *8.

By contrast, the issue in *Amgen* was

> [w]hether all binders or disintegrants in the claimed formulation are subject to the specific binder or disintegrant limitations. The answer, we conclude, is no. There is no language in Amgen's claim indicating that every binder or disintegrant in the claimed formulation must be within the Markush groups. Instead, the claim recites "at least one" binder or disintegrant "selected from the group consisting of" various excipients.

Id. The court concluded that "[t]he plain language of this claim requires 'at least one' of the Markush members and certainly does not indicate that the only binders and disintegrants in the claimed formulation are those listed in the groups." *Id*.

The court went on to note that,

> [i]mportantly, we also have the "comprising" language. . . . [T]he language of the binder and disintegrant limitations is not inconsistent with the presence of binders and disintegrants beyond those identified in those limitations. Amgen's use of the

> "comprising" transition phrase reinforces the conclusion that the language of those limitations is best construed not to foreclose such additional binders and disintegrants. Thus, optional additional binders and disintegrants not recited in the Markush group may be included in the claimed formulation.

Id.

The *Amgen* court's claim interpretation is directly applicable to the very similar language of Appellant's claims. Thus, we conclude the similar language of the claims here require one or more of the recited disintegrants, but do not exclude the presence of Patel's swellable clay disintegrant.

Appellant also argues that the record shows a nexus between the evidence of secondary considerations, which relates to EXJADE®, and the claimed invention. Req. Reh'g 9. Appellant points to "Statement[s] of Fact throughout the prosecution history and record of this case . . . that EXJADE® is the commercial embodiment of the claimed subject matter." *Id*. at 10 (emphasis omitted). Specifically, Appellant points to statements made in remarks filed January 12, 2018, and in the Appeal Brief, stating that EXJADE® is the commercial embodiment of the claimed subject matter, that EXJADE® is "[t]he current subject matter," or that EXJADE® "is the invention disclosed and claimed." *Id*. at 10–11. Appellant also "chooses at this time to state the fact, in no uncertain terms, that Example 2 of the specification is the RLD [reference-listed drug] formulation of EXJADE®, *per se*." *Id*. at 17 (emphasis omitted).

These arguments are unpersuasive because they are simply that: arguments, not evidence. Relying on attorney argument as evidence to establish a factual matter is erroneous. *See Worlds Inc. v. Bungie, Inc.*, 903 F.3d 1237, 1246 (Fed. Cir. 2018) ("[W]e have some concern that the Board

may have relied on attorney argument as evidence that Activision was not controlling or funding these IPRs. *See . . . Icon Health & Fitness, Inc. v. Strava, Inc.*, 849 F.3d 1034, 1043 (Fed. Cir. 2017) ('Attorney argument is not evidence.'). . . . In light of these concerns, we find it appropriate to remand this case to the Board for further consideration.").

To be clear, we agree with Appellant that, if the evidence of record indicated that the components labeled "1.1" are fillers, components "1.2" are disintegrants, and components "1.3" are binders, the compositions described in the Specification's Example 2 would appear to meet the limitations of the claims on appeal. Evidence supporting the argument in the Request for Rehearing that Example 2 of the Specification is the formulation of EXJADE® thus would be one way to establish a nexus between the claimed invention and the evidence pertaining to EXJADE®. Other evidence could also establish the required nexus; e.g., a declaration under 37 C.F.R. § 1.132 that includes a factual basis for concluding that EXJADE® meets the limitations of the claims. The current record, however, lacks such evidence.

Appellant has submitted the "list of inactive ingredients that . . . exists on the original NDA 21-882 FDA-approved EXJADE® label." Req. Reh'g 12 (emphasis omitted), citing Exhibit I. Appellant's Exhibit I includes a description of EXJADE® that lists inactive ingredients including "crospovidone (NF)" and "microcrystalline cellulose (NF)." Req. Reh'g, Exhibit I, at 1. Crospovidone is cross-linked polyvinylpyrrolidone. Spec. 4. Thus, Appellant's evidence shows that EXJADE® includes at least one of the compounds recited as disintegrants in the claims. However, the evidence does not show that the total amount of the recited disintegrant(s) in

EXJADE® is "about 5 to 40% by weight based on the total weight of the tablet," as required by the claims. The EXJADE® label therefore is insufficient to establish a nexus between the claimed invention and the evidence pertaining to EXJADE®.

Appellant cites *In re DBC*, 545 F.3d 1373 (Fed. Cir. 2008), as supporting its position that the EXJADE® label shows that EXJADE® falls within the scope of the claims. Req. Reh'g 13–14. The record in *DBC*, however, included "three declarations pursuant to 37 C.F.R. § 1.132 . . . describ[ing], among other things, the ingredients in XanGo™ juice and the process for making it." *In re DBC*, 545 F.3d at 1383. In one declaration, the declarant "aver[red] personal knowledge of the contents of XanGo™ juice, based on discussions with employees, contractors, and officers of DBC." *Id*. The court held that "[u]nder the circumstances of th[at] case, no more is required to demonstrate that the XanGo™ juice falls within the scope of the claims, particularly when the product label itself demonstrates as much." *Id*.

Here, by contrast, the record does not include a declaration under 37 C.F.R. § 1.132 showing that EXJADE® falls within the scope of the instant claims, and the submitted product label does not show as much. Thus, *In re DBC* does not support reversal on the facts of this case.

DECISION SUMMARY

Outcome of Decision on Rehearing:

Claims	35 U.S.C. §	Reference(s)/Basis	Denied	Granted
16, 27–31	103(a)	Lattmann, Patel	16, 27–31	

Final Outcome of Appeal after Rehearing:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
16, 27–31	103(a)	Lattmann, Patel	16, 27–31	

REHEARING DENIED