Trials@uspto.gov
571.272.7822

Paper No. 12
Entered: December 7, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CSL BEHRING GMBH and CSL BEHRING LLC,
Petitioner,

v.

SHIRE VIROPHARMA INC.,
Patent Owner.

Case IPR2017-01512
Patent 9,616,111 B2

Before LORA M. GREEN, MICHAEL J. FITZPATRICK, and MICHELLE N. ANKENBRAND, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

CSL Behring GmbH and CSL Behring LLC (collectively "Petitioner" or "CSL") filed a Petition requesting an *inter partes* review of claims 1–18 of U.S. Patent No. 9,616,111 B2 (Ex. 1001,[1] "the '111 patent"). Paper 1 ("Pet."). Shire ViroPharma Inc. ("Patent Owner" or "Shire") filed a Preliminary Response to the Petition. Paper 8 (Prelim. Resp.).

Institution of an *inter partes* review is authorized by statute when "the information presented in the petition . . . and any response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314; *see* 37 C.F.R. §§ 42.4, 42.108. Upon considering the Petition, the Preliminary Response, and the cited evidence, we decline to institute an *inter partes* review of any of the challenged claims.

A. Related Proceedings

The '111 patent is asserted in *Shire ViroPharma Inc. v. CSL Behring LLC*, Case No. 17-414 (D. Del.). Pet. 63; Paper 5, 1.

B. The '111 Patent (Ex. 1001)

The '111 patent issued April 11, 2017, with Stephen Ruddy, Mark Cornell Manning, and Ryan Erik Holcomb as the listed co-inventors. Ex. 1001-A. The patent "provides compositions and methods for the

[1] We note that Petitioner attempted to file the '111 patent as Exhibit 1000, and its prosecution history as Exhibit 1001. Allowed exhibit numbers for Petitioner, however, start at "1001," and, thus, both the '111 patent and the prosecution history are designated in PTAB E2E as Exhibit 1001. Given that we are denying institution, we are not requiring Petitioner to correct the numbering of its exhibits. In this Decision, we cite the '111 patent as Ex. 1001-A and its file history as Ex. 1001-B.

treatment and/or prevention of disorders associated with C1 esterase inhibitor deficiency." *Id.* at 1:20–22.

The '111 patent teaches that "[h]ereditary angioedema (HAE) is a rare, life-threatening, genetic disorder caused by a deficiency of the C1 esterase inhibitor." *Id.* at 1:31–33. The disorder is "a result of a defect in the gene controlling the synthesis of the C1 esterase inhibitor." *Id.* at 1:39–41. According to the '111 patent, the "restoration of active C1 esterase inhibitor levels in patients having a disorder associated with deficient or reduced levels of active C1 esterase inhibitor (e.g., HAE) is an effective measure for treating such disorders." *Id.* at 2:7–10. The '111 patent notes that intravenous administration of a C1 esterase inhibitor, such as that under the trade-name of Cinryze, was known. *Id.* at 2:10–13. The '111 patent teaches "[s]urprisingly, the subcutaneous ['sc'] administration of the C1 esterase inhibitor is sufficient to maintain the blood levels of the C1 esterase inhibitor." *Id.* at 2:15–18. Thus, the '111 patent teaches formulations for subcutaneous administration. *Id.* at 2:13–15.

C. Challenged Claims

Petitioner challenges claims 1–18 of the '111 patent. Claim1 is the only independent challenged claim and is reproduced below:

> 1. A method for treating hereditary angioedema (HAE), said method comprising subcutaneously administering to a subject in need thereof a composition comprising a C1 esterase inhibitor, a buffer selected from citrate or phosphate, and having a pH ranging from 6.5-8.0, wherein the C1 esterase inhibitor is administered at a concentration of at least about 400 U/mL and a dose of at least about 1000 U, and wherein the administration of the composition comprising the C1 esterase inhibitor increases the level of C1 esterase inhibitor in the blood of the subject to at least about 0.4 U/mL, and wherein the C1 esterase inhibitor comprises an amino acid sequence at least

95% identical to residues 23 to 500 of SEQ ID NO:1.

Ex. 1001-A, 13:13–25.

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–18 of the '111 patent on the following grounds (Pet. 15, 38):

References	Basis	Claims Challenged
Schranz[2] (as evidenced by Cinryze Label[3] and Bock[4]), Gatlin,[5] Pharming,[6] and Levi[7]	§ 103(a)	1–18

[2] Schranz et al., *Safety, Pharmacokinetics (PK), and Pharmacodynamics (PD) of Subcutaneous (SC) CINRYZE® (C1 Esterase Inhibitor [Human])with Recombinant Human Hyaluronidase (rHuPH20) in Subjects with Hereditary Angioedema (HAE),* ViroPharma Incorporated, Poster L21 presented at the 2012 American Academy of Allergy, Asthma & Immunology annual meeting (Ex. 1004) ("Schranz").

[3] Cinryze® Prescribing Information, ViroPharma Incorporated, Nov. 2012 (Ex. 1010) ("Cinryze label").

[4] Bock et al., *Human C1 Inhibitor: Primary Structure, cDNA Cloning, and Chromosomal Localization*, 25 BIOCHEM. 4292–4301 (1986) (Ex. 1011) ("Bock").

[5] Larry A. Gatlin & Carol A. Brister Gatlin, *Formulation and Administration Techniques to Minimize Injection Pain and Tissue Damage Associated with Parenteral Products*, Chapter 17 *in* INJECTABLE DRUG DEVELOPMENT: TECHNIQUES TO REDUCE PAIN AND IRRITATION 401–421 (Pramod K. Gupta & Gayle A. Brazeau, eds., Interpharm Press 1999) (Ex. 1006) ("Gatlin").

[6] Mannesse et al., WO 2007/073186 A2, published June 28, 2007 (Ex. 1007) ("Pharming").

[7] Levi et al., *Self-administration of C1-inhibitor concentrate in patients with hereditary or acquired angioedema caused by C1-inhibitor deficiency*, 117 J. ALLERGY CLIN. IMMUNOL. 904–908 (2006) (Ex. 1009) ("Levi").

References	Basis	Claims Challenged
Jiang[8] (as evidenced by Cinryze Label and Bock), Gatlin, Pharming, Zuraw,[9] and Levi	§ 103(a)	1–18

Petitioner relies also on the Declaration of Timothy Craig, D.O. (Ex. 1012), the Joint Declaration of Thomas Machnig, M.D, and Hanno Waldhauser (Ex. 1013-A[10]), the Declaration of Hubert Metzner, Dr. rer. nat. (Ex. 1014), and the Declaration of Christopher J. Roberts, Ph.D. (Ex. 1015).

II. ANALYSIS

A. Claim Construction

We interpret claims using the "broadest reasonable construction in light of the specification of the patent in which [they] appear[]." 37 C.F.R. § 42.100(b); *see also Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under the broadest reasonable construction standard, claim terms are generally given their ordinary and customary meaning as would be understood by one of ordinary skill in the art at the time of the invention. *In re Translogic Tech., Inc*., 504 F.3d 1249, 1257 (Fed. Cir. 2007). "Absent claim language carrying a narrow meaning, the PTO should only limit the

---

[8] Jiang et al., *Subcutaneous Infusion of Human C1 Inhibitor in Swine*, 136 CLIN. IMMUNOL. 323–328 (2010) (Ex. 1005) ("Jiang").

[9] Zuraw et al., *Nanofiltered C1 Inhibitor Concentrate for Treatment of Hereditary Angioedema*, 363(6) N. ENGL. J.MED. 513–522 (2010) (Ex. 1008) ("Zuraw").

[10] Exhibit 1013 submitted with the Petition was refiled as Exhibit 1013-A after authorization by the Board to add language in a form prescribed by 28 U.S.C. § 1746, and the signatures of those individuals executing the declaration. Paper 9, 3.

claim based on the specification . . . when [it] expressly disclaim[s] the broader definition." *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004). We determine that no explicit construction of any claim term is necessary to determine whether to institute a trial in this case. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy. . . .'" (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

B. Obviousness over the Combination of Schranz (as evidenced by Cinryze Label and Bock), Gatlin, Pharming, and Levi

Petitioner asserts that claims 1–18 are rendered obvious by the combination of Schranz (as evidenced by Cinryze Label and Bock), Gatlin, Pharming, and Levi. Pet. 15–37. Patent Owner contends that Petitioner has not established a reasonable likelihood that the claims are rendered obvious by the combination of Schranz (as evidenced by Cinryze Label and Bock), Gatlin, Pharming, and Levi. Prelim. Resp. 6–53. And in particular, Patent Owner asserts that Petitioner has not established that Schranz is prior art to the challenged patent. *Id.* at 6–16.

i. Availability of Schranz (Ex. 1004) as Prior Art

35 U.S.C. § 311(b) states that a "petitioner in an inter partes review may request to cancel . . . claims of a patent only on a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications." Before considering the ground before us based on Schranz, we must address whether Petitioner has provided a sufficient threshold showing that Schranz constitutes prior art under 35 U.S.C. § 102—a legal question based on underlying factual determinations. *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568

(Fed. Cir. 1987); *Kyocera Wireless Corp. v. Int'l Trade Comm'n*, 545 F.3d 1340, 1350 (Fed. Cir. 2008).

Schranz, as Petitioner acknowledges, "is a hardcopy handout of a poster that was presented at the 2012 American Academy of Allergy, Asthma & Immunology ('AAAAI') annual meeting that was held from March 2 to March 6 in Orlando, Florida." Pet. 15 (citing Ex. 1013-A, ¶¶ 2–3). Relying on *In re Klopfenstein*, 380 F.3d 1345 (Fed. Cir. 2004), Petitioner asserts that Schranz "qualifies as a printed publication under 35 U.S.C. § 102(b)." Pet. 17.

Petitioner relies heavily on the Joint Declaration of Thomas Machnig and Hanno Waldhauser (Ex. 1013-A, "Joint Declaration") in asserting that Schranz is a printed publication. Pet. 17–18. Specifically, Petitioner relies on the Joint Declaration in asserting that the "AAAAI meeting at which *Schranz* was presented was attended by nearly 5,000 physicians and specialists in the area of allergy and immunology, as well as by academics and industry representatives in the field," that the "poster was displayed on March 6th and was accessible to all attendees, and the authors were present near the poster to answer questions," and that "the poster's abstract was published prior to the meeting in February 2012, and handouts of the poster were also freely available at the meeting." *Id.* at 17 (citing Ex. 1013-A ¶¶ 2–5).

Patent Owner responds that Exhibit 1013-A has two declarants, and, as such, it "'obscures the precise nature and origin of a number of factual assertions' to such an extent that it fails to demonstrate that *Schranz* was disseminated at all." Prelim. Resp. 9 (quoting *Dep't of Justice v. Iris Corp. Berhad*, IPR2016-00497, 9–10 (July 25, 2016) (Paper 7) (holding a joint

declaration to be an improper "combined document") (hereinafter, "*Dep't of Justice*")); (also citing Fed. R. Evid. 602 ("Need for Personal Knowledge")). Again quoting *Dep't of Justice,* Patent Owner asserts that the "Joint Declaration here also 'invites innumerable practical difficulties . . . in assessing the reliability of the statements made.'" *Id.* at 9–10 (quoting *Dep't of Justice* 10).

We agree with Patent Owner that the Joint Declaration of Thomas Machnig, M.D. and Hanno Waldhauser presents practical difficulties in the ability to determine the reliability of the statements made and the knowledge of each of the individual declarants. Dr. Machnig is a "trained physician for internal medicine and hold[s] the position of Director Medical Affairs at CSL Behring since Sept. 2010." Ex. 1013-A ¶ 1.a. In contrast, Mr. Waldhauser is a "trained commercial clerk and marketing / communication specialist and hold[s] currently the position of Director Marketing at CSL Behring and was acting as Senior Global Product Manager in March 2012 at time of the 2012 AAAAI Annual Meeting (March 2-6, 2012)." Ex. 1013 ¶ 1.b.

The declarants jointly state that "[w]e both attended the 2012 American Academy of Allergy, Asthma & Immunology (AAAAI) annual meeting that was held from March 2 to March 6 in Orlando, Florida." *Id.* ¶ 2. The declarants also note jointly that the Schranz poster was "displayed as a late breaker abstract" in the poster viewing area that was accessible to all registered delegates and exhibitors that attended the conference. *Id.* ¶ 4. In particular, the declarants jointly state "[i]n our recollection, the poster was presented by one of the authors on-site (as mandated by the conference) and discussed with relevant physicians who are actively treating patients with

Hereditary Angioedema as well as other industry representatives of other manufacturers of HAE therapies (including CSL Behring) while it was on display." *Id.* In addition, Dr. Machnig and Mr. Waldhauser jointly declare that "[h]andouts of the poster were freely available and picked-up by us as well as by other poster viewers." *Id.* ¶ 5.

As was the case in *Dep't of Justice*, the use of a joint declaration "invites innumerable practical difficulties in cross-examining the witnesses, in assessing the reliability of the statements made, and in evaluating the weight to be accorded to the opinions expressed." *Dep't of Justice* 10. For example, Dr. Machnig and Mr. Waldhauser declare in "our recollection." Ex. 1013-A ¶ 4. It is unclear how two different declarants can have the same "recollection." In addition, the declarants state that "[h]andouts of the poster . . . [were] picked up by us." *Id.* ¶ 5. It is unclear from the Joint Declaration, however, if both declarants were together when the hand-out was picked-up, or if each declarant picked up the handout at separate times.

We, therefore, afford the Joint Declaration of Dr. Machnig and Mr. Waldhauser little weight. *See Dep't of Justice* 11. As it is the primary evidence on which Petitioner relies to demonstrate that Schranz is prior art, we determine that Petitioner has not made a threshold showing that Schranz is prior art to the '111 patent. As Petitioner has not sufficiently demonstrated that Schranz is prior art to the '111 patent, we determine that the Petition does not demonstrate a reasonable likelihood that challenged claims 1–18 are rendered obvious by the combination of Schranz (as evidenced by Cinryze Label and Bock), Gatlin, Pharming, and Levi.

C. Obviousness Over the Combination of Jiang (as evidenced by Cinryze Label and Bock), Gatlin, Pharming, Zuraw, and Levi

Petitioner asserts that claims 1–18 are rendered obvious by the combination of Jiang (as evidenced by Cinryze Label and Bock), Gatlin, Pharming, Zuraw, and Levi. Pet. 38–50. Patent Owner contends that Petitioner has not established a reasonable likelihood that the claims are rendered obvious by the combination of Jiang as evidenced by Cinryze Label and Bock, Gatlin, Pharming, Zuraw, and Levi. Prelim. Resp. 17–47, 53–55. Among other arguments, Patent Owner asserts that we should exercise our discretion under 35 U.S.C. § 325(d), as the United States Patent and Trademark Office ("Office") already has considered Jiang. *Id.* at 53–55.

i. Analysis: 35 U.S.C. § 325(d)

Petitioner contends that the Examiner rejected the claims as being rendered obvious over Jiang as combined with a reference that recommended a total injection volume of approximately 2mL for subcutaneous administration. Pet. 11 (citing Ex. 1001-B, 3034–38); *see also id.* at 2 (noting that the Examiner relied on Jiang as the closest prior art, "and its disclosure of subcutaneous ('sc') administration of a 100U/mL formulation of C1-INH.").

According to Petitioner:

> With the aid of a declaration from a Shire employee, Dr. Schranz, which pointed to no evidence or support in the prior art, Shire made three main arguments: (1) there was a consensus in the field that C1-INH could not be formulated at a high-concentration in view of its large size, high glycosylation, high viscosity, and propensity to aggregate; (2) the claimed high-concentration formulations exhibited unexpected bioavailability; and (3) there was a long-felt need for subcutaneously-administered C1-INH that others had tried and

> failed to satisfy. Ex. 1002, 5-11 (¶¶ 11-24); Ex. 1001[-B], 2854-55, 2859-62, 3078-85.

Id. at 12 (footnote omitted); *see also* Ex. 1002 (Declaration of Dr. Schranz submitted during prosecution).

Petitioner notes that the Examiner initially did not find the Declaration of Dr. Schranz to be persuasive, with the Examiner stating that proteins of 150 kilodaltons or larger were known to be administered subcutaneously without major problems, and that the ordinary artisan would have reasonably expected that doubling the dosage would lead to roughly doubling of the bioavailability. *Id.* at 12–13 (citing Ex. 1001, 3040–3044). Petitioner asserts, however, that the Examiner withdrew the rejection and allowed the claims on essentially the same information, "concluding that '[t]he declaration and evidence as submitted by the Applicants as of 11 November 2016 has been found sufficient by the Examiner to establish secondary considerations in the form of long felt need and failure of others to rebut the *prima facie* case of obviousness.'" *Id.* at 13 (quoting Ex. 1001-B, 3453); *id.* at 50. Petitioner contends that "the Office . . . was mistakenly persuaded by Shire's unsubstantiated and misleading claims of long-felt need." *Id.* at 13; *see also id.* at 38 (stating that "Shire never overcame the Office's *prima facie* rejection based on *Jiang*.") In addition, Petitioner asserts that the "Examiner also overlooked the closest prior art," Schranz, "which Shire submitted for the first time in an IDS one week before receiving a Notice of Allowance." *Id.* at 13–14 (footnote omitted) (citing Ex. 1001-B, 3129–3132).

Petitioner asserts that "Shire's arguments regarding these alleged secondary considerations mischaracterized the evidence, misrepresented the facts, and misled the Examiner into concluding that those skilled in the art

had tried and failed to achieve a high-concentration sc C1-INH formulation." Pet. 50. Specifically, Petitioner contends that, as evidenced by Schranz, any need had been met at the time of invention, that is, March 2013. *Id.* at 52–53, 56. In addition, relying on *Media Technologies Licensing, LLC v. Upper Deck Co.*, 596 F.3d 1334, 1338–39 (Fed. Cir. 2010) (rejecting long-felt-but-unresolved-need argument that proposed an "overbroad" definition of the need and an "exceedingly narrow" definition of success), Petitioner argues that Applicant Shire defined the need overly broadly, that is, as subcutaneous treatment of HAE, and at the same time, defined success overly narrowly, that is, subcutaneous delivery of 1000–2000 U C1-INH in two to four milliliters, which "misled the Office into allowing the '111 patent." *Id.* at 51 (citing Ex. 1001-B, 2854, 2861).

In challenging the claims, the Petition relies on Jiang for disclosing a comparison on subcutaneous and intravenous administration of Cinzyme prepared at a concentration of 100U/ml. Pet. 38. According to the Petition, "[a]s the Office acknowledged, *Jiang* does not teach the claimed concentration of at least 400U/mL." *Id.* at 39 (citing Ex. 1001-B, 3035).

The Petition then relies on Gatlin for teaching that the ordinary artisan would have understood that subcutaneous injections should be limited to about 2 mL. *Id.* In that regard, we note that Petitioner acknowledges that, although the Examiner did not rely on Gatlin, the Examiner relied upon a reference with similar teachings in rejecting the claims. *Id.* at n.10. Thus, according to the Petition, "by increasing the concentration of *Jiang*'s formulations from 100U/mL to 400-575U/mL, [the ordinary artisan] could have administered the same 800-1150U doses in 2mL injections." *Id.* at 39 (citing Ex. 1012 ¶ 53; Ex. 1015 ¶ 52).

Patent Owner counters that we should deny institution under 35 U.S.C. § 325(d) "because CSL advances substantially the same art and arguments that were considered—and rejected—by the Patent Office during prosecution." Prelim. Resp. 3. In particular, Patent Owner argues that the Examiner did not just consider Jiang, but used that reference as combined with a reference with a similar disclosure to that of Gatlin in multiple rejections over the prior art. *Id.* at 3–4, 53.

According to Patent Owner, Petitioner is incorrect in asserting that the Examiner determined that Shire (Patent Owner) had not overcome the prima facie case, as the Examiner withdrew the rejection based not only on the secondary considerations, but also because Shire had overcome Jiang. *Id.* at 54. Specifically, Patent Owner notes that the Examiner stated in the Reasons for Allowance that "no obviousness rejection can be made in light of the secondary consideration[s] ***and*** nothing in the prior art suggests the dosages as instantly claimed for subcutaneous administration." *Id.* at 54–55 (quoting Ex. 1001-B, 3453) (alteration original).

We have discretion under 35 U.S.C. § 325(d) to reject a petition when the same or substantially the same prior art or arguments were presented previously in another proceeding before the Office. The relevant portion of that statute is reproduced below:

> In determining whether to institute or order a proceeding under this chapter, chapter 30, or chapter 31, the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.

35 U.S.C. § 325(d).

In the instant proceeding, we agree with Patent Owner that Petitioner is essentially making the same arguments as to obviousness over Jiang that

the Examiner already considered. The prosecution history demonstrates that the Examiner considered many of the same issues with respect to the Schranz Declaration as Petitioner is arguing here. Although the Examiner noted in allowing the claims that Applicant Shire had established the secondary consideration of long-felt need and failure of others, the Examiner also stated that the art did not suggest the claimed dosage.

We determine, therefore, that the Examiner did address the Schranz Declaration, and the Examiner's concerns are similar to those raised by Petitioner in the instant proceeding. That is, as the Examiner stated:

> The Examiner has considered the arguments found in Dr. Schranz's declaration concerning difficulty in higher concentration formulation. However, Dr. Schranz's declaration provides little more than an assertion that it is difficult to reach such a concentration formulation, as opposed to actual evidence establishing that this (1) was a recognized problem in the art and (2) was generally not achievable via other means.

Ex. 1001-B, 3041. Thus, the Examiner did acknowledge the lack of supporting evidence in the Schranz Declaration demonstrating that it was difficult to reach the claimed concentration.

The Examiner also addressed the issue of long-felt need. *Id.* at 3043–3044. Again, the Examiner noted that Dr. Schranz's Declaration "merely provide[s] assertions," without providing any supporting evidence. *Id.* at 3043. According to the Examiner: "The long-felt need may be present as alleged, but the arguments as such are right now merely assertions/opinions of a single expert, rather than evidence from the art as a whole that this is truly an art-recognized long felt need." *Id.* at 3044. The prosecution history, thus, does not support Petitioner's assertion that the Examiner was misled into allowing the challenged claims. *See* Pet. 51. Moreover, to the extent

that Petitioner is relying on the Schranz poster presentation as evidence that there was no long-felt need, as discussed above, Petitioner has not made a threshold showing to demonstrate that Schranz is prior art to the challenged patent.

Further, in indicating allowable subject matter, the Examiner noted that the prior art did not provide a dose of at least 400 U/ml, as the claims require. Ex. 1001-B, 3453. The Examiner noted that the declaration and evidence submitted by applicants was sufficient "to establish secondary considerations in the form of long felt need and failure of others," stating that "[a]s no obviousness rejection can be made in light of the secondary consideration[s] and nothing in the prior art suggests the dosages as instantly claimed for subcutaneous administration, the claims are found to be novel and unobvious." *Id.* Again, the prosecution history does not support Petitioner's assertion that the claims were allowed based on secondary considerations alone (Pet. 51), but also on the basis that the prior art did not suggest the claimed dosage. Importantly, Petitioner does not address that statement in the Petition, but instead characterizes the Examiner's statement of reasons for allowance (Ex. 1001-B, 3453) as being based on only the secondary consideration of long-felt need. *See* Pet. 50.

We determine, therefore, that Jiang was previously presented to, and considered by, the Office in the same substantive manner as Petitioner now advocates, and, thus, the same prior art and arguments were previously presented to the Office. Accordingly, balancing the competing interests and taking full account of the facts and equities involved in this particular matter, we exercise our discretion to deny the Petition as to the combination of Jiang (as evidenced by Cinryze Label and Bock), Gatlin, Pharming, Zuraw, and

Levi and decline to institute an *inter partes* review of that ground under 35 U.S.C. § 325(d).

III. CONCLUSION

For the foregoing reasons, we deny the Petition and do not institute trial as to any of the challenged claims of the '111 patent. Specifically, as to the challenge over the combination of Schranz (as evidenced by Cinryze Label and Bock), Gatlin, Pharming, and Levi, Petitioner has not made a threshold showing that Schranz is prior art to the challenged claims. And as to the challenge over the combination of Jiang (as evidenced by Cinryze Label and Bock), Gatlin, Pharming, Zuraw, and Levi, we exercise our discretion under 35 U.S.C. § 325(d) and decline to institute that challenge as we determine that essentially the same prior art and arguments were previously presented to the Office.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is denied as to all the challenged claims of the '111 patent.

PETITIONER:

Anthony C. Tridico
Amanda K. Murphy
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP,
anthony.tridico@finnegan.com
amanda.murphy@finnegan.com

PATENT OWNER:

Edgar H. Haug
Angus Chen
Andrew S. Wasson
Andrew S. Roper
HAUG PARTNERS LLP
EHaug@haugpartners.com
AChen@haugpartners.com
AWasson@haugpartners.com
aroper@haugpartners.com