UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANDOZ INC.,
Petitioner,

v.

ACERTA PHARMA B.V.,
Patent Owner.

Case IPR 2023-00478
Patent No. 10,272,083

PATENT OWNER'S AUTHORIZED SUR-REPLY

I. Section 325(d) – The Same or Substantially the Same Art and Arguments Were Previously Presented to the Patent Office.

There is no merit to the three arguments Sandoz raises in its Reply.

First, Sandoz contends that Barf is not the "same" as Barf-PCT. Reply, 1. But the relevant legal standard is whether Barf and Barf-PCT are "substantially the same." The specifications of Barf and Barf-PCT are identical, providing what Sandoz admits are the "same disclosures" as Barf's claims, Pet., 2, including acalabrutinib, treatment of MCL, and the dosing range. The Examiner considered those disclosures in Barf-PCT. POPR, 20-21. Sandoz's Reply does not address the numerous cases where the Board has found references with a common specification but different claims to be substantially the same. *Id.*, 21-22 (citing cases).

Second, Sandoz argues that Cheson is not cumulative because Smyth and Evarts' statements were "generic" rather than providing "specific motivations." Reply, 2. To the contrary, the Examiner considered the motivation provided by Smyth and Evarts to dose more than once daily. The Examiner initially found, for example, that it would be obvious to "follow" the teachings in Smyth and Evarts related to twice-daily dosing of compounds like ibrutinib to treat lymphomas. POPR, 23, 34; EX1004, 1035. Cheson thus discloses "the same proposition as previously presented prior art." *Panduit Corp. v. Corning Optical Communications LLC*, IPR2021-01562, Paper 20 at 15-16 (P.T.A.B. April 6, 2022); POPR, 23.

Third, Sandoz asserts the Examiner cited Barf-PCT "only as a secondary reference," and while "*Patent Owner* included Barf-PCT's dosing range in a block quote . . . *the Examiner* never cited or relied on it." Reply, 2-3. Those points are irrelevant. Art "previously presented to the Office" under § 325(d) includes "art made of record by the Examiner, and art provided to the Office by the applicant." *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 7-8 (P.T.A.B. Feb. 13, 2020) (precedential); *Keysight Technologies, Inc. v. Centripetal Networks, Inc.*, IPR2022-01421, Paper 9 at 9-10 (P.T.A.B. March 22, 2023) (rejecting argument that § 325(d) requires Examiner to discuss particular reference). The fact that Applicant quoted the relevant disclosure to the Examiner ensured that he considered it.

Sandoz also contends the Examiner "did not consider the Petition's arguments that a skilled artisan would have arrived at the claimed dosing regimen using clinical data, FDA guidance, and routine animal studies." Reply, 3. Not so. The Examiner considered arguments of routine dose finding and optimization when he initially concluded it would be obvious to "optimize the treatment of leukemia." POPR, 26.

II. Section 325(d) – The Examiner Did Not Materially Err.

The Examiner reasonably concluded the art as a whole—rather than cherrypicked soundbites from select references—pointed the POSA away from the claimed 100 mg, twice-daily dose. The prevailing wisdom at the priority date

required a "a large, once daily dosing" of a BTK inhibitor for an effective treatment of blood cancers. POPR, 40-42. The art focused on ibrutinib's FDA-approved 560 mg dose, and higher clinical doses for CC-292. *Id.*, 51-52. In light of that art, the Examiner found it unexpected that the Byrd 2016 study and Example 2 of the '083 patent would demonstrate superior, sustained levels of BTK inhibition, and an improved safety profile, using a 100 mg, twice-daily dose of acalabrutinib. *Id.*, 15, 40-42. Byrd is a preeminent researcher in the field and Sandoz's references extensively cite his clinical work. *E.g.*, EX1008, 4, 10; EX1019, 5; EX1029, 9. Given Byrd's direct involvement in ibrutinib clinical trials and data analysis, Byrd 2016's conclusions about the unexpected benefits of acalabrutinib's dosing regimen over ibrutinib's are highly probative. The Examiner did not err in crediting Patent Owner's evidence of unexpected properties grounded in the Byrd study.

Nor did Patent Owner "ignore" Advani and the FDA review, which Sandoz argues provide the expectation the Examiner found to be missing. Reply, 3-4; Pet. 31-33. Patent Owner addressed these arguments and the data at the heart of those references. POPR, 51. Patent Owner cited Advani in the provisional application to which the '083 patent claims priority, EX1004, 527, 573, and in the patent, EX1001, 56:19-26, 72:3-12. The Examiner further considered Advani's data when reviewing an IDS reference, WO 2013/059738, that had the same data. EX1004, 1048

(reference), 1052 (signature/initials). The data in the FDA review that Sandoz and its expert cite is the same Advani data. Pet., 19-20, Reply, 4.[1]

The Board has repeatedly exercised its § 325(d) discretion to deny institution where, as here, the Examiner's treatment of unexpected properties was reasonable. *Apotex Inc. et al. v. Auspex Pharmaceuticals, Inc.*, IPR2021-01507, Paper 9 at 33-36 (P.T.A.B. Mar. 9, 2022); *Biocon Pharma Limited v. Novartis Pharmaceuticals Corp.*, IPR2020-01263, Paper 12 at 15-18 (P.T.A.B. Feb. 16, 2021); *Initiative for Medicines, Access & Knowledge, Inc. v. Gilead Pharmasset LLC*, IPR2018-00125, Paper 9 at 17-18 (P.T.A.B. May 24, 2018); *Risen Pharma Tech. Co. Ltd. v. Alzheon, Inc.*, IPR2022-01200, Paper 14 at 31-35 (P.T.A.B. Jan. 9, 2023).

III. A Certificate of Correction Would Remove Barf as Prior Art.

Sandoz argues a certificate of correction "would not apply retroactively to this proceeding." Reply, n.1. Acerta has filed an authorized motion for leave to seek the certificate. Paper 11. The Director has issued certificates regarding joint research agreements promptly, making it likely that, if filed, a certificate will be of record early in the proceeding. *Commonwealth Sci. Indus. Research Org. v. Basf Plant*, PGR2020-00033, Paper 33 (P.T.A.B. May 20, 2021). Where a certificate affects the

[1] The Examiner not having the expert declaration is irrelevant; opponent declarations are rare in prosecution. The data cited in the declaration was before the Examiner.

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