UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GENZYME CORPORATION,
Petitioner

v.

GENENTECH, INC. AND CITY OF HOPE,
Patent Owners

Case No. IPR2016-00383
U. S. Patent No. 6,331,415

Petitioner's Reply to Patent Owners' Preliminary Response

As authorized by the Board (Paper 11), Petitioner Genzyme Corp. submits this Reply to Patent Owners' Preliminary Response ("POPR"), addressing the limited issue of the applicability of 35 U.S.C. §§ 315(e)(1) and 325(d) to Genzyme's Petition for *Inter Partes* Review of U.S. Patent No. 6,331,415 ("Cabilly II patent"). Patent Owners seek summary dismissal of Genzyme's IPR under §§ 315(e)(1) and 325(d), precluding the Board from reaching the significant new questions of patentability (based on a new prior art reference, the Salser patent) of the challenged "Cabilly II" patent claims presented by Genzyme. That Patent Owners dedicated nearly one-third of the POPR to these non-merit, threshold arguments telegraphs little faith in the validity of their patent. This is not surprising. The Salser patent has substantially different (but equally compelling) teachings—in both detail and functionality—than the prior art Bujard patent that was already considered favorably by the Board in instituting trial. The Board should therefore decline to dismiss the proceedings and agree to hear Genzyme's substantive arguments on invalidity. At a minimum, the Board should permit Genzyme's IPR to proceed to trial on the claims that were not instituted previously.

I. Sanofi and Regeneron's IPR Challenge to the Cabilly II Patent, the Decision Instituting Trial, and Genzyme's IPR

Sanofi-aventis U.S. LLC ("Sanofi U.S.") and Regeneron Pharmaceuticals filed IPR2015-01624 on July 27, 2016 ("Sanofi/Regeneron IPR"), challenging the validity of claims 1-4, 9, 11, 12, 14-20 and 33 of the Cabilly II patent. The petition

relied primarily on the Bujard patent as the base prior art reference and was supported by the expert declaration of Jefferson Foote. Sanofi U.S. identified Sanofi SA—the ultimate parent company (based in France) of Sanofi U.S.—as a real party-in-interest. This Panel issued an Institution Decision on February 5, 2016, permitting the matter to proceed to trial on Grounds 2 and 3, covering claims 1-4, 11, 12, 14, 18-20 and 33. IPR2015-01624, Paper 15, at 17-22. The Panel did not institute trial on Ground 1 and found Ground 4 to be redundant of Ground 2. *Id.* at 13-16, 23-24. Because claims 9 and 15-17 ("non-instituted claims") were not part of Grounds 2 and 3, they were not instituted on any ground.

On December 30, 2016—after IPR2015-01624 was filed, but before the Institution Decision was issued—Genzyme Corporation filed the present IPR. Genzyme identified Sanofi SA, its ultimate parent company, as a real party-in-interest. The Genzyme Petition challenged the same Cabilly II patent claims as the Sanofi/Regeneron Petition, but relied on a different base prior art reference (the Salser patent) for anticipation, and different grounds for the obviousness combinations, supported by the declaration of a different expert, Margaret Baron.

The table below sets out the challenged claims and grounds in both IPRs, as well as their present disposition following the Sanofi/Regeneron Institution Decision. Claims and grounds in green were instituted in the Sanofi/Regeneron IPR; claims and grounds in red were not. The claims in yellow are Genzyme's

§ 103 challenge to the non-instituted claims—a statutory ground for invalidity never presented (by any combination of references) in the Sanofi/Regeneron IPR for these claims.

	Challenged Claims														
Grounds	**1**	**2**	**3**	**4**	**9**	**11**	**12**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**33**
	Sanofi/Regeneron IPR														
1: Bujard (§102)	✓		✓	✓	✓	✓	✓		✓	✓	✓		✓		✓
2: Bujard + Riggs (§103)	✓		✓	✓		✓	✓	✓					✓		✓
3: Bujard + Southern (§103)	✓	✓										✓		✓	✓
4: Cohen + Riggs (§103) *(Redundant to Ground 2)*	✓		✓	✓		✓	✓	✓							✓
	Genzyme IPR														
1: Salser (§102)	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓
2: Salser + Ochi (I) (§103)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
3: Salser + Southern (§103)		✓										✓		✓	

II. The Board Should Not Dismiss the Petition Under 35 U.S.C. § 315(e)(1)

The relief that Patent Owners seek under § 315(e)(1)[1] is premature and overbroad. Patent Owners ask for immediate dismissal[2] of the entirety of

[1] Patent Owners cite to 35 U.S.C. § 325(e)(1) as the basis for dismissal. *See* POPR at 20-21. Because § 325(e) is the estoppel provision for post-grant reviews, Genzyme assumes Patent Owners intended to rely on 315(e)(1), which contains identical estoppel language in the IPR context.

[2] No later than July 7, 2016, the deadline for institution under § 314(b)(1).

Genzyme's IPR based on the possibility that the earlier-filed Sanofi/Regeneron IPR will reach a final written decision nine months from now[3] on no more than a subset of the Cabilly II patent claims in Genzyme's Petition. This extraordinary request is not warranted by the text of § 315(e)(1) or the decisions of the Board. Indeed, Patent Owners invite this Panel to improperly ignore the temporal limitations of the statute, which require that there be a final written decision on a first IPR before the second IPR can be subject to estoppel. *See* § 315(e)(1).

Genzyme is aware of no panel that has granted dismissal of a second petition under 315(e)(1) based on a first petition that had not yet reached a final determination.[4] Even when a final written decision in an earlier IPR was imminent (five weeks away), the Board has declined to dismiss a later-filed IPR, finding patent owner's request "premature." *Kofax. Inc. v. Uniloc USA, Inc.*, IPR2015-

[3] February 7, 2017, is the § 316(a)(11) one-year deadline for the final written decision in the Sanofi/Regeneron IPR.

[4] Patent Owners (POPR at page 21) rely on *Toyota Motor Corp. v. Cellport Systems, Inc.*, IPR2015-01422, Paper 8, in support of their argument. That decision incorrectly cites § 325(e)(1) as the applicable estoppel provision for IPRs. Nevertheless, the panel appears to have relied on the possibility of a future estoppel only as a basis to exercise discretion to deny institution under other statutory and regulatory grounds. IPR2015-01422, Paper 8, at 19-20.

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