

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TORRENT PHARMACEUTICALS LIMITED,
Petitioner,

v.

MERCK FROSST CANADA & CO.,
Patent Owner.

Case IPR2014-00559
Patent 6,448,274 B2

Before LORA M. GREEN, ERICA A. FRANKLIN, and
ZHENYU YANG, *Administrative Patent Judges*.

YANG, *Administrative Patent Judge*.

DECISION
Order Denying Petitioner's Request for Rehearing
37 C.F.R. § 42.71

I. INTRODUCTION

Torrent Pharmaceuticals Limited (“Petitioner”) filed a Petition for an *inter partes* review of claims 1 and 2 of U.S. Patent No. 6,448,274 (“the ’274 patent”). Paper 1 (“Pet.”). The Board denied the Petition. Paper 8 (“Dec.”). Petitioner filed a request for rehearing of the Board’s Decision.¹ Paper 9 (“Reh’g Req.”).

For the following reasons, we deny Petitioner’s request.

II. STANDARD OF REVIEW

When rehearing a decision on institution, the Board reviews the decision for an abuse of discretion. 37 C.F.R. § 42.71(c). An abuse of discretion occurs when a “decision was based on an erroneous conclusion of law or clearly erroneous factual findings, or . . . a clear error of judgment.” *PPG Indus. Inc. v. Celanese Polymer Specialties Co.*, 840 F.2d 1565, 1567 (Fed. Cir. 1988) (citations omitted). The request must identify, specifically, all matters the party believes the Board misapprehended or overlooked. 37 C.F.R. § 42.71(d).

¹ In an email to the Board dated November 14, 2014, lead counsel for Patent Owner Merck Frosst Canada & Co. stated that the ’274 patent “is now expired due to failure to pay the annuity fee. Merck has no intention of reviving this patent. Therefore, we submit that Torrent Pharmaceutical’s Motion for Reconsideration is moot and should be denied or dismissed as such.” Ex. 3001. We disagree. The expiration of a challenged claim, in and of itself, does not moot the unpatentability determination. *See, e.g., Toyota Motor Corp. v. Leroy G. Hagenbuch*, Case No. IPR2014-00124 (PTAB May 8, 2014) (Paper 14) (instituting *inter partes* review of claims of an expired patent).

III. DISCUSSION

In our Decision denying the Petition, we declined to institute an *inter partes* review of the challenged claims for anticipation by Fenton and obviousness over Fenton and Ashton. Dec. 7–10. In its rehearing request, Petitioner only seeks redress on the obviousness ground. Reh’g Req. 1.

According to Petitioner, we “misapprehended (1) the proper standard here for chemical obviousness and (2) the nature of Petitioner’s argument of how the prior art would have led the skilled person to obtain the specific molecules recited [in] the ’274 patent claims.” *Id.*

Petitioner alleges that we misapprehended the applicable law of obviousness because we stated:

Petitioner bases its asserted obviousness ground on the structural similarities between the claimed compound and the prior art compounds. [Citation omitted]. Generally, in such cases, to establish obviousness of a claimed compound, a challenger of the claim needs to identify some reason that would have led a skilled artisan to select and then modify a known compound. *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1357 (Fed. Cir. 2007).

Reh’g Req. 1–2 (quoting Dec. 8). Petitioner acknowledges that “‘in general’ the lead compound test is applicable in analyzing the skilled person’s motivation to achieve a claimed compound.” Reh’g Req. 4. According to Petitioner, however, in *Eisai Co. Ltd. v. Dr. Reddy’s Labs., Ltd.*, 533 F.3d 1353 (Fed. Cir. 2008), “the Federal Circuit specifically noted the applicability of other analyses, in step with *KSR*,” such that an “‘easily traversed, small and finite number of alternatives . . . might support an inference of obviousness.’” Reh’g Req. 4–5 (quoting *Eisai*, 533 F.3d at 1359). But, as the Federal Circuit noted in *Eisai*, the Supreme Court’s

analysis in *KSR* relied on several assumptions, including “presuppos[ing] that the record up to the time of the invention would give some reasons, available within the knowledge of one of skill in the art, to make particular modifications to achieve the claimed compound.” *Eisai*, 533 F.3d at 1359. In discussing this presumption, the court cited *Takeda*, reiterating that “in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound.” *Id.* (quoting *Takeda*, 492 F.3d at 1357). Accordingly, we determine that Petitioner has not established any error in our understanding and application of that principle of law.

Next, Petitioner alleges that we misapprehended the nature of its argument concerning the teachings of the prior art. Reh’g Req. 6. Petitioner points to the Decision where we referred to two compounds expressly listed in Fenton (compounds DI and DJ). *Id.* (citing Dec. 9–10). According to Petitioner, even though it asserted those two as the closest prior-art compounds, it did not assert them as lead compounds in analyzing obviousness. *Id.* As we noted in the Decision, Petitioner asserted those two compounds when discussing secondary considerations. Dec. 9–10. We explained that because Petitioner failed to establish a prima facie case of obviousness, we “need not examine the argument on secondary considerations.” *Id.* at 9. We then added that, had Petitioner intended to rely on these two compounds to establish a prima facie case of obviousness, it could not do so because it provided no reason that would have led a skilled artisan to select and then modify those two compounds. *Id.* at 10. In other words, our discussion relating to the selection of compounds DI and DJ as

lead compounds was based on a hypothetical assertion, and did not form the basis of our obviousness analysis. Further, as discussed in the Decision, we denied the Petition not because Petitioner failed to preselect “some full-fledged ‘lead compounds’” (*see* Reh’g Reg. at 7), but because “Petitioner has not shown that one of ordinary skill would have had a reason or motivation to modify the . . . prior art compounds” (Dec. 9).

Petitioner emphasizes that the benzamide backbone, the starting material of its obviousness analysis, is not an actual lead compound. Reh’g Reg. 6–7. We do not disagree. Regardless of how it characterizes the starting material, however, Petitioner failed to explain why a skilled artisan would have selected the substituents at six positions of the formula with a benzamide backbone to arrive at the claimed compound. *See* Dec. 9.

Petitioner insists that it “relied on the prior art’s express reasons for selecting particularly preferred substituents.” Reh’g Reg. 6. But the prior art provided numerous preferred substituents at each position. For example, according to Petitioner, challenged claim 1 has cyclopropylmethyl at the position corresponding to R² in Fenton. Pet. 17. Petitioner pointed to various teachings in Fenton, including: (1) “Further preferred” R² is alkyl substituted by halo, or cycloalkyl, cycloalkenyl or cyclothioalkyl; and (2) “Exemplary alkyl groups include methyl, fluoromethyl, difluoromethyl, trifluoromethyl, cyclopropylmethyl, cyclopentylmethyl, ethyl, *n*-propyl, *i*-propyl, *n*-butyl, *t*-butyl, *n*-pentyl, 3-pentyl, heptyl, octyl, nonyl, decyl and dodecyl.” *Id.* (citing Ex. 1002, 8:11–13, 13:7–13). It then leapt to the conclusion that “Fenton thus prefers cyclopropylmethyl at the R² position.” *Id.* Petitioner also pointed to Ashton for its preference of alkyl groups and “more especially, the cyclopentyl group” at R². *Id.* at 30 (citing Ex. 1003,

3). Similar to its analysis of Fenton, Petitioner jumped from Ashton's preference of *cyclopentyl* to its assertion that a skilled artisan would have chosen *cyclopropyl*, the substituent of the claimed compound. *Id.* Because Petitioner failed to explain why a skilled artisan would have picked cyclopropylmethyl over dozens of other substituents at the R² position, we described Petitioner's arguments as "tenuous at best." Dec. 9.

We nevertheless further entertained Petitioner's contentions to illustrate the point that "[f]ocusing on the obviousness of substitutions and differences instead of on the invention as a whole . . . was a legally improper way to simplify the difficult determination of obviousness." Dec. 9 (quoting *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1383 (Fed. Cir. 1986)). We stated:

Here, even assuming, as Petitioner contends, one skilled in the art would have chosen, *separately*, difluoromethyl at R¹, cyclopropylmethyl at R², 3,5-dihalopyrid-4-yl N-oxide at R³, oxygen at both Z¹ and Z², and CONH- at Z³, Petitioner has not sufficiently explained why one skilled in the art would have selected the claimed substituents at each of the six independent positions *all at once*.

Id.

In its rehearing request, Petitioner challenges this statement. Reh'g Req. 9. Petitioner misunderstands our reasoning. Again, using R² as an example, even if we were to assume a skilled artisan would have made the allegedly preferred substitutions at R¹, R³, Z¹, Z², and Z³ as claimed, Petitioner did not explain why a skilled artisan would have, at the same time, chosen cyclopropylmethyl over dozens of other preferred substituents at R². *See supra* at 5.

In its rehearing request, Petitioner repeatedly argues that this is a case where there was a design need or market pressure to solve a problem, and that there were a finite number of identified, predictable solutions. Reh'g Req. 5–6, 7, 10, 11. As an initial matter, Petitioner never made this assertion in the Petition, and thus, we could not have misapprehended it. *See* 37 C.F.R. § 42.71(d). More importantly, the possibility of solutions allegedly identified in the prior art is too numerous to qualify as “a finite number.” Indeed, Petitioner’s analyses of at least R¹ and R³ are similar to that of R². *See, e.g.*, Pet. 16–19. In other words, the prior art teaches various possible preferred substituents at these positions. As a result, there are hundreds, if not thousands, of combinations with different substituents at the six positions of the benzamide backbone. The Petitioner pointed to no persuasive evidence and provided no explanation why a skilled artisan would have picked the single combination with the substituents as in the claimed compound.

In sum, in the Petition, Petitioner did not establish a reasonable likelihood that it would prevail in showing Fenton and Ashton would have rendered the challenged claims obvious. On rehearing, we see no error in our fact findings or conclusions of law. Thus, we conclude that Petitioner has not demonstrated that we abused our discretion in denying institution of the challenged claims.

IV. ORDER

Accordingly, it is

ORDERED that Petitioner’s request for rehearing is *denied*.

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