

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COMPLEX INNOVATIONS, LLC,
Petitioner,

v.

AMGEN INC.,
Patent Owner.

Case IPR2016-00085
Patent 7,829,595 B2

Before LORA M. GREEN, JONI Y. CHANG, and
JACQUELINE T. HARLOW, *Administrative Patent Judges*.

HARLOW, *Administrative Patent Judge*.

DECISION
Denying Request for Rehearing
37 C.F.R. § 42.71

Petitioner, Complex Innovations, LLC (“CI”), requests rehearing of the Board’s Decision (Paper 8) (“Decision”) denying *inter partes* review of claims 1–25 of U.S. Patent No. 7,829,595 B2 (Ex. 1001, “the ’595 patent”). Paper 9 (“Req. Reh’g.”). For the reasons that follow, CI’s request for rehearing is *denied*.

ANALYSIS

Pursuant to 37 C.F.R. § 42.71(d):

A party dissatisfied with a decision may file a single request for rehearing without prior authorization from the Board. The burden of showing a decision should be modified lies with the party challenging the decision. The request must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, or a reply.

When reconsidering a decision on institution, we review the decision for an abuse of discretion. 37 C.F.R. § 42.71(c). An abuse of discretion exists where a “decision [i]s 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).

CI seeks rehearing of our denial of *inter partes* review of claims 1–25 as obvious under 35 U.S.C. § 103(a) in view of Van Wagenen (Ex. 1003),¹ the Handbook of Pharmaceutical Excipients (“HPE”) (Exs. 1012, 2005),²

¹ Van Wagenen et al., US 6,211,244 B1, issued Apr. 3, 2001.

² Handbook of Pharmaceutical Excipients (Arthur H. Kibbe, ed., 3rd ed.

and the general knowledge of a person of ordinary skill in the art. Req. Reh’g. 1; Decision 5, 16. In particular, CI contends that we abused our discretion by purportedly failing to recognize that “all of the elements of the claimed invention were known in the prior art.” *Id.* 2–3. CI also asserts that we misapprehended or overlooked the standard for obviousness set forth in *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), “by failing to consider that in certain chemical arts a POSITA’s practice of selection and routine formulation or experimentation is sufficient for an obviousness determination.” Req. Reh’g. 3–7.

CI’s first argument, that we abused our discretion in allegedly failing to recognize that “all of the elements of the claimed invention were known in the prior art” (Req. Reh’g. 2–3), is inapt. Our Decision is not premised on a determination that cinacalcet was unknown in the prior art. *See* Decision 9–12. Neither is it premised on CI’s failure to identify where Van Wagenen discloses cinacalcet. *See id.* Rather, it is based on the absence of any showing of a reasonable likelihood of success in establishing that it would have been obvious to use an amount of cinacalcet HCl *within the range claimed* in the ’595 patent. *Id.*

For example, we explained that “CI does not identify any disclosure in the prior art that an amount by weight of cinacalcet HCl within the claimed range should be used” (Decision 10), and “Dr. Chambliss’ testimony is insufficient to establish that it would have been obvious to include from

2000).

about 10% to about 40% by weight of cinacalcet HCl in a pharmaceutical composition” (*id.* at 11). We further determined that, in view of the evidence presented, including evidence of exemplary compositions having active agents present in amounts inconsistent with the claimed range of cinacalcet, Dr. Chambliss’ testimony was unpersuasive. *Id.* at 11–12 (citing *Rohm and Haas Co. v. Brotech Corp.*, 127 F.3d 1089, 1092 (Fed. Cir. 1997)).

CI’s second argument, that we misapprehended or overlooked the standard for obviousness set forth in *KSR* “by failing to consider that in certain chemical arts a POSITA’s practice of selection and routine formulation or experimentation is sufficient for an obviousness determination” (Req. Reh’g. 3–7), is likewise unavailing. In particular, CI asserts that “a POSITA seeking a cinacalcet formulation would be motivated to select each individual excipient based on its prior art properties listed in the Handbook of Pharmaceutical Excipients (‘HPE’), *i.e.*, *KSR*’s ‘finite number of identified, predictable solutions.’” *Id.* at 4. CI further contends that “[a]fter selection of the known excipients for combination with cinacalcet, a POSITA would have arrived at the ’595’s claimed composition through routine formulation or experimentation, which is explained as commonly used by a POSITA in the pharmaceutical arts.” *Id.*

As an initial matter, we observe that the view of *KSR* advanced by CI is incomplete. *KSR* makes plain that “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” 550 U.S. at 418. Rather, “there

must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006); *see also KSR*, 550 U.S. at 418 (“To facilitate review, this analysis should be made explicit.”).

Moreover, and critically, CI never explains why a relevant skilled artisan would have selected cinacalcet for inclusion in a pharmaceutical composition in the first place. *See* Decision 14. Instead, CI’s analysis starts from the premise that “a POSITA *seeking a cinacalcet formulation* would be motivated to select each individual excipient based on its prior art properties listed in the Handbook of Pharmaceutical Excipients.” Req. Reh’g. 4 (emphasis added). The absence of any showing that we overlooked argument in the Petition as to why a relevant skilled artisan would have wanted to include cinacalcet in a pharmaceutical composition is fatal to CI’s rehearing request.

CI similarly fails to identify “a reason a relevant skilled artisan would have selected the claimed combination of excipients from among the 210 options presented by HPE.” Decision 14–15. For example, CI offers no explanation why a relevant skilled artisan would have chosen to include six excipients in a cinacalcet composition, rather than five, or perhaps seven. Nor does CI explain why that artisan would have selected the particular excipients claimed in the ’595 patent, in lieu of other excipients with similar properties disclosed by HPE. *Id.* at 14–15.

CI nevertheless contends that we erred in determining that Dr. Chambliss’ testimony concerning the rationale to combine cinacalcet

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.