

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INDIVIOR INC.
Petitioner

v.

RHODES PHARMACEUTICALS L.P.
Patent Owner

Case IPR2018-00795
Patent 9,370,512

PATENT OWNER'S SURREPLY TO PETITIONER'S REPLY

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As authorized in Paper 19, Patent Owner Rhodes Pharmaceuticals L.P. submits this Surreply to Petitioner's Reply filed August 7, 2018.

Petitioner's Reply does not change the Board's analysis under 35 U.S.C. § 325(d). A full-length English language version of the Cremer reference cited by Petitioner (EX1004) was cited during prosecution of the subject U.S. Patent No. 9,370,512 ("the '512 patent") and was discussed in detail during the prosecution of the parent patent before the same Examiner (CA 2,274,910 "Cremer CA;" EX2002; *see* POPR at 8). The Examiner, fully aware of the teachings of Cremer, found the claims of the '512 patent to be patentable. The Board should exercise its discretion under § 325(d) and deny institution of *inter partes* review.

I. The Examiner Was Aware of the Teachings of Cremer CA

It is undisputed that Cremer CA was of record in the prosecution history of the '512 patent and its parent, U.S. Patent No. 9,101,625 ("the '625 patent"). *See* POPR at 8 and 19-20; Reply at 2, fn. 2. The Examiner noted in each Information Disclosure Statement where Cremer CA was cited that the reference was considered. POPR at 8 and 19-20; EX2009 at 3; EX1002 at 58. Moreover, the prosecution history of a parent application is considered part of the file history of the child application. *See Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1333

(Fed. Cir. 2003); POPR at 6. The disclosures of Cremer CA were discussed on the record during prosecution of the '625 patent. POPR at 6-19. Further, the Office Actions from prosecution of the '625 patent were considered by the Examiner during prosecution of the '512 patent. EX1002 at 204-205. Thus, these disclosures in Cremer CA are part of the prosecution history of the '512 patent.

As such, the record shows that the Examiner of the '512 patent was well aware of the teachings of Cremer CA when he allowed the claims of the '512 patent. Nothing in Petitioner's Reply casts doubt on this conclusion.

II. § 325(d) Only Requires that Substantially the Same Art from the Petition Was Applied During Prosecution

The German language Cremer PCT (WO1998/26780) was formally cited as an anticipating reference during prosecution. EX1003, 142-144. While Petitioner applies Cremer in an obviousness context, Section 325(d) gives the Board discretion when "the same or substantially the same prior art **or** arguments previously were presented to the Office." 35 U.S.C. § 325(d), emphasis added. The Board has confirmed that it may exercise its discretion when substantially the same art was presented during prosecution even if substantially the same arguments were not. *See, e.g., R.J. Reynolds Vapor Company v. Fontem Holdings I B.V.*, IPR2017-

01118, Paper 8 (October 4, 2017) at 4-5. Thus, the fact that Cremer was applied as an anticipating reference during prosecution does not preclude the Board from denying institution under § 325(d). Instead, as discussed in the POPR and further below, the way Cremer was considered during prosecution warrants denial.

III. The Examiner Fully Considered the Teachings of Cremer CA/PCT

As discussed in the POPR, to address the rejection over Cremer PCT during prosecution of the '625 patent, Applicant contrasted the teachings of Cremer CA with the claims pending at the time in a response filed October 22, 2012. Applicant argued that Cremer CA did not disclose that the buprenorphine was "dissolved or homogeneously dispersed" in the dosage form, as was recited in then-pending claim 1. POPR at 10-13; EX1003 at 98-100. And Applicant not only addressed the pending anticipation rejection, but also provided arguments as to how the pending claims were nonobvious over Cremer. POPR at 11-13; EX1003 at 100-103. The Examiner was certainly aware of Applicant's arguments regarding Cremer, as he issued an Advisory Action in response. EX1003 at 86-88.

Subsequent to the Advisory Action, Applicant filed an Amendment on March 21, 2013, ("March 21 claims") that included new independent claim 21 and claim 30 that depended from claim 21 and recited that the buprenorphine was

"dissolved or homogeneously dispersed" in the film. POPR at 13-19; EX1003 at 75-84. As shown in the POPR, the elements of claim 30 are substantially similar to those of claim 1 of the subject '512 patent. POPR at 13-17. Applicant argued that previously-pending claim 1 should have been allowable over Cremer for reasons of record, but also provided additional reasons why new claim 21 was distinguishable from Cremer. POPR at 17; EX1003 at 83.

In the next Office Action, the Examiner noted that the arguments filed on March 21, 2013 had been considered and that rejections not reiterated were withdrawn. POPR at 17; EX1003 at 68. This Office Action did not include any rejection based on Cremer, indicating that the Examiner did not find Cremer to be applicable to the pending claims. EX1003 at 66-74. Because one of the previously-pending rejections was based on Cremer and was withdrawn, the Examiner must have considered the claims filed on March 21, 2013 in view of Cremer.

Petitioner states that only the "mucoadhesive properties" distinguished the March 21 claims from Cremer and that the Examiner did not find that the "dissolved or homogeneously dispersed" element of the claims was not taught by Cremer. Reply at 4. But there is no evidence in the record supporting Petitioner's assertion. Claim 21 of the March 21 claims recited that the "dosage form is in the

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