

An “Overly Demanding Standard?”: The Written Description Requirement

Indivior UK Ltd. v. Dr. Reddy's Laboratories SA, Case No. 20-2073 (Fed. Cir. 2021)

By: Robyn Bowland and Victoria Hanson | December 3, 2021

On November 24, 2021, the Court of Appeals of the Federal Circuit (“CAFC”) affirmed a Patent Trial and Appeal Board (“PTAB”) decision invalidating most of the claims of a patent on opioid addiction treatment because the amounts of compounds described in the patent and ranges listed in the claims were not disclosed in a parent application that pre-dated the alleged prior art. Judge Richard Linn dissented, highlighting a lack of consensus at the CAFC on what satisfies the written description requirement.

Indivior’s Patent Application 9,687,454 (“’454 patent”), which describes orally dissolvable films containing therapeutic agents, claimed priority to the 2009 filing date of a parent application, U.S. Patent Application 12/537,571 (“’571 application”). Claims 1, 7, 8, and 12 of the ’454 patent included language such as “about 40 wt % to about 60 wt %”, “about 48.2 wt % to about 58.6 wt %”, and “about 48.2 wt %.” The ’571 application, on the other hand, included Tables 1 and 5 which disclosed formulations with 48.2 wt % and 58.6 wt % polymer and disclosed that “the film composition contains a film forming polymer in an amount of at least 25% by weight of the composition” or, as an alternative, “at least 50%.”

Dr. Reddy’s Laboratories, Inc. (“DRL”) petitioned for *inter partes* review of the ’454 patent, alleging that the ’454 patent was not entitled to the 2009 priority date because the polymer weight percentage limitations of the ’454 patent did not have written description support in the ’571 application. Indivior argued that the percentage limitations were disclosed in the ’571 application because the combination of the disclosures in the ’571 application encompassed the claimed ranges in the ’454 patent. The PTAB found that all of the challenged claims except claim 8 of the ’454 patent were not entitled to the 2009 priority date because the subject matter of the claims was not disclosed in the ’571 application because it did not “discuss or refer to bounded or closed ranges of polymer weight percentages.”

On appeal, the CAFC upheld the PTAB’s ruling and affirmed its finding that the polymer range limitations were not supported in the ’571 application. The CAFC found that the ranges of about 40% to 60% or about 48.2% to 58.6% claimed in the ’454 patent were not found in the ’571 application, which instead used phrases like “at least 25%” and “at least 50%” and used descriptions of various formulations that include specific examples, not ranges. The CAFC stated that “[f]or written description support of a claimed range, more clarity is required.” Judge Linn dissented, reasoning that the ranges were actually present in the ’571 application and this written description for ranges was an “overly demanding standard.” He argued that the ranges the majority said were not found in the ’571 application were actually present and that at least 25% or 50% meant “25%-100%” or “50%-100%” which fell within the ranges.

This split decision underscores a tension within the CAFC regarding what satisfies the written description requirement and how specific a specification should be. This disagreement appeared again less than a week later in *Biogen Int’l GMBH v. Mylan Pharma Inc.*, Case No. 20-1933 (Fed. Cir. Nov. 30, 2021), which featured a split court in which the majority found a patent invalid based on an insufficient written description. In light of this lack of agreement on what constitutes a sufficient written description, an applicant should err on the side of filing applications for specific ranges or amounts as soon as possible.