



## **Pre-Issuance, Industry-Standard Monitoring and Copying of a Product Does Not Support a Finding of Willful Infringement of Method of Use Patent**

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Plaintiffs Bioverativ Inc., Bioverativ Therapeutics Inc. and Bioverativ U.S. LLC (collectively “Bioverativ”) sued defendants CSL Behring LLC, CSL Behring GmbH and CSL Behring Lengau AG (collectively “CSL”) for infringement of three patents directed to methods of treating hemophilia by administering a chimeric factor IX (FIX) polypeptide according to claimed dosing regimens. Bioverativ further alleged that CSL willfully infringed the claims based on its sale of Idelvion®, a chimeric FIX polypeptide that comprises FIX and albumin as its binding partner.

In support of its willfulness allegations, Bioverativ alleged that CSL developed its product using confidential information it obtained from Bioverativ’s predecessor during discussions to co-develop and manufacture a half-life extended FIX product—discussions that occurred before the priority date and nearly a decade before the patents issued. Bioverativ further alleged that CSL targeted the same dosing regimen that was disclosed in confidence. Bioverativ also pointed to CSL’s monitoring of Phase III clinical data to match the dosing interval, arguing that CSL was attempting to “match” Bioverativ’s dosing interval.

On summary judgment, the court disagreed that Bioverativ’s allegations could support a finding of willfulness or enhanced damages. Specifically, the court found that none of CSL’s pre-issuance activities constituted willful infringement. First, the court explained that monitoring clinical trials does not show copying. At most, it shows an interest in how clinical trials are progressing, which amounts to competitive intelligence gathering. And because the parties agreed that competitive intelligence is “standard in the pharmaceutical industry,” such

pre-patent surveillance activities, without more, do not amount to “elaborate copying” or “consciously wrongful,” “malicious” behavior. Likewise, the use of confidential information obtained nearly seven years before the patents issued in 2017 relating to a pharmaceutical product could not support a finding of willful infringement of method of treatment claims.

The court also addressed the alleged post-issuance activities and found they too did not rise to the level of wanton, malicious and bad-faith behavior necessary for willful infringement. Notably, the product accused of practicing the claimed methods entered the market more than a year before the patents issued. In other words, at the time it was launched, it did not infringe any of the asserted patents. And, as a result, there could be no willful infringement until the litigation was filed. The court noted that this timeline necessarily complicated matters for both parties. For the plaintiff, it was difficult to identify any difference in the defendants’ pre-issuance and post-issuance activities. Here, knowledge of the patents at the time of their issuance was undisputed. But no other post-issuance evidence existed to support a finding of willful infringement, and there was no evidence that the claimed methods of treatment were copied. For these reasons, the court granted summary judgment of no willful infringement.

#### **Practice Tips:**

- Evidence that a party is acting consistently with industry standards may help refute allegations of willful infringement, but it may not be sufficient to negate evidence of direct copying. Therefore, companies engaged in competitive monitoring should be cognizant of the manner in which information is collected and disseminated.
- In a similar vein, patentees asserting claims of willful infringement should identify evidence that indicates an accused infringer’s conduct goes beyond standard monitoring. This may be particularly true in cases where a patent to methods of treatment issues after a product used in the method enters the market.

*Bioverativ Inc. v. CSL Behring LLC*, No. 17-914-RGA (D. Del. Mar. 23, 2020)

## **Categories**

District Court

Willful Infringement

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