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Federal Circuit Grants Injunction Keeping Sandoz's Biosimilar Version of Neupogen Off Market Until Appeal Decided

Paul A. Calvo, Ph.D. and Timothy J. Shea, Jr.

The Federal Circuit yesterday granted Amgen's motion for a preliminary injunction to keep Sandoz's biosimilar form of Neupogen off the market until the Court renders its decision on the merits of the appeal. The parties had previously agreed to an expedited briefing schedule, and oral arguments are set to be heard on June 3. FDA previously approved Sandoz's biosimilar application on March 6 of this year, but Sandoz had agreed not to market the product until May 11 absent judicial intervention. The Federal Circuit's decision today will keep the biosimilar off the market for at least a few more weeks. Given that this will be the Federal Circuit's first decision interpreting several key provisions of the Biologics Price Competition and Innovation Act (BPCIA), it is difficult to speculate exactly when the Court will render a final decision.

The order granting the preliminary injunction does not provide any insight into the Court's reasoning. It states simply that "[t]he motion is granted, effective immediately," and the parties are directed to brief the issue of "what amount of a bond, if any, should be posted for each day that the injunction is in place."

The appeal involves the parties' disputed interpretations of certain key provisions of the BPCIA, including: (i) whether the patent exchange provisions of the statute are mandatory; (ii) whether the 180-day notice of commercial marketing required by the statute can be provided before actual licensure of the biosimilar product; and (iii) whether a declaratory judgment of infringement, validity, or unenforceability is the only remedy for a biosimilar applicant's failure to comply with the provisions of the BPCIA.

The Federal Circuit's decision on the preliminary injunction is opposite to that reached by the lower court. The district court had denied Amgen's motion for an injunction pending appeal after it had earlier ruled in favor of Sandoz's interpretation of all of the statutory provisions at issue. In considering Amgen's injunction request, the Federal Circuit had to determine whether Amgen had made a strong showing that 1) it was likely to succeed on the merits; 2) it would be irreparably injured absent a stay; 3) the stay would not substantially injure the other parties interested in the proceeding; and 4) the public interest lies with Amgen. Although the Federal Circuit did not provide any rationale for its decision today, it is safe to say that it appears more likely than the district court to rule in Amgen's favor on the merits of the appeal.

For more information, please contact:

Paul A. Calvo, Ph.D., Director
pcalvo@skgf.com

Timothy J. Shea, Jr., Director
tshea@skgf.com

