

BPCIA Provides Exclusive Remedies for Generics' Failure to Provide Reference Product Manufacturers with Confidential Access

In *Amgen Inc. v. Sandoz, Inc.* 2017-12-14, Appeal No. 2015-1499, (N.D. of California) the Court of Appeals for the Federal Circuit ("Federal Circuit") on remand from the Supreme Court of the United States ("Supreme Court") held that Section 262(l)(2)(A) of the Biologics Price Competition and Innovation Act ("BPCIA") of 2009 is not enforceable by state law injunction. Previously, the Supreme Court found that Section 262(l)(2)(A) was not enforceable by federal law injunction.

The BPCIA establishes a pathway for generic manufacturers to gain FDA approval for their generic biological products. A generic manufacturer must establish that its generic is highly similar to an already approved biological product ("reference product"). A portion of this Act (262(l)(2)(A)) states that a generic manufacturer "shall" give the reference product manufacturer confidential access to manufacturing information "no later than 20 days after the FDA accepts its application for review." The penalty outlined in the BPCIA for not giving this access is that the reference product manufacturer may seek a declaratory judgment of infringement, validity or enforceability of its patents.

Relying on BPCIA procedures, Sandoz attempted to obtain FDA approval for its generic biologic of Amgen's Neupogen®. However, Sandoz did not provide Amgen with confidential access to manufacturing information. Amgen sued Sandoz, arguing that, due to Sandoz's non-compliance with Section 262(l)(2)(A), Amgen is entitled not only to the remedies outlined in the BPCIA, but also to additional federal and state law remedies, such as injunctive relief. The Supreme Court found that the remedies outlined in the BPCIA were the exclusive federal remedies for not complying with (262(l)(2)(A), and that Amgen could not seek an injunction under federal law to stop Sandoz from manufacturing its generic product. However, the Supreme Court remanded to the Federal Circuit to decide whether Amgen could seek a state law injunction.

On remand, Amgen argued that California state laws are not preempted by the BPCIA because California state laws provide remedies for its injuries that are not available under the BPCIA. Sandoz argued that the BPCIA intended to preempt state law regarding patent disputes.

The Supremacy Clause of the United States Constitution states that federal law preempts state law. However, it has long been established that if federal law attempts to legislate in an area of law that states have traditionally policed, then the federal law will be interpreted not to preempt the state law unless the federal law was clearly meant to do so.

The Federal Circuit agreed with Sandoz and held that the BPCIA preempts state law claims. Thus, Amgen cannot stop Sandoz from continued manufacture of its generic biologic and must seek remedies provided by the BPCIA.

We at Wood Phillips stay abreast of the current law to ensure that our clients' intellectual property rights are protected. If you have questions about the scope of the rights available to protect your invention, please contact an attorney at Wood Phillips.