

LEGAL UPDATES

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Supreme Court Hands Down Two More Intellectual Property Decisions

The U.S. Supreme Court continues to actively influence intellectual property law this term with its issuance of another two decisions in June that refine both patent and trademark law. The Court's June 12 decision on pre-market patent disputes over biosimilar drugs paves the way for generic biologic drug companies to go to market more quickly, while the Court's June 19 ruling on derogatory language in trademarks expands the boundaries of what is an acceptable trademark for registration purposes.

Biosimilar Drugs

In *Sandoz Inc. v. Amgen Inc.*, the Court considered the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which was enacted during the Obama administration to govern approval of biologic drugs derived from natural, biological sources. A primary goal of the BPCIA is to resolve questions of patent infringement and validity prior to commercial marketing of the drug. To achieve this goal, the BPCIA requires an applicant to provide its application materials and manufacturing information to the manufacturer ("sponsor") of the corresponding biologic. The BPCIA further requires the applicant to give notice to the sponsor at least 180 days before marketing the biosimilar commercially.

Sandoz did not provide the requisite materials to Amgen. Rather, one day after the Food and Drug Administration (FDA) notified Sandoz that the agency had accepted Sandoz's application for review, Sandoz notified Amgen both that Sandoz had filed an application *and* that Sandoz intended to commercially market the drug immediately upon receiving FDA approval. Sandoz further informed Amgen that Sandoz would not provide its application and related materials, and that Amgen could bring instead a declaratory judgment action.

The Supreme Court considered: (1) whether the requirement that an applicant provide its application and manufacturing information to the sponsor is enforceable by injunction under federal law, and (2) whether an applicant must provide notice to the sponsor of its intent to market a biosimilar before obtaining a license from the FDA to market the product. The Supreme Court resolved both of these issues in favor of the generic drug company and reversed the Federal Circuit's decision below.

The Court found that an injunction under federal law is not available to enforce compliance with the mandatory disclosure provisions of the BPCIA, although it left open the door for a lower court finding that such an injunction could be available under state law. In addition, the Court noted that failure to comply with the statutory disclosure provisions may be used against the biosimilar manufacturer in other ways as well. The Supreme Court concluded that the applicant may provide notice of intent to commercially market the biosimilar either before or after receiving an FDA license.

Trademarks and Free Speech

In *Matal v. Tam*, the Supreme Court ruled that derogatory language contained in a trademark is protected under the First Amendment's freedom of speech clause. The Court thus ruled that the U.S. Patent and Trademark Office (USPTO) cannot reject a trademark application solely on the basis that the mark contains derogatory language.

Simon Tam, lead singer of an Asian-American band, sought to register the band's name, The Slants, with the USPTO. Consistent with the "disparagement clause" of the federal trademark statute, which prohibits registration of trademarks that disparage "persons, living or dead, institutions, beliefs, or national symbols," the USPTO denied Tam's application and found that "The Slants" was a derogatory reference to persons of Asian descent. Rather than intending a racial slur, Tam claimed that his choice of names was a way to "reclaim and take ownership of stereotypes about people of Asian ethnicity." He argued that the law violated his rights to free speech under the Constitution.

The Trademark Trial and Appeal Board affirmed the USPTO and refused to let Tam register his mark. The Federal Circuit ultimately reversed, holding the federal law concerning "derogatory" marks to be unconstitutional. The government appealed the decision to the Supreme Court, arguing that the statute was constitutional either as "government speech" or "subsidized speech," two exceptions to free speech claims under the First Amendment.

The Court rejected the government's arguments, ruling that the statute was an impermissible attempt by the government to regulate the content of speech. Although the ruling specifically addresses only the prohibition against "disparaging" marks under the statute, it is likely that parallel prohibitions under the statute against "immoral" and "scandalous" marks may be successfully challenged as well.

What This Means to You

At its core, the Supreme Court's holding in *Sandoz* provides generic companies in the biosimilar space the opportunity to go to market sooner than the Federal Circuit's original interpretation of the law allowed.

With the *Tam* decision, companies can push the limits of what it means to be edgy as they develop new brands. The decision also has repercussions for previous high-profile trademark decisions, such as the USPTO's past decision to cancel the Redskins football team's trademarks deemed to be disparaging to Native Americans. The scope of this protection still remains to be seen, and courts will be urged to maintain tight limits on what constitutes speech or expression within a trademark.

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For more information on how these decisions may affect your company's business, please contact a member of Husch Blackwell's Intellectual Property Litigation group.