Biologics/Biosimilars

The Biologics Price Competition and Innovation Act of 2009 (BPCIA), enacted in March 2010 as part of the Affordable Care Act, provides a new pathway for FDA approval of biosimilar products in the United States. At the same time, demand by patients, insurers and government agencies for lower cost biopharmaceuticals is increasing exponentially. Regulatory change combined with societal pressure for more affordable health care will greatly expand the global market for biosimilars over the next decade.

Biopharmaceutical companies that can effectively compete in this emerging marketplace will be rewarded. The biosimilar market is expected to be worth nearly $20 billion in 2014 — and another $100 billion in branded biologic products are slated to lose patent protection by 2020. In order to capture valuable market share and achieve profitability, biosimilar product sponsors need legal counsel with experience in patent law, government regulation, and both biological and chemical sciences. Cozen O'Connor has a team of 20 dedicated professionals with this experience and is a recognized leader in helping clients understand BPCIA regulations.

Typical pharmaceuticals, often-referred to as a "small molecule drugs," have simple structures and are made by combining specific ingredients through ordered chemical processes under defined reaction conditions. Biologics, in contrast, are very large, complex molecules or mixtures of molecules that are manufactured by living systems such as microorganisms, plant cells, and animal cells. Small molecule drugs have well-defined chemical structures that can be precisely copied and confirmed through various analytical techniques. This means that the safety and efficacy of a generic small molecule drug can be confirmed without the need for clinical trials. Biologics are difficult, if not impossible, to definitively characterize, and establishing the safety and efficacy of a biosimilar product is a far more complex and costly endeavor.

The inherent differences between small molecule drugs and biologics create unique legal challenges. Attorneys at Cozen O'Connor can provide sophisticated advice on the full range of critical issues such as winning FDA approval, bringing a new biosimilar to market, responding to branded efforts to maintain exclusivity after patent expiration, and negotiating the thicket of validity and infringement issues posed by branded companies' patent portfolios.

The question of what studies the FDA will require in order to approve a biosimilar product can mean the difference between success and failure. In order to win FDA approval, small molecule drugs must be shown to be chemically identical and biologically equivalent to the branded drug. This is generally shown through relatively simple in vitro and in vivo studies without the need for clinical trials. According to requirements in the BPCIA, biosimilar applicants must demonstrate a product's biosimilarity or interchangeability using data derived from analytical studies, animal studies, and – importantly – one or more clinical studies, unless the FDA determines that certain studies are unnecessary. Cozen O'Connor can advise clients on how to design and promote a successful biosimilar application.

The law that regulates the introduction of generic drugs includes various sales and data exclusivities to balance the incentives for market entry for branded and generic companies alike. The BPCIA attempts a similar balancing act for biologic drug makers by establishing various exclusivities and other provisions that govern when and how new biosimilars can be marketed. Cozen O'Connor helps clients develop a smart strategy for market entry that satisfies statutory requirements and maximizes profitability.

Finally, because of the difficulty of characterizing biologics, branded companies often argue that the product is the process and try to maintain confidentiality regarding all aspects of the manufacturing

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process. As patent protection expires and biosimilar product applications are filed, branded companies are likely to try to protect their exclusivity by other means, such as citizen petitions and supply chain leverage. Cozen O'Connor attorneys are well prepared to respond to all such efforts and will protect clients' lawful right to compete.

OUR TEAM

The members of Cozen O'Connor's Biosimilars team have long been leaders in the intellectual property bar. They understand the legal, regulatory, economic and scientific issues that underlie and influence both the generic pharmaceutical and biosimilar industries. Our team includes attorneys with advanced scientific degrees in organic chemistry, molecular cell biology, immunology, and biophysics, as well as former senior research scientists in industry and academia. Our team also includes seasoned patent litigators with over 20 years of experience, federal prosecutors, registered patent attorneys, a former patent examiner for the U.S. Patent and Trademark Office, and the former general counsel for the U.S. Office of Personnel Management. We at Cozen O'Connor understand how science and the law interact with respect to biosimilars, and we are able to help our clients navigate this complex and emerging field of law.

Experience

Represented Apotex Inc. and Apotex Corp. in a patent infringement action regarding Apotex's biosimilar applications to make biosimilar versions of Amgen's NEULASTA® and NEUPOGEN® products. We navigated Apotex through the Biologics Price Competition and Innovation Act's "patent dance," and in the first BPCIA case to go to trial, we obtained a verdict of noninfringement. This result was affirmed on appeal to the U.S. Court of Appeals for the Federal Circuit.

Represented Apotex Inc. in a patent infringement action regarding Apotex's ANDA to make a generic version of AVODART® (dutasteride). Settled prior to trial.

Represented Sandoz Inc. in a patent infringement action regarding Sandoz's ANDA to make a generic version of Alcon's eye allergy product PATANOL® (olopatadine hydrochloride). Case settled.

Represented Sandoz Inc. in a patent infringement action regarding Sandoz's ANDA to make a generic version of Abbott's cholesterol product NIASPAN® (niacin). Settled prior to trial.

Represented Sandoz Inc. in a patent infringement action regarding Sandoz's ANDA to make a generic version of Abbott's cholesterol medication TRILIPIX® (fenofibric acid). Settled prior to trial.

Represented Innopharma, Inc. in a patent infringement action regarding Innopharma's ANDA to make a generic version of Spectrum's FUSILEV® (levoleucovorin injection).

Represented Sandoz Inc. in patent infringement action regarding Sandoz's ANDA to make a generic version of Helsinn's anti-nausea product ALOXI® (palonosetron hydrochloride injection).

Represented Sandoz Inc. in a patent infringement action regarding Sandoz's ANDA to make a generic version of Roche's VALCYTE® (valganciclovir hydrochloride).

Represented Sandoz Inc. in a patent infringement action regarding Sandoz's ANDA to make a generic version of Shire's ADHD product INTUNIV® (guanfacine hydrochloride). Settled prior to trial.

Represented Apotex Inc. in a patent infringement action regarding Apotex's ANDA to make a generic version of PRISTIQ® (desvenlafaxine). Settled prior to trial.

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Represented Apotex Inc. in a patent infringement action regarding Apotex's ANDA to make a generic version of ACULAR LS® (0.4% ketorolac tromethamine). Led the negotiations that resulted in a successful settlement of the matter after the close of expert discovery.

Trial counsel for Apotex Inc. and Apotex Corp. in a patent infringement action regarding Apotex's ANDA to make a generic version of LYSTEDA® (tranexamic acid). After a two week trial, received a favorable decision of non-infringement on all three patents in-suit. Successfully argued on appeal with the Federal Circuit affirming the trial court decision.

Represented Sandoz Inc.in a patent infringement action regarding Sandoz's ANDA to make a generic version of Abbott's ZEMPLAR® (paricalcitol). Settled prior to trial.

Represented Mylan Pharmaceuticals, Inc. in a patent infringement action regarding Mylan's ANDA to make a generic version of Pfizer's cardiovascular product CADUET® (atorvastatin calcium and amlodipine besylate). Settled prior to trial.

Represented Actavis in a patent infringement action regarding Actavis' ANDA to make a generic version of King's pain product AVINZA® (morphine sulfate). Settled after trial.

Represented Sandoz Inc. in a patent infringement action regarding Sandoz's ANDA to make a generic version of Merck's anti-nausea product EMEND® (aprepitant).

Represented Sandoz Inc. in a patent infringement action regarding Sandoz's ANDA to make a generic version of Allergan's glaucoma drops COMBIGAN® (brimonidine tartrate/timolol maleate).

Represented Apotex Inc. in a patent infringement action regarding Apotex's ANDA to make a generic version of Sanofi-Aventis' anticancer product TAXOTERE®, the active ingredient of which is docetaxel. Following a two-week trial, obtained an order for Apotex striking down the patents-in-issue as invalid as obvious and unenforceable due to Sanofi-Aventis' inequitable conduct in procuring the patents. Successfully argued on appeal with the Federal Circuit affirming trial court decision (April 2012). Of import is that inequitable conduct defense remains viable in ANDA litigations because of this ruling.

Represented Apotex Inc. in a patent infringement action regarding Apotex's ANDA to make a generic version of Wyeth's anti-depressant product EFFEXOR XR® (venlafaxine hydrochloride). Settled on favorable terms during trial.

Represented Sandoz Inc. in a patent infringement action regarding Sandoz's ANDA to make a generic version of Endo's pain product OPANA® ER (oxymorphone hydrochloride).

Lead counsel for Sandoz Inc. in a patent infringement action regarding Sandoz's ANDA to make a generic version of Medicis' acne product SOLODYN® (minocycline hydrochloride).

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