wiley

Hatch-Waxman Act Litigation

Drawing on the experience of a skilled team of patent trial lawyers with an in-depth understanding of the intricacies of Food and Drug Administration (FDA) regulatory schemes, Wiley has a proven track record of guiding our clients to successful outcomes in complex Hatch-Waxman patent actions. For more than 25 years, we have effectively advocated our clients' interests in federal and state courts across the country and before regulatory agencies in the nation's capital. Representing both plaintiffs and defendants in high-profile and high-stakes cases, we have earned a reputation for our ability to devise and execute innovative, creative, and ultimately successful legal strategies – successes that include securing for our client in the BlackBerry patent dispute, after a successful jury trial, one of the largest patent settlements to date.

Our Team

Neal Seth leads a group of over 20 intellectual property attorneys with Hatch-Waxman capabilities. Our team, whose ranks include more than a dozen attorneys admitted to practice before the U.S. Patent and Trademark Office (USPTO) and four who served as judicial clerks to the U.S. Court of Appeals for the Federal Circuit, has patent litigation experience that spans a diverse range of technologies including those utilized in pharmaceuticals – such as modified/extended-release dosage forms and active pharmaceutical ingredients – biotechnology, medical devices, pesticides, and many other industries.

Our Approach

Wiley utilizes a cross-disciplinary approach that allows us to augment our considerable patent litigation experience with that of the firm's deep bench of attorneys specializing in intellectual property and FDA/regulatory matters. In doing so, we fully leverage our thorough understanding of the unique issues and challenges presented in Hatch-Waxman cases, including the additional complexities and opportunities for efficiencies that arise in the context of multi-defendant litigations.

Hatch-Waxman Patent Litigation Experience

Wiley's substantial Hatch-Waxman Act patent litigation experience includes matters handled from pre-trial through appeals in numerous districts. Select cases include:

- *In re Omeprazole Patent Litigation:* Secured a significant victory for clients Mylan Inc. (formerly Mylan Laboratories Inc.), Mylan Pharmaceuticals Inc., Laboratorios Dr. Esteve, S.A., and Esteve Quimica, S.A. in their defense of a protracted multidistrict patent infringement action brought by AstraZeneca in the

Southern District of New York against five accused generic products. The case involved Astra's Prilosec® (omeprazole) proton pump inhibitor product. The district court issued an opinion ruling that Mylan/Esteve and one other defendant did not infringe the asserted patents, and this decision was affirmed on appeal. Mylan had launched its omeprazole product at risk of incurring substantial damages prior to trial. Wiley continues to represent Mylan in this action in connection with pending antitrust counterclaims filed by Mylan, which are currently stayed.

- *Alza Corp. v. Mylan Labs., Inc.:* Successfully represented Mylan through appeal in a patent infringement action brought by Alza, a division of Johnson & Johnson, in the Northern District of West Virginia. The case involved the urinary incontinence drug Ditropan XL® (sustained-release oxybutynin chloride). Wiley obtained judgment for Mylan of non-infringement and invalidity based on anticipation and obviousness following a two-week bench trial, which was affirmed by the Court of Appeals for the Federal Circuit.
- *Ortho-McNeil Pharm., Inc. v. Mylan labs. Inc.:* Represented Mylan in an infringement action brought in the Northern District of West Virginia involving the antibiotic drug Levaquin® (levofloxacin). After a more than five-week bench trial, the court found in favor of plaintiffs, ruling that Mylan had not proven by clear and convincing evidence that the patent covering the active pharmaceutical ingredient was invalid, which was upheld on appeal.
- *Schering Corp. v. Zenith Goldline Pharms. Inc.:* Successfully represented Zenith Goldline in an infringement action brought by Schering in the District of New Jersey. This was a multi-defendant consolidated case involving the antihistamine drug Claritin® (loratadine). Wiley, in cooperation with co-defendants, obtained summary judgment of invalidity for Zenith, which was affirmed on appeal.
- *Merck & Co., Inc. v. Mylan Pharms. Inc:* Successfully represented Mylan in an infringement action brought by Merck in the Eastern District of Pennsylvania. The case involved the drug Sinemet® CR (sustained release carbidopa/levodopa). Wiley obtained summary judgment of non-infringement, which was affirmed on appeal. Carbidopa-levodopa was one of Mylan's top-selling products for a number of years.
- *OSI Pharms., Inc. v. Mylan Pharms. Inc:* Currently representing Mylan in an infringement action brought by OSI, Pfizer and Genentech in the District of Delaware. The case involves the cancer drug Tarceva® (erlotinib). Discovery is ongoing.
- *Eurand, Inc. et al. v Mylan Pharms. Inc., et al.:* Currently representing Mylan in an infringement action brought by Eurand, Cephalon, and Anesta AG in the District of Delaware. The case involves the drug Amrix® (an extended release dosage form of the skeletal muscle relaxant cyclobenzaprine HCl). Discovery is ongoing.

We have also been involved in Hatch-Waxman litigations concerning the following products, among others:

- Acetaminophen IV (Ofirmev®)
- Allopurinol (Zyloprim®)
- Aripiprazole (Abilify®)

- Bendamustine (Treanda®)
- Bortezomib (Velcade®)
- Dextromethorphan/Quinidine (Nuedexta®)
- Dutasteride (Avodart®)
- Fenofibrate (Antara®)
- Fesoterodine (Toviaz®)
- Gabapentin (Gralise®)
- Interferon (Roferon®-A)
- Micronized Glyburide (Glynase®)
- Romidepsin (Istodax®)
- Tamoxifen Citrate (Nolvadex®)
- Tolterodine Tartate (Detrol® LA)
- tPA (Activase®)

Contact Us

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