INNSIGHT
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GENERICSWEB
THE SEARCH IS OVER

INNsight article by Stephen M. Hash, Deirdre M. Dorval and Michael A. Valek, April 2012

Stephen M. Hash's practice primarily focuses on patent litigation, with a concentration in the areas of pharmaceuticals, biotechnology, medical devices, agricultural products and food products. Stephen has experience in all phases of patent litigation, including pretrial, trial and appeal. Stephen also advises clients on both the acquisition and enforcement of patents. His technical background is in life sciences, with a particular focus on immunology and molecular biology. Stephen has litigated a number of cases related to his technical knowledge, including biotechnology, pharmaceutical, and medical device technologies, as well as cases relating to technologies in the mechanical, electrical, semiconductor, and chemical fields.

Deirdre M. Dorval's principal area of practice is intellectual property, primarily in the areas of Hatch-Waxman Paragraph IV pharmaceuticals, chemical arts, biotechnology, and other life science-related areas. Her litigation experience includes trial experience, formulating claim construction and litigation strategy, drafting various dispositive and non-dispositive motions, drafting preliminary injunction motions, identifying prior art to invalidate asserted patents, handling various discovery matters, preparing witnesses for deposition and trial testimony, and preparing expert reports. Deirdre also has experience formulating inter partes reexamination requests and analyzing intellectual property portfolios.

Michael A. Valek's principal area of practice is patent litigation. He has assisted in the successful representation of clients in a variety of fields, including computer software in a variety of different applications, polymer chemistry, biochemistry and protein engineering, mechanical devices, and wind turbine generators. His litigation experience includes trial and Markman proceedings, preliminary injunction and summary judgment hearings, formulation of claim construction and litigation strategy, examination of both expert and fact witnesses, and preparation of expert reports. Prior to joining Vinson & Elkins, Michael served as law clerk to The Honorable Timothy B. Dyk of the U.S. Court of Appeals for the Federal Circuit.

Federal Circuit Confirms ANDA Filer May Carve Out Patented Uses To Avoid Infringement

On February 9, 2012, a three judge panel of the United States Court of Appeals for the Federal Circuit (Federal Circuit) confirmed that the filing of an Abbreviated New Drug Application (ANDA) directed to an FDA-approved unpatented use of a pharmaceutical composition does not constitute infringement of method patents covering other FDA-approved uses of the same composition. Consistent with its precedent, in AstraZeneca Pharmaceuticals LP v. Apotex Corporation, the Federal Circuit held that there can be no infringement of a method patent if the ANDA lists only non-patented uses of the pharmaceutical composition. Nos. 2011-1182, -1183, -1184, -1185, -1186, -1187, -1188, -1189, -1190, Slip Op. (Fed. Cir. Feb. 9, 2012); see also Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348 (Fed. Cir. 2003).

The Hatch-Waxman Act allows generic pharmaceutical companies to file different types of statements along with their ANDA. A statement made under 21 U.S.C. § 355(j)(2)(A)(viii) certifies that a method of use patent covers the pharmaceutical composition, but the ANDA does not seek approval for a use covered by the patent. Infringement of method claims under § 271(e)(2) requires filing an ANDA wherein at least one "use" listed in the ANDA is claimed in a patent. Nothing requires that an ANDA must encompass every FDA-approved indication. If the FDA approves a pharmaceutical composition for multiple uses, some of which are covered by method patents and some of which are not, an ANDA filer can carve out the patented uses in its application to avoid infringement of the method patents. Once approved, the ANDA filer can market a generic version of the pharmaceutical composition for the unpatented uses.

The argument that even if the generic is only formally approved for unpatented uses, doctors and pharmacists will nonetheless substitute the generic for all uses was once again expressly rejected in AstraZeneca. Judge Lourie, writing on behalf of the court, explained that allowing a § 271(e)(2) infringement claim based on this type of speculative argument "would allow a pioneer drug manufacturer to maintain de facto indefinite exclusivity over a pharmaceutical compound by obtaining serial patents for approved methods" and was thus contrary to the statutory scheme established by the Hatch-Waxman Act. Slip Op. at 18-19.

What This Means for You

ANDA applicants can effectively carve out patented uses to avoid infringement of method of use patents for pharmaceutical compounds. This decision reaffirms that generic drugs may enter the market for non-patented, approved uses for a pharmaceutical composition that is not otherwise covered by an unexpired patent on the pharmaceutical composition itself. The content of this article is intended to provide a general guide to the subject matter. Specialist advice should be sought about your specific circumstances.

Stephen M. Hash, Deirdre M. Dorval and Michael A. Valek
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shash@velaw.com
ddorval@velaw.com
mvalek@velaw.com