

THE PATENTABILITY OF CHIRAL DRUGS POST-*KSR*: THE MORE THINGS CHANGE, THE MORE THEY STAY THE SAME

By Miles J. Sweet

Perhaps more than most, the pharmaceutical industry is dependent on patent protection. The commercialization of discoveries and inventions related to new drugs and therapeutics must necessarily operate within the regulatory frameworks governing health and safety. This inherently public disclosure precludes protection of valuable intellectual property by alternative means such as trade secret. Consequently, there is a rich history of jurisprudence related to patentability in the chemical arts, as the issues surrounding novelty and obviousness often serve as central points of contention in patent infringement litigation.

This Note examines the Federal Circuit's approach to the patentability of an important class of pharmaceutical products known as chiral drugs—drugs based on enantiomers—particularly in view of the standard for determining nonobviousness expressed by the Supreme Court in *KSR International Co. v. Teleflex Inc.*¹ Part I introduces the basic concept of chirality and its significance to the pharmaceutical industry.

Part II addresses the doctrines of novelty and nonobviousness related to enantiomers, focusing on the touchstone of structural similarity and the requirements related to motivation established in pre-*KSR* case law. The cases show that an enantiomer is patentable over its previously disclosed racemate with respect to novelty, but that there is no easy conclusion with respect to nonobviousness.

Part III considers the lessons stemming from a number of recent post-*KSR* decisions on the obviousness of chiral drugs. First, the difficulties associated with resolving racemic mixtures and unexpected properties are critical to preserving the nonobviousness of enantiomers. Second, the mere desirability and knowledge of the potential therapeutic advantages that single-enantiomer drugs may hold have not been held as adequate motivation to employ known separation techniques on disclosed racemic mix-

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1. 127 S. Ct. 1727 (2007).