Finding Safe Harbor

Protections from Infringement for Using Patented Inventions During the Regulatory Approval Process

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Development and testing of new therapeutics can be a costly and difficult undertaking; obtaining FDA approval alone can easily cost millions of dollars. In some instances, obtaining regulatory approval can require use of patented inventions, a serious roadblock if a license cannot be obtained. However, in the context of the regulatory approval process, patented inventions can be used in certain circumstances without a license and ***without being considered an act of infringement.***

35 U.S.C. § 271(e)(1) provides:

> (1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

This "Safe Harbor" provision has been broadly interpreted by US Courts as exempting activities with an ultimate commercial benefit as long as the conduct is ***reasonably related*** to gaining information relevant to the FDA approval process. Thus, activities such as using research tools, supplying active ingredients, and stockpiling drug inventories may be protected from infringement provided that there is a clear link between such conduct and efforts to secure regulatory approval. A number of US Courts have provided guidance on what is (and what is not) protected under the Safe Harbor provision.

For example, Pre-FDA approval conduct has been found to be protected by 35 U.S.C. § 271(e)(1) as long as it is reasonably related to the development and submission of information to FDA, regardless of the attendant consequences of the activity. *See*, *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.* 809 F.3d 610 (Fed. Cir. 2015). In fact, the *Momenta* court noted that using patented compounds for developing information for FDA submission was subject to Safe Harbor *even if* such information was not actually submitted to the FDA. Further, the manufacturing of alleged infringing medical devices and their sales to hospitals and international distributors to support clinical trials have been found to be protected activities under the Safe Harbor. *See*, *Intermedics, Inc. v. Ventritex, Inc.*,775 F. Supp. 1269 (N.D. Cal. 1991).

However, "Basic scientific research on a particular compound, performed without the intent to develop a particular drug or a reasonable belief that the compound will cause the sort of

physiological effect the researcher intends to induce, is surely not 'reasonably related to the development and submission of information' to the FDA." *See, Merck KGaA v. Integra* (545 U.S. 193 (S. Ct. 2005) at 205–206).

In some instances, the Safe Harbor provision can reduce costs associated with obtaining regulatory approval by eliminating the need to obtain licenses for patented inventions. However, the Safe Harbor provision may negatively affect the commercial value of patents on inventions that can be used during the regulatory approval process, such as research tools and devices. Thus, the impact of the Safe Harbor provision on products and patents in the medical and veterinary fields should be considered as part of any strategic analysis.

For more information, contact **Bill Schmidt**.