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Client Alert

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Non-regulated Inventions Do Not Have Safe Harbor From Infringement Under Hatch-Waxman

After years of uncertainty, a Federal appeals court has ruled that the Hatch-Waxman safe harbor exemption from patent infringement does not apply to certain types of patented inventions. The Hatch-Waxman Act provides a safe harbor that immunizes competitors from infringement of patented inventions used solely for uses reasonably related to the development and submission of information needed for Federal regulatory approval. For a number of years, court decisions have determined the scope of this exemption, with a clear trend to extending the safe harbor to more activities and more types of inventions. Based on this trend, a belief developed that the use of any patented invention, including research tools, for research related to the development of data for regulatory submission is covered by the Hatch-Waxman safe harbor. Now, in the case of Proveris Scientific Corporation v. Innovasystems, Inc., 2007-1428 (Fed. Cir. 2008), the Court of Appeals for the Federal Circuit has ruled that patented inventions that are not subject to Federal regulatory approval do not come under the safe harbor provision. Thus, competitors that use non-regulated patented inventions to develop regulatory information risk patent infringement. The safe harbor remains for use of regulated patented inventions to develop regulatory information.

Congress enacted the Hatch-Waxman Act in order to eliminate two unintended distortions of the effective patent term resulting from the premarket approval required for certain products under the Federal Food, Drug, and Cosmetic Act ("FDCA"). These distortions are: (1) the reduction of effective patent life due to delays in marketing a product caused by FDA premarket approval and (2) the complementary extension of effective patent life at the end of the patent term by delays in competitors' ability to gather premarket approval data for a product about to come off patent. The Hatch-Waxman Act sought to eliminate these distortions via two key provisions: (1) patent term extension for patents claiming a product that was subject to regulatory delays caused by the FDA premarket approval process ("patent term extension provision") and (2) a safe harbor from patent infringement that immunized competitors from infringement of a patented invention when used solely for uses reasonably related to the development and submission of information needed for regulatory approval ("safe harbor provision"). The basic idea behind the second, safe harbor provision was to allow competitors to begin the regulatory approval process while the patent was still in force, which would allow the competitors to gain approval and be ready to market a competing product as soon as the

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product came off patent.

The patent term extension provision was limited to patented products that were a human drug product or any medical device, food additive, or color additive subject to regulation under the FDCA. The language of the safe harbor provision, however, just uses the term "patented product." As a result, there has been discussion, debate and litigation over what patented inventions are covered by the safe harbor provision. On one side of the debate, it was argued that any patented invention that was used solely for uses reasonably related to the development and submission of information needed for regulatory approval was entitled to safe harbor protection from infringement. On the other side of the debate, it was argued that only patented drugs were entitled to safe harbor protection based on the focus of Congress on speeding generic drugs to market when the Hatch-Waxman Act was enacted. The Supreme Court rejected this limited argument in Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661 (1990), holding that a regulated medical device (and other products subject to the patent term extension provision) was entitled to safe harbor protection from infringement. The breadth of the safe harbor provision remained unclear in terms of what other patented inventions it might cover.

The question of what patented inventions are covered by the safe harbor provision came up in a controversial Supreme Court case, Merck v. Integra, 545 U.S. 193 (2005). However, although third parties requested that the Supreme Court deal with this question in amicus briefs, the Supreme Court decided the case on grounds that did not deal with the scope of inventions covered by the safe harbor. When the Integra case was reheard by the lower court following the Supreme Court decision, the lower court also did not deal with the scope of inventions covered by the safe harbor, despite a vigorous dissent that the issue of whether patented research tools were entitled to safe harbor protection needed to be addressed by the court. Integra v. Merck, 496 F.3d 1334 (Fed. Cir. 2007). Research tool inventions are inventions that are used as tools to perform research. A microscope and a reagent for an assay are examples of research tools. The dissent noted that the Integra case involved research tool inventions, that the Supreme Court specifically declined to address whether or not research tool inventions were covered by the safe harbor, that many research tool inventions would be worthless if they received safe harbor protection, and that rendering research tool inventions worthless was contrary to good public policy and not necessary to accomplish the purposes of the Hatch-Waxman Act. Because the majority in the Integra case did not address whether research tool inventions were covered by the safe harbor, the questioned remained open. However, because the result in the Integra case effectively failed to find the research tool patents infringed, the case created the impression that research tool inventions would be given safe harbor protection under the Hatch-Waxman Act.

Now, in the Proveris case, the Federal Circuit has directly answered the question of the scope of patented inventions entitled to safe harbor protection. The court ruled that patented inventions that are not subject to Federal regulatory approval do not come under the safe harbor provision. The Proveris case involves a patent to an apparatus that is used to test the spray from drug delivery devices. Although the apparatus is used to test products and devices that are subject to Federal regulatory approval, the apparatus itself is not subject to regulatory approval. This is generally true of most research tool inventions. Innovasystems

was selling an apparatus that falls within the claims of the apparatus patent and Proveris, the owner of the patent, accused Innovasystems of patent infringement. Innovasystems argued that because its apparatus was a patented product used (by its customers) solely for uses reasonably related to the development and submission of information needed for regulatory approval, it was immune from infringement of the Proveris patent under the safe harbor provision of the Hatch-Waxman Act. Neither the trial court nor the Federal Circuit agreed and the Federal Circuit affirmed that the Innovasystems apparatus infringed the Proveris patent.

The Federal Circuit looked to the Supreme Court Eli Lilly case discussed above in deciding that non-regulated patented products do not fall within the safe harbor provision of the Hatch-Waxman Act. In holding that regulated medical devices are entitled to safe harbor protection, the Supreme Court in the Eli Lilly case reasoned that the patent term extension provision and the safe harbor provision of the Hatch-Waxman Act were intended by Congress to be complementary because they each corrected complementary distortions in the effective term of patent protection for regulated products. Based on this, the Supreme Court held that the patented products eligible for the safe harbor provision were at least all of the patented products that are eligible for the patent term extension provision and included regulated medical devices. The Federal Circuit in the Proveris case adopted this logic from the Supreme Court and held that the scope of patented products eligible for the safe harbor provision should be the same as the scope of the patented products eligible for the patent term extension provision. The Federal Circuit reasoned that this maintained the balance and complementarity between the two provisions that Congress intended and that the Supreme Court recognized. Based on this, the Federal Circuit stated that patented products that are not entitled to the patent term extension provision of the Hatch-Waxman Act (that is, patented products that are not subject to Federal regulatory approval) are also not covered by the safe harbor provision of the Hatch-Waxman Act. Because the Innovasystems apparatus is not subject to Federal regulatory approval, and because the apparatus covered by the Proveris patent is not entitled to the patent term extension provision (because the patented apparatus is not subject to Federal regulatory approval), the Federal Circuit held that the Innovasystems apparatus is not covered by the safe harbor provision of the Hatch-Waxman Act.

The holding and basis of the Proveris decision seems to establish a clear limit on the application of the safe harbor provision of the Hatch-Waxman Act. The Proveris decision also seems to revive the value of research tool inventions, which had been questioned in recent years.