PATENTWATCH

Merck and Integra battle on

German company Merck KGaA and Integra Lifesciences continue to argue over Merck's alleged infringement of Integra's peptide patents in a case that has significant ramifications for the pharmaceutical industry. The case, now awaiting a decision from the US Supreme Court, hinges on the scope of an 'FDA exemption' statute that allows scientists to ignore patents while they conduct research on drugs that they hope will be approved by the FDA. Merck argues that their preclinical experiments were all aimed at getting FDA approval and that the exemption therefore protects them, but Integra maintain that Merck's experiments were general biological research not protected by the statute.

Integra holds patents protecting its RGD peptides, a group of integrin-binding compounds discovered and patented originally by scientists at the Burnham Institute. Merck became interested in integrins as anticancer targets and in the mid-1980s collaborated with scientists at the Scripps Institute to show that blocking integrins can inhibit angiogenesis. Their work, using the Burnham Institute's RGD peptides, led to several potential cancer therapies including one drug currently in clinical trials. However, in 1996, after Merck declined to license the relevant patents, the Burnham Institute (and subsequently Integra) sued for infringement, claiming that the use of three specific RGD peptides in Merck's research was in violation of their patents.

The case has since lingered in US District and Federal courts. The Federal Circuit upheld the District Court's decision to award damages to Integra, stating that the FDA exemption statute exists primarily to ensure that generic drugs can enter the market as soon as possible after patent expiration on a branded drug. Because Merck's research was not 'solely for uses reasonably related to the development and submission of information to the FDA' , the Federal Circuit ruled that the exemption does not apply. The case has now moved to the Supreme Court, where Merck is expected to have argued that the FDA exemption should include *in vitro* and *in vivo* preclinical research in addition to clinical trials as a requisite to information submitted to the FDA.

The lawsuit has divided the research community, with large pharmaceutical companies warning that any ruling that narrows the scope of the FDA exemption will stifle drug discovery research and increase development time and costs. However, companies that produce research tools used in drug research are alarmed by the leeway given to the pharmaceutical industry and are demanding stronger patent protection for their products.

Oral arguments in the case were heard at the Supreme Court on 20th April. The drug discovery industry awaits the outcome.

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