Merck KGaA v. Integra Lifesciences

WIGGIN AND DANA

Counsellors at Law

PRINCIPAL CONTACTS

Dale L. Carlson
203.498.4385
dcarlson@wiggin.com

James F. Farrington
203.363.7614
jfarrington@wiggin.com

Elizabeth A. Galletta
203.498.4345
egalletta@wiggin.com

Todd E. Garabedian
860.297.3716
tgarrabedian@wiggin.com

Merton G. Gollaher
203.498.4362
mgollaher@wiggin.com

Patricia K. Melick
203.363.7615
pmelick@wiggin.com

Gregory S. Rosenblatt
203.498.4566
grosenblatt@wiggin.com

William A. Simons
203.498.4502
wsimons@wiggin.com

William J. Speranza
203.363.7637
wsperanza@wiggin.com

In a significant decision sure to have a major impact on the pharmaceutical industry, the United States Supreme Court today held that the "safe harbor provision" of 35 U.S.C. §271(e)(1), which exempts from infringement, among other things, the making or using of a patented compound "solely for uses reasonably related to the development and submission of information [to the FDA]," is to be read quite broadly. At the same time, however, the Court held that it was not presented with, and so expressed no view about, the question of "whether, or to what extent, §271(e)(1) exempts from infringement the use of 'research tools' in the development of information for the regulatory process."

The particular fact pattern in which this case arose involved the use by Merck (including by and through the Scripps Institute) of certain "RGD peptides" which were embraced by patents owned by Integra. These uses by Merck and Scripps included testing and characterization of the patented peptides, using them as controls, and the like, in connection with preclinical research directed at developing drugs to inhibit angiogenesis. The Court of Appeals for the Federal Circuit had upheld a jury verdict for Integra, finding that the uses by Merck and Scripps of the patented RGD peptides were not "reasonably related" to the development of information for submission to the FDA, and thus were infringements, inasmuch as many of the experiments related to merely identifying potential or best drug candidates, developing data relating to candidates not ultimately submitted for FDA approval, and conducting experiments not ultimately submitted to the FDA.

In vacating that decision, and remanding the case to the Federal Circuit for consideration in view of its holding, the Supreme Court held, in a unanimous decision, that:

(1) the §271(e)(1) exemption applies to use of a patented compound in preclinical studies (such as related to submission of an IND), and is not restricted to use in studies related to clinical trials;

(2) the exemption applies to use of a patented compound in preclinical studies even to the extent that the studies are directed to more than just the safety of the potential drug candidate;

(3) the exemption does not categorically exclude experimentation on drugs that are not ultimately the subject of an FDA submission; and

(4) the exemption does not categorically exclude use of a patented

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compound in experiments that are not ultimately submitted to the FDA.

Broadly speaking with respect to the last two holdings, the Court stated that where a drug maker has a "reasonable basis for believing" that its experiments using a patented compound "would, if successful, be appropriate to include in a submission to the FDA," and that the experiments "will produce the types of information that are relevant to an IND or NDA," then such uses are "reasonably related" to the "development and submission of information [to the FDA]" and are thus exempt from infringement under §271(e)(1).

The Federal Circuit had rationalized that a broad reading of §271(e)(1) would deprive so-called "research tool" patents of any value, and at least for this reason the Merck v. Integra ruling has been anxiously awaited by companies owning such research tool patents. As noted, however, the Supreme Court determined that it was not presented with this issue, and so need express no view about it, because Integra "have never argued that the RGD peptides were used by Scripps as research tools, and it is apparent from the record that they were not." Thus, the opinion unfortunately does not directly resolve whether the unauthorized use in basic drug research and development of common types of patented research tools, such as assays for preliminarily assessing the efficacy of various compounds for a particular effect, might be entitled to the §271(e)(1) exemption. It will, therefore, remain to be seen how the principles of Merck v. Integra will be applied to these situations by the lower courts.

Nothing in this Advisory constitutes legal advice, which can only be obtained as a result of personal consultation with an attorney. The information published here is believed to be accurate at the time of publication, but is subject to change and does not purport to be a complete statement of all relevant issues.

One Century Tower
P.O. Box 1832
New Haven CT
06508-1832
Telephone 203.498.4400
Telefax 203.782.2889

400 Atlantic Street
P.O. Box 110325
Stamford CT
06911-0325
Telephone 203.363.7600
Telefax 203.363.7676

450 Lexington Avenue
Suite 3800
New York NY
10017-3913
Telephone 212.490.1700
Telefax 212.490.0536

One CityPlace
185 Asylum Street
Hartford CT
06103-3402
Telephone 860.297.3700
Telefax 860.525.9380

Quaker Park
1001 Hector Street, Ste. 240
Conshohocken PA
19428-2395
Telephone 610.834.2400
Telefax 610.834.3055

www.wiggin.com

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