



Holme Roberts & Owen LLP

Attorneys at Law

HRO CONTACTS

In Salt Lake City
David O. Seeley
david.seeley@hro.com
801-323-3274

Thomas J. Rossa
thom.rossa@hro.com
801-323-3279

Jeffery M. Lillywhite
jeff.lillywhite@hro.com
801-323-3215

In Boulder
Jason D. Haismaier
jason.haismaier@hro.com
303-417-8503

Craig C. Garby
craig.garby@hro.com
303-417-8548

In Denver
Lynn P. Hendrix
lynn.hendrix@hro.com
303-866-0460

Donald L. Samuels
donald.samuels@hro.com
303-866-0548

Jan N. Steiert
jan.steiert@hro.com
303-866-0412

In Colorado Springs
Susan D. Campbell
susan.campbell@hro.com
719-381-8451

Steven B. Smith
steve.smith@hro.com
719-381-8457

In San Francisco
Ola L. Clinton
ola.clinton@hro.com
415-268-1966

In London
Zarko Iankov
zarko.iankov@hro.com
+44 207 320 6464

In Munich
Jens Roehrborn
jens.roehrborn@hro.com
+49 89 38 39 80-120

Peter Katko
peter.katko@hro.com
+49 89 38 39 80-130

June 15, 2005

Advertising Material

Intellectual Property Law Alert

A Publication of the Intellectual Property Group of Holme Roberts & Owen LLP

SUPREME COURT ALLOWS MORE DRUG RESEARCH ACTIVITIES

The United States Supreme Court ruled on June 13, 2005, that drug researchers may use compounds patented by others in research that is reasonably related to the development and submission of information to the Food and Drug Administration (FDA).

The 271 (e) (1) Exception

Congress established an exception in 1984 to the general rule that one may not make, use, sell or offer to sell any patented invention during the term of a patent. This exception, now Section 271(e)(1) of the patent statute, allows drug researchers to make, use, offer to sell, sell, and import some patented substances if done 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.

Merck v. Integra

Integra Lifesciences had a number of patents directed to a peptide sequence having useful properties. Merck KGAA funded research during the term of those patents on various peptides, which ultimately led to filing of an infringement lawsuit by Integra against Merck.

The issue of exemption under Section 271(e)(1) arose during the course of that lawsuit, where Integra argued that only preclinical data relating to safety of the drug is subject to the exemption. Integra asserted that preclinical studies related to a drug's efficacy, mechanism or action, pharmacokinetics, and pharmacology are not reasonably included in an IND or and NDA, and thus are outside the scope of the exemption.

The Supreme Court disagreed, holding that the Section 271(e)(1) exemption extends to all uses of patented inventions that are "reasonably related" to the development and submission of any information under the Federal Food, Drug, and Cosmetic Act. This was found to include preclinical studies of patented compounds that are "appropriate for submission to the FDA in the regulatory process." The Court stated that "[t]here is simply no room in the statute for excluding certain information from the exemption on the basis of the phase of research in which it is developed or the particular submission in which it could be included." The Supreme Court also stated that the use of a patented compound in experiments, where the experiments themselves are not included in a submission to the FDA, does not render the use infringing, because one cannot know at the outset what information may be included in a submission. Hence, the Court reasoned that the use of patented compounds in preclinical studies is protected under Section 271(e)(1) as long as there is a reasonable basis for believing that the experiments will produce the type of information relevant to an Investigational New Drug (IND) or New Drug Application (NDA).

What Does This Mean For You?

Although this decision shows that the exemption under Section 271 (e) (1) is broader than some had thought, it seems likely that various factors may affect the applicability of the exemption in particular situations. Accordingly, we strongly urge anyone contemplating research activities using a patented substance to seek legal counsel before commencing that research.

This Alert is a publication of Holme Roberts & Owen LLP and should not be construed as legal advice or a legal opinion on any specific facts or circumstances. Nor is it intended to address specific issues that may arise in particular circumstances or all of the provisions relating to the subject matter addressed. This update is published for general information purposes only, and you are urged to consult legal counsel concerning your own situation and any specific legal questions you may have. For further information regarding the subject matter addressed by this Update, please contact any of the attorneys listed.