

IP in the LIFE SCIENCES INDUSTRY
Genomic Pharmaceuticals

RESEARCH TOOL PATENTS

U.S. Litigation and Licensing

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MADEY v. DUKE UNIV.
(2002), *cert. denied*

Strictly Limited Research Exemption

- Research exception is “very narrow and strictly limited”
- Disqualified if “slightest commercial implication”
- No immunity if “in any way commercial”
- No immunity if research furthers “business objectives,” including non-profit, educational
- Exception limited to amusement, curiosity, philosophical (scientific) inquiry

RESEARCH EXEMPTION FROM INFRINGEMENT

- **35 USC 271(e)(1) “safe harbor”**
- **“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 ... solely for uses reasonably related to the development and submission of information [to FDA]”**
- **Congressional intent: generic pharma companies**

INTEGRA V. MERCK KGaA (2003)

Narrow Safe Harbor for Tools

- **New life for tool patents**
- **Drug candidate identification and pre-clinical studies not protected by “safe harbor”**
- **Use of research tool for FDA-related activities is not exempt from infringement**
- **Must be solely for use related to developing information for FDA submission**

*UNIV. ROCHESTER v.
G. D. SEARLE (2004)*

Challenge to Reach-Through Claims

- **Claims held invalid**
- **Inadequate description**
- **Application filed in 1992, describing gene for COX-2**
- **Must be in possession of claimed invention**
- **Historical background not included in patent**
- **Enablement will be next problem**

BAYER AG v. HOUSEY (2003)

Offshore Loophole for Tool Use

- **No infringement of U.S. tool patent when used outside U.S.**
- **Bayer used a screening method in Germany**
- **Method was claimed in a U.S. patent**
- **Drug product imported into U.S.**
- **Court says information not protected, only products**
- **No infringement, no royalties**

KINIK CO. v. ITC (2004)

Importation of Product Made by
U.S. Patented Process – Trade Law

- **Use of a process outside U.S. violates U.S. trade law**
- **Patent law exceptions do not apply to U.S. trade law**
- **Even if product of the patented process is “materially changed”**

NON-SPECIFIC PATENTING ISSUES

Anticipating Litigation

- **Claims drafted for court interpretation**
- **Claim structure and multiple independent claim alternatives**
- **Equivalents**
- **Inherent anticipation**
- **Avoiding invalidity—Prior art and an adequate search**
- **Avoiding patent unenforceability**
- **Opinion of outside counsel for litigation perspective**
- **“A good lawyer keeps the client out of court”**

PATENTING RECOMMENDATIONS

Minimizing Risk Exposure

- **“A patent is a right to go to court”**
- **Focus on litigation perspective**
- **Legal and business strategy to anticipate and cover likely infringers**
- **Claim structure and claim alternatives**
- **Use broad description of invention, enablement**
- **Coordinate patent and FDA submission**
- **Claim and include support of equivalents**
- **Get early outside legal opinion for litigation perspective and strategy**

RECOMMENDATION FOR RISK MANAGEMENT Opinion Letters

- Freedom to operate (clearance) opinion
- Non-infringement opinion
- Invalidity opinion
- Effect of *Knorr* (2004)
- If a litigant does not get an opinion of counsel, not fatal– BUT . . . what will a jury think?

RECOMMENDATION FOR LICENSING Strategies

- **Define the licensed technology consistent with patent claims**
- **Define royalties consistent with *Integra* and *Univ. of Rochester***
- **Reach-through royalties if supported by claims**
- **License, design around, litigate**

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