

# Japan Institute of Invention & Innovation

International Patent Licensing Seminar 2005

IP and Genomic Pharmaceuticals  
Treatment of Research Tool Patents



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Merck Perspective on International  
Biotechnology Patent Practices

Joseph F. DiPrima

Vice President and Assistant General Counsel

Merck & Co., Inc.

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# Mission – Merck IP Departments

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- To protect the Company's current and future products and processes and its research activities throughout the world wherever meaningful patent protection can be secured and enforced
- To assure that the Company has freedom to operate
- To respect the valid and enforceable patents of others

# Third-party Research Tools Patent Matters

- Parties obtaining Research Tool Patents
  - PhRMA companies
  - BIO companies
  - Universities
  - Individual Inventors
- Consistent Approach to All Research Tool Patent Matters

# Approach To Research Tools Patent Matters

- Patent Invalidity and Infringement Assessment
  - If Patent Deemed Valid
    - License
    - Design around
    - Move location
    - Research not undertaken
  - If Patent Deemed Invalid or Not Infringed
    - Research undertaken

# Patents Impact On Research Activities

- Patent Environment for Research – More Complex
- Research Resources spent on “Design Around” and Location Changes
- IP Department Resources spent on Validity and Infringement Opinions and Litigation
- Patent Issues Manageable – Resource Intensive



# Opportunities for Improvement

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- Improve Quality of Granted Patents
- Adopt Best Licensing Practices
- Encourage Placing Non-commercial Research Data into the Public Domain
- Expand Research Exemption



# Quality of Granted Patents

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- Enhance Resources to Patent Offices
- Ensure Examiners Sufficiently Trained in Appropriate Technology
- Ensure Examiners Sufficient Time to Review All Patent Applications
- Harmonize Patentability Guidelines for Research Tools
- Same Standards for Patentability

# Merck Position – Best Licensing Practices

- All Bio-Medical Research Tool Patents – Widely Accessible
- Extensive Use of Non-exclusive Licenses
- Remuneration Consistent with the Advancement of Bio-Medical Research
- Reach-through Royalties for use of Research Tool – Impermissible
- Stanford and University of California-San Francisco
  - Cohen & Boyer Basic Biotechnology Patent Licenses

# Non-commercial Research Data into the Public Domain

- Merck Gene Index Project
  - Started in 1994
  - ESTs in Public Database
- SNP Consortium
  - Started in 1999
  - 1.5 million SNPs in Public Domain
- Sanger Institute (Wellcome Trust)
  - Genomic Data from the Human Genome Project – Publicly Available



# Research Exemption

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- Use of a Research Tool to Understand, Evaluate or Improve the Tool or Find a New Use for the Tool should be Exempt from Infringement
- Comparative Law of Experimental Use
  - United States
  - European Union
  - Japan



# Research Exemption – U.S.

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- Court of Appeals for the Federal Circuit Decisions in *Integra* and *Madey* Cases
  - Narrowed Statutory (Bolar) and Common-Law (*De minimus*) Exemptions
  - Extended to Research Universities
  - *Integra* Case – Petition to Supreme Court



# Research Exemption – U.S.

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- Dissent in *Integra* Case – the Better Policy Rationale:
  - “The subject matter of patents may be studied in order to understand it, or improve upon it, or to find a new use for it, or to modify or “design around” it. Were such research subject to prohibition by the patentee the advancement of technology would stop, for the first patentee in the field could bar not only patent protected competition, but all research that might lead to such competition, as well as barring improvement or challenge or avoidance of patented technology.”

# Research Exemption – European Union & Japan

- “Acts Done for Experimental Purposes Relating to the Subject Matter of the Invention”
- “Not Extend to the Working of the Patent Right for the Purposes of Experiment or Research”
- Experimentation on Patented Subject Matter – Exempted
- Experimentation with or using Patent Subject Matter – Not Exempted



# Conclusions

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- Research Tool Patent Issues Manageable – Resource Intensive
- Improvements are possible
  - Improve Quality of Granted Patents
  - Adopt Best Licensing Practices
  - Encourage Placing Non-commercial Research Data into the Public Domain
  - Expand Research Exemption



# Acknowledgement

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Charles M. Caruso  
International Patent Counsel  
IP Policy and Legislation