De Jure and *De Facto* Research Use Exemptions in Patent Law

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Overview

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I. Standard Forms of *De Jure* Research Use Exemptions

- Research and Development (R&D) Exemptions
  - Unauthorized making, using, or selling of patented inventions is normally an infringement of exclusive patent rights
  - In some countries, the unauthorized import of products embodying the patented invention, or resulting from the patented process, is also an infringement of exclusive patent rights
  - Absent an exemption, even noncommercial research, or commercial R&D not directly related to an existing product in the marketplace, also constitute patent infringement

I. Standard Forms of *De Jure* Research Use Exemptions

- Research and Development (R&D) Exemptions
  - Thus, some countries exempt some types of R&D under a statutory or case law based research use exemption
  - Countries may distinguish between exempting noncommercial research – i.e., R&D that is not intended to lead directly to saleable products in the marketplace – and commercial R&D that is expected to produce such products
  - Noncommercial R&D exemptions may seem easier to justify, but in many countries even noncommercial R&D (i.e., university research) can lead to new patents which themselves may be licensed out for compensation

I. Standard Forms of *De Jure* Research Use Exemptions

- Regulatory Review Exemptions
  - In countries that require a new drug pre-market regulatory review process, pioneer drug patent owners may enjoy a *de facto* patent term extension if generic drug manufacturers cannot use the pioneer drug in the review process until it is off patent
  - Thus, many countries allow for a regulatory review exemption for research "on" the pioneer drug, regardless of whether there might be an R&D exemption
  - Such regulatory review exemptions often distinguish between research "on" and research "with" the patented pioneer drug

I. Standard Forms of *De Jure* Research Use Exemptions

- *De Jure* Research Use Exemptions in the United States
  - The United States currently has a very limited "common law" research use exemption that has some similarities with noncommercial R&D exemption in other countries
  - The exemption originated in case law from the early nineteenth century which held Congress could not have intended to restrict the unauthorized use of patented inventions solely for philosophical inquiry
  - Recently, in *Madey v. Duke* the Federal Circuit announced that this exemption was extremely narrow and did not apply to university research because universities are essentially "in business"

I. Standard Forms of *De Jure* Research Use Exemptions

- *De Jure* Research Use Exemptions in the United States
  - The United States also has a regulatory review exemption alternately called: the "Hatch-Waxman" exemption (after the name of the statute that created it); the 271(e) exemption (after its codification section in the U.S. Code); and/or the Roche Bolar or Bolar Amendment exemption (after a case that prompted passage of the Hatch-Waxman Act to secure the exemption)
  - This 271(e) exemption was recently interpreted quite broadly by the U.S. Supreme Court in *Merck v. Integra* ("any use" of a patented invention as part of research on the path to a regulatory review process is exempt)

II. *De Facto* Research Use Exemptions in the United States

- A *De Facto* Research Use Exemption for Federally Funded Research
  - Under section 202(c)(4) of the Bayh-Dole Act as codified federal research funding recipients must grant the U.S. government a non-exclusive license to any patents arising from the research for use by or on behalf of the government
  - The government can then authorize and consent to use of this license on its behalf by extramural researchers performing new government research (as confirmed in *Madey v. Duke* on remand)
  - This is *not* "march-in rights" under section 203 of Bayh-Dole as codified

II. *De Facto* Research Use Exemptions in the United States

- A *De Facto* Research Use Exemption for Federally Funded Research
  - This *is not* "march-in rights" under section 203 of Bayh-Dole as codified
  - Public Health Service (PHS) and National Institutes of Health (NIH) seem to have relied on this government license when establishing Memorandum of Understanding (MOU) with Wisconsin Alumni Research Foundation (WARF) and WiCell Institute regarding free government sponsored research using WARF patented stem cells as at least the first WARF stem cell patent arose from NIH funded research

II. *De Facto* Research Use Exemptions in the United States

- 11th Amendment State Sovereign Immunity

- No one can use federal courts to sue individual states
- Patent suits are limited to federal courts
- Therefore, patent owners cannot sue states for infringement
- Upheld by courts, *but* it has prompted some (unsuccessful) bills in Congress
- Universities that are truly state agencies (e.g., the University of Washington and the California Institute for Regenerative Medicine (CIRM)), can thus infringe patents with no recourse for patent owners
- This is not considered a “taking” for purposes of U.S. constitutional law

II. *De Facto* Research Use Exemptions in the United States

- IP "Takings" Clause
- 28 USC Sec 1498 first enacted in response to Krupp's U.S. munitions patent suit seeking injunction against head of US military ordnance for infringement
- Provides that only remedy for patent owner is compensation in Court of Claims
- Later amended to immunize government contractors from suit so long as government agency gave clear authorization and consent for infringing activities; sole remedy again is compensation from US in Court of Claims
- Recently reaffirmed in *Zoltek v U.S.* and *Madey v. Duke*

III. Policy Considerations for Research Use Exemptions

- Competitors vs. Government/Public Research
- Research use exemptions for government/public research may be easier to justify than those for competitive commercial research
- However, even government/public research can lead to valuable patented inventions
- Thus, perhaps the test is when/whether the unauthorized researcher begins to receive an income stream from his activities; at that point, the exemption should cease and payments begin
- Additionally, the U.S. disfavors compulsory licenses as devices to grant patent licenses to competitors to compete with patent owner; thus research use exemptions that mimic this will likely be disfavored as well

III. Policy Considerations for Research Use Exemptions

- Commercial vs. Non-Commercial Research
- *Madey v. Duke* found that universities and non-profits are essentially commercial competitors now, so they are (should) no longer eligible for the narrow U.S. common law research use exemption
- Is this true generally, i.e., “commercialized” campuses?
- If so, then the commercial/non-commercial distinction or justification for a research use exemption may dramatically reduce the number of entities eligible for such an exemption
- What is wrong with a robust research use exemption even for commercial competitors?

III. Policy Considerations for Research Use Exemptions

- Regulatory Review Exemptions
- Policymakers should distinguish between research "on" a patented drug – i.e., study of the drug for purposes of creating fully bioequivalent generic versions – and research "with" a patented drug – i.e., using the drug to perform other sorts of research; research "on" the drug hews closest to the policy justifications for regulatory review exemptions
- The U.S. Supreme Court appeared to ignore or misunderstand this distinction in *Merck v. Integra* and may have allowed the 271(e) exemption to cover research both on and with patented drugs; of course, this does not help research outside of the pharmaceutical area

III. Policy Considerations for Research Use Exemptions

- Combining Exemptions?
- Because different kinds of research use exemptions have different scopes of coverage, follow on researchers may seek to combine them to gain broader or “longer” coverage
- E.g., in the U.S. one could theoretically combine the 202(c)(4) government license under Bayh-Dole with the 271(e) exemption to gain continuous coverage from public basic research through private commercialization R&D

III. Policy Considerations for Research Use Exemptions

- Conclusion
- Policymakers should be aware of the full range of research use exemptions – from full exemptions even for competitive commercial R&D to very narrowly tailored *de facto* exemptions for government research – and employ models that match broad research, public domain, and competition policies in their country
- For example, the U.S. frowns upon compulsory licenses and government granted head starts to a patent owner's competitors, thus it's exemptions are largely limited to limited to government use and regulatory review

III. Policy Considerations for Research Use Exemptions

- Conclusion
- However, policymakers may decide that the sorts of knowledge spillovers that might occur where strong, broad competitive commercial exemptions allow robust experimentation on and with a competitor's patented materials lead to a stronger innovation based economy overall – perhaps not so dissimilar from that of Silicon Valley