Public-Private Partnerships and *De Facto* Research Use Exemptions: Case Study of the Thomson Stem Cell Patents

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Overview

- WARF's management of the Thomson stem cell patents
- The Public Health Service MOU
- A *de facto* research use exemption within federal extramural research
- State sovereign immunity "exemptions"
- Sec. 1498 IP "takings" with compensation
- Themes
- A full discussion of this material is forthcoming in an article in the 2006 Symposium issue of Berkeley Technology Law Journal

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Background of WARF/Thomson Patents

- Public Health Service (PHS) funded U Wisconsin research leading to first Thomson patent (5,843,780)(1998); assigned to Wisconsin Alumni Research Foundation (WARF)
    - WARF has been assigned further Thomson patents: 6,200,806 and 7,005,252. Neither states that the U.S. has rights
- WARF licensed the Thomson patents to WiCell Research Institute with rights to sublicense
- WiCell administers both the Thomson patents *and* approved stem cell lines that Thomson derived (governed by material transfer agreements (MTAs)—not IP; state contract law)
- WARF granted exclusive license to Geron for R&D in therapeutic and diagnostic fields of use (1999): standard TT deal

PHS MOU with WiCell (2001)

• Government rights in first Thomson patent include mandatory worldwide non-exclusive license "to practice or have practiced for or on behalf of the United States" the invention

• This license grant must be included in every federal funding agreement (35 USC 202(c)(4)); *it is not connected with* "march-in rights" (35 USC 203)

• WiCell and PHS executed a Memorandum of Understanding (MOU) to set out the mechanism by which future PHS extramural researchers would request samples of Thomson stem cell lines; this includes the agreement that PHS researchers can practice the Thomson patents directly under the PHS funding non-exclusive license (MOU is *not* a license)

The Current Scope of Permissible Stem Cell Research

- 2001 Bush Order + WARF/Thomson patents + Geron's exclusive license = tightly controlled stem cell research field
  - But, government license requirement under Bayh-Dole prevents WARF from completely tying up federally funded research
  - However, because approved *stem cell lines* (not the IP) were derived without federal funding, owners still retain some leverage over federally funded research
  - Also, Bush Order sharply reduces the amount of research that could have operated within the government license zone
  - Arguably, Bush could have controlled stem cell research better by allowing it to be more broadly federally funded; instead, he drove it into private and state funding arrangements outside of federal control

A *De Facto* Research Use Exemption for Federally Funded Research

- Step 1: research leading to patent at least partially funded by federal agency (Bayh-Dole governs)
- Step 2: federal agency (partially) funds new projects so that other researchers are now practicing the patented invention on behalf of the United States.
- New researchers are directly covered under Bayh-Dole government license (*not* a sublicense, assignment, or transfer)
- Scope/value of this research zone determined by amount of federal research funding: currently still a large percentage for most US research universities (especially states schools like U. Wash.)

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11th Amendment State Sovereign Immunity

- No one can use federal courts to sue individual states
- Patent suits 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., UW), can thus infringe patents with no recourse for patent owners (*not* a taking)
- Not all state universities are state agencies though
- Is California Institute for Regenerative Medicine (CIRM) a state agency?

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; sole remedy again is compensation from US in Court of Claims
- Only used for munitions patents so far, but nothing in statutory language limits it to munitions (note 1498 also allows government to infringe copyrights as well)
- Recently considered in Zoltek v U.S. (Fed. Cir., 3/31/2006)

Themes

- U.S. disfavors compulsory licenses as devices to grant patent licenses to competitors to compete with patent owner

- Research use exemptions that mimic this will likely be disfavored as well

- *Madey v. Duke* simply acknowledged that universities and non-profits are essentially commercial competitors now, so no longer eligible for common law research use exemption (note that if the Supreme Court wanted to preserve this exemption they should have accepted *Madey* on cert.)

Themes

• Supreme Court did dramatically broaden scope of 271(e) (regulatory review exemption), but this does not help research *per se*, especially at universities that generally don't pursue regulatory approval for new drugs

• But Bayh-Dole license + 271(e) may give continuous coverage from public basic research through private commercialization R&D)

• Conclusion: research exemptions in US limited to government use and regulatory review – probably because of antagonism towards compulsory licenses to competitors – but this may still achieve non-commercial goals of most research use exemptions