SCIENCE AND THE PATENT SYSTEM

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OUTLINE OF PRESENTATION

- Parallels between the scientific and the patent systems
- Contrasts between the two systems
- The hard issue: research tools
  - Examples
  - The balance needed
  - Studies
  - Approaches based on scope of patentability
  - Approaches based on experimental use exemption
  - Approaches based on licensing principles
  - Approaches based on research funding
- A reality check

PARALLELS

INCENTIVES

Recognition	Patent
(Nobel Prize)	monopoly

REQUIREMENTS

Something new	Non-obviousness, etc.
Publication	Publication

(R. Eisenberg, Yale L.J., 1987)

DIFFERENCES

- Confidentiality of information at different points (?)
- Ability to verify earlier findings (depending on national principles on experimental use)
- Ability to build on earlier findings
  - Academic credit v.
  - Patent principles for inventions and experimental use

THE RESEARCH TOOL BALANCE

Invention or discovery 1 is a means to develop invention or discovery 2

- Examples
- The rational objective for the law
- Ways to achieve it

RESEARCH TOOL EXAMPLES - HISTORICAL

- The telescope and astronomy
- The microscope and cellular biology
- Fluorescence based microscopy and contemporary biology
- The scanning tunnel microscope and contemporary surface physics
- Gene sequencing and contemporary medicine and biology
- Biotechnology and pharmaceutical industry

THE GOAL

- Appropriate balance between incentives for development of the initial invention/discovery and for its utilization for subsequent invention/discovery
- And (at least in my judgment) don’t want initial inventor to have control of subsequent invention (rejecting Dam’s “Prospect model” (1977))

FACTORS COMPLICATING THE BALANCE

- Some, but not all, initial invention is supported by public or non-profit funding
- Some, but not all, initial invention will be made available at a reasonable cost as a matter of normal business incentives.
- University researchers may not have a budget for licensing fees
- Some of the more contemporary examples involve initial inventions of contested patentability

EXAMPLES

	Non-profit	Profit
Readily made available	Information, e.g. gene sequences, and agricultural germplasm (traditionally)	Devices – e.g. analytic balances & microscopes, PCR
Not readily made available	Expensive reagents and laboratory animals	Inventions key to a business plan: receptors, stem cells

THE TENSION & REALITY OF THE ISSUE

- Supreme Court in *Brenner v. Manson* (1966): Until the process claim [to a group of compounds whose “utility” has not been demonstrated] has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development, without compensating benefit to the public.

THE KEY STUDIES

- Walsh, Cohen, & Arora (2003)
- Edwards (2003)
- Sampat (2004)
- Murray & Stein (2005)
- SIPPI (2005)
- Walsh, Cho & Cohen (2005)
- NRC Genomic & Protein Committee (2006)
- Wright & Pardey (2006) (summarizing earlier work)

WALSH, COHEN, & ARORA

- Drug discovery not substantially impeded
- Little evidence that university research impeded except in genetic diagnostic context
- Some delays in negotiating access and some access limitations in areas of targets and fundamental discoveries
- Some areas where research redirected, but most say no valuable projects stopped
- Problems avoided by “working solutions”
  - License
  - Inventing around
  - Infringement
  - Challenging patents
  - Developing public tools

EDWARDS

- Based on a study of licensing agreements
- For pharmaceutical products, assuming $ 100 M sales
  - Univ gets $ 3.7 M or 7 % of profits
  - Biotech gets $ 14.3 M or 29 % of profits
  - Pharm gets $ 32 M or 64 % of profits
- Nature/Biotechnology 2003

SAMPAT AND MURRAY & STERN

- Citation studies based on comparing genomic patents and publication rates
- Found 9 to 17 % reductions in publication following issue of patent

WALSH, CHO & COHEN & SIPPI

- Patents rarely complicate life for university researchers
- Walsh et al:
  - Only 5 % regularly check for patents
  - ~ 1 % each modified a research approach or delayed research
- SIPPI
  - 40 % of researchers seeking a patented technology (= ~ 10 % of all researchers) had difficulties
    - 76 % of these in industry
    - 35% in academia

WRIGHT & PARDEY

- Anecdotal examples for agriculture
- Found several land grant projects blocked by inability to obtain licenses
  - UC tomato
  - UC strawberry
  - Michigan turf grass
  - Australian lupin

POSSIBLE INTEGRATION

- Patents don’t greatly complicate university research – possibly because university researchers ignore them
- The industry situation may be quite different (but remember policies in some industries against reading patents)
- More likely to be problems with agriculture and with genomic patents
- And this might change with more complex research processes (National Research Council, 2006)

RESPONSES – PATENTABLE SUBJECT MATTER

- Discovery/invention line as posed in *Metabolite* and in *Ariad v. Lilly*
- Information/tangible invention line as attempted for computer-oriented invention

MORE ON DISCOVERY/INVENTION

- Statutory language not decisive on the real issue
- Movement to basics understandable
  - Long-term history on the genomic inventions
  - Genetic resources
- Greatest concern when a large area is preempted
- Or when there is need to use many different inventions as a way to achieve new progress
  - The trend in biology – sources
  - Cf Affymetrix/Barton amicus brief in *Metabolite*

MORE ON TANGIBILITY

- Course of computer science – obvious tension as innovation occurs at a more abstract level
- Difficulties in U.S. (*Diamond v. Diehr* - 1981) and in EU (*IBM* - 1998)
- Interacts with biology:
  - Measurements of gene sequences etc.
  - Measurements of correlations
  - Biological models

RESPONSES: EXPERIMENTAL USE

- Three quite different principles
  - Possible exception for non-commercial/scientific curiosity type use
  - Possible exception for use to understand and improve the invention (as opposed to use for the research purposes for which it was intended)
  - Bolar exemption and *Merck v. Integra* (2005)
- The first is probably non needed and is becoming indefensible as the distinction between commercial and non-commercial research evaporates
- The second is reasonable and almost certainly wise
- The third appropriate in some contexts, but not as a general principle
- And there is a major difficulty in obtaining damages for use of a research tool

RESPONSES: LICENSING BEHAVIOR

- When might there be economic incentive to license the tool exclusively, but there is social benefit in licensing it non-exclusively?
- Are there plausibly useful legal principles?
  - Patent misuse/abuse of dominant position
  - Essential facility doctrine
  - Dependency license (e.g. Spanish patent law article 86)
  - Others?

OBVIOUS ECONOMIC BALANCE

- Licensing judgment depends on relation between
  - Return from exclusive license for part of market v.
  - Return from non-exclusive licenses for a broader part of the market
- Note that reach-through royalties are possible in either case (and increase administrative costs)
- Similarity to decision for vertical integration – when will a process technology evolve
  - Through vertically-integrated firms that control their technological advances or
  - Through supply firms that provide their expertise to any willing manufacturer in the business?

KEY SHAPING FACTORS

- Is the monopoly itself important?
  - Yes if further research is needed (a pharmaceutical product)
  - Possibly if it enables earlier inventor to obtain significantly greater return (Celera)
- Are there significant differences between the parties in risk-aversion or ability to pay?
  - May favor reach-through royalties
- Can the technology be readily evaluated?
- Are there many different markets?
- Can use of the technology be policed?

LICENSING BEHAVIOR SUMMARY

- When is it socially wise to license the invention widely/non exclusively?
  - When many different applications seem likely
  - Or when research would benefit from many different teams at work
  - When many inventions have to be combined for subsequent research
- These could sometimes be resolved by a licensing principle

RESPONSES: RESEARCH DONORS

- Possibility that donors can impose restrictions on exercise of patents in a way that solves some of problem:
  - E.g. NIH standards on genomic inventions (2005)
  - Rockefeller Foundation efforts at open-source biology
- However, at least some universities view this as inconsistent with their rights under Bayh-Dole
- And some donors are asserting similar rights
  - EMBRAPA – restricting research use by licensees
  - Howard Hughes – sharing royalties
- Possibility of pools (SNP consortium)

REALITY CHECK: RESEARCH TOOL CASES

- PCR – Roche
- Transgenic research mice – DuPont
- Cre-lox – DuPont/BMS
- Genomes – Celera, Incyte
- Stem cells – WARF/Geron
- BRCA – Myriad
- Array – (Affymetrix)

REALITY CHECK II

CASE	PATENT/ SCOPE ISSUE?	RESEARCH EXEMPTION ISSUE?	LICENSING/ COMPETITION LAW ISSUE?
PCR			
Mice	Yes		
Cre-lox			
Genome	Yes	Yes?	Yes
Stem cell	Yes		Yes?
BRCA	Yes	Yes?	Yes
Array	Yes	Yes?	Yes

MY JUDGMENTS

- We are not currently at the correct balance
- The problem is more serious for industry than for academia
- Achieving proper balance will require several responses:
  - Patentable subject matter/scope
  - Experimental use
  - Non-profit licensing
  - Broader licensing/competition principles

THANK YOU

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