

The Patenting and Licensing of Research Tools and Biomedical Innovation

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1

The Changing Context of Biomedical Innovation

- Technological change
- Policy change
- Change in participants

2

Concerns Raised

- Anti-commons: Numerous claimants lead to breakdown and loss of collective surplus (e.g., GoldenRice™)
- Limitations on subsequent discovery and improvement due to use of patents on upstream, foundational discoveries
- Excessive transaction costs: delays, litigation
- But be mindful of benefits of patents

3

Outline of Paper

- Incidence of breakdown in IP negotiations
- Why not more?
- Other policy issues due to IP
 - Targets
 - Delays, Costs

4

Data and Method

- 45 interviews
- Nine pharmaceuticals firms
- 14 biotech firms
- University personnel
- Patent attorneys, government officials, etc.

5

Preconditions for Breakdown

- Growing number of patents
 - Overall
 - Per Innovation
- Many Biotech Firms: approx. 1300
 - From 1993-2000, biotech R&D effort more than doubled
- Increase in University Patenting
- Defensive patenting

6

Preconditions (cont.)

“The patent landscape has gotten much more complex in the 11 years I’ve been here. When I started and we were interested in assessing the third party patent situation, back then, it consisted of looking at [4 or 5 named firms]. If none were working on it, that was the extent of due diligence. Now, it is a routine matter that when I ask for some search for third party patents, it is not unusual to get an inch or two thick printout filled with patent applications and granted patents. With the growth of biotech around the world, you have greater numbers and they overlap to a greater extent. In addition to dealing with patents over the end product, there are a multitude of patents, potentially, related to intermediate research tools that you may be concerned with as well.” (Biotech IP executive)

7

Breakdown?

- Vast majority of respondents (over 90%) say: “Never happens”
- Royalty stacking rarely forecloses innovation
 - About half complained of licensing costs, but only one (of 30) respondents pointed to a case where a project was stopped
- ESTs: early concerns appear unrealized
- But concern about delays, costs- complexity increases the cost of research (see below)

8

Effects on University Research

- Most non-commercial research uses OK
- But, conflict over competitive use of diagnostics using patented genes
 - One study: 25% of labs reported abandoning tests
 - Hemochromatosis study: 4% abandoned, 19% did not develop tests
- Use of diagnostic clinical tests integral to research

9

University Research (cont.)

“There is no clear line to be drawn between clinical testing and research testing, because the state of the art of genetic tests is such that much more clinical study is necessary to validate and extend the early discovery of a disease gene. Thus, the restriction of physicians from performing clinical testing will directly reduce the knowledge about these genes.” (Merz, 2000)

10

Why Not More Breakdown?

- Relevant number of patents is moderate: 0-6
- “Working Solutions” combine:
 - License negotiation
 - General purpose tools widely licensed
 - Inventing around
 - Off-shore
 - Challenge in Court
 - Infringement/“Informal Research Exemption”

11

Why Not More? (cont.)

“If someone has a patent on genes, when the gene encodes a therapeutic product and they are ahead of us, we drop those projects. That is different than the case of a gene as a target for a small molecule screen. There we don’t drop the project. If it is just an application, it is not till the patent issues that it is infringing. Lots of these patents are pretty thin. It is an issue whether it is valid. Third, you can do things offshore. Fourth, it may be available for license and fifth, they don’t tend to enforce them .”(Pharmaceutical executive)

12

Infringement/“Informal Research Exemption”

- Universities
 - Feel free to use technologies for “research”
 - Firms generally refrain from asserting (though clinical diagnostics are exception)
- Firms
 - Hard to detect
 - About one third mention using this strategy, most say others do this
 - If need be, can challenge in court, invalidate
 - May take license later if target proves useful
- “Rational Forbearance”

13

Infringement/“Informal Research Exemption” (cont.)

“I think all the firms in the industry take on some infringement risk, because the behavior in the industry is that you have to try a million things to find one that is promising. Once you identify the promising candidate, then you look into licensing the research tools or sequences you used.” (IP attorney)

14

Institutional Responses

- “Public” databases
 - GenBank
 - Merck Gene Index
 - The SNPs Consortium
- New PTO guidelines
- Court’s narrowing of broad early claims
- NIH advocating for university/government researchers

15

Potential Problem Area: Targets

- Complaints about being excluded widespread
- Owners say it is appropriate to exclude
- Possible cost: diminished variety of attack

16

Delays/Costs

- Limited data
- Delays during negotiation-often several months
- MTAs a particular concern
 - May be little change in likelihood of exchange of materials: scientific competition
 - Big increase in negotiation time: Days -> Months
- Litigation costs (limited evidence)
 - \$1-10 million
 - Distraction, loss of managers', scientists' time
- But, AIPLA and BIO data show apparent decline in patent attorney effort per R&D dollar

17

Additional Issues

- Asymmetric Contracting
 - Size affects terms of access to research tools
- Avoiding Crowded Art
 - Technological opportunity is high
 - Social welfare effect is uncertain

18

Discussion

- General purpose tools
 - Infringement as price discrimination
 - Reduces social welfare loss
- Special purpose tools
 - Monopolize/exclusive license
 - Possible social welfare loss from sacrificing variety of approaches and unanticipated follow-on research

19

Conclusions

- Increasing complexity of patent landscape
- Little breakdown
- Development of “working solutions”
- Concern over targets and other special purpose patented discoveries
 - Patents doing what they are supposed to do
 - Some concern about social welfare implications

20

Conclusions (cont.)

- Some evidence of increasing costs, though legal effort data suggest no increase relative to R&D
- And remember:
 - Patents encourage tool discovery
 - Tools increase R&D productivity
- Could still get problems in the future
- Debate over whether costs of target patents acceptable