An empirical analysis of patenting and licensing practices of research tools from three perspectives

Sadao Nagaoka*
Institute of Innovation Research, Hitotsubashi University
May 2006

*2-1 Naka Naka Kunitachi Tokyo Japan 186-8603 Fax: 81-425-80-8410.
E-mail addresses: nagaoka@iir.hit-u.ac.jp
Introduction

In Japan, the use of a patented invention for the research on the subject matter would not constitute infringement while their use as research tools would constitute infringement. Research exemption for research on the subject matter seems to make good economic sense in the context of perpetual R&D competition (Nagaoka and Aoki(2006)).

In this paper we provide an analysis of research tools in life science area from three perspectives:

1. The research tool patents in the 47 key inventions in the life science area

2. The licensing conditions for research tools as disclosed mainly by the US biotech firms

3. Access problems as seen by Japanese pharmaceutical and biotechnology firms
I. The research tool patents in the 47 key inventions in the life science area

• Based on the joint research with Koichiro Onishi (2006), supported by the JPO

• We have analyzed the structural characteristics of the 47 key foundational inventions in the life science area across the world, identified by the JPO, which covers recombinant DNA technology by Cohen and Boyer, PCR (Polymerase chain reaction) technology, “Axel” patent, phage display technology etc.
How important are the research tools among these key inventions?

[Bar chart and pie chart showing the distribution of patents among final products, research tools, dual inventions, and patents for final products from different regions (EU, Japan, USA, Others)].
Who owns them (by organizations)?

- Research tools
  - Other
  - Pharmaceutical and other firms
  - Boitech
  - University & National laboratory

- Dual
  - Other
  - Pharmaceutical and other firms
  - Boitech
  - University & National laboratory

- Patents mainly for final products
  - Other
  - Pharmaceutical and other firms
  - Boitech
  - University & National laboratory
Who owns them (by periods)?

Note. This table covers two types (research tools and dual) of key inventions.
How important are the government interests?

Note. This table covers two types (research tools and dual) of key inventions.
How globally are they applied for patents?

Note. This table covers two types (research tools and dual) of key inventions.
In summary,

• Almost 80% of the key inventions in life science area can be used as research tools.
• University and national laboratories used to be granted the significant proportion of these inventions, but their share has declined significantly over time.
• There are government interests in half of the university patents.
• The share of trilateral applications is high, 60%.
II. The licensing conditions for research tools as disclosed by biotech firms

• Based on the joint research with Kenta Nakamura (2006), supported by the JPO

• We have uses the licensing database in the life science area of RecapIP, which covers more than 800 contracts, mainly disclosed by US biotech firms either as licensees or licensors.
The Proportions of exclusive licenses by the stages of research (Ex-post license)

Note. Ex-post license is that made after the completion of the research by the licensor.
Royalty rate of ex-post licensing by stage of research

Graph showing the number of contracts and royalty rates across different stages of research:
- Discovery
- Lead Molecule
- Preclinical
- Clinical
- Post Clinical

The graph indicates a higher number of contracts and royalty rates as the research progresses from discovery to post-clinical stages.
Licensing conditions by types of technology (Ex-post licensing)

![Chart showing licensing conditions by types of technology]

- **Exclusivity, %**
  - Tool: 40%
  - Dual: 90%
  - Drug: 50%

- **Royalty, %**
  - Tool: 0%
  - Dual: 40%
  - Drug: 20%
The ratios of exclusive licenses by the types of contracts and licensors

Note. Ex-ante license is made before the undertaking of the research by the licensor and involves the financial contribution by the licensee to the research project committed at that stage.
In summary,

- The frequency of exclusivity provisions and the level of royalty are lower for the discovery stage than in the downstream stage, and lower for the licensing of tools than for the product technology, as expected.
- Lower royalty for upstream technology would reflect higher risk and more R&D cost to be paid solely by the licensee in its commercialization.
- Ex-ante licensing involves more exclusivity than ex-post licensing.
- Ex-post licensing by a university often involves exclusivity (even after controlling the stage of research and technologies in our econometric analysis), which may reflect the financial constraint on the university in a licensing negotiation.
III. Access problems as seen by Japanese pharmaceutical and biotechnology firms

- A survey on the member firms of the Japan Pharmaceutical Manufactures Industry Association (75 firms) and the Japan Bio-industry Association collected in January 2004
- 68 responding firms and 36 firms of them use research tools
- The following is my analysis based on the above survey results
At what stage does a firm engage in the search of research tool patents?

(multiple answers allowed)
The response of a firm when it discovers the "blocking" research tool patent granted

(multiple answers allowed)
"Reasonableness" of the licensing conditions offered by the research tool patentee as seen by the user firm
Outcomes when “unreasonable” licensing conditions are offered by the patentees

(multiple answers allowed)
Licensing conditions offered by the research tool patentee

(multiple answers allowed)

Relative to the responding firms using research tools

- Other
- Lump-sum
- Mile-stone
- Rights on final product, such as reach-through royalty
- Cross license
In summary,

• A firm often does not give up research even if it finds a “blocking” research tool patent. It seeks a license from the patentee, it uses alternative research tools etc.

• A firm often finds the licensing conditions offered by a patentee “unreasonable” in light of the strength of the patentability, the level of royalty, royalty stacking, the remaining length of patent term etc.

• On the other hand, the licensing deals are more often struck than not.
Concluding comments (preliminary)

- Patent protection of research tools would stimulate their development and might also facilitate ex-post licensing rather than ex-ante licensing which is often exclusive, as long as it meets clear patentability standard.

- For the efficient use of the research tools,
  1. Avoidance of royalty stacking due to multiple licensing and
  2. cost-based or free non-exclusive licensing of government supported inventions of research tools, unless their development requires exclusivity

would be important.
References


• Koichiro Onishi and Sadao Nagaoka, 2006, “Structural characteristics of key inventions in the life science area," based on the research project report on patent protection of upstream inventions supported by the JPO, forthcoming as a Working Paper of the Institute of Innovation Research, Hitotsubashi University