

Guideline for Research Tool Patent Licensing (proposal)

January 16, 2006
Intellectual Property Committee
Japan Pharmaceutical Manufacturers Association

Guideline

Research tool patent should be widely and non-exclusively licensed under reasonable conditions in which the licensor and the licensee are fairly treated so that pharmaceutical research and development activities will not be hindered.

- No precedent has been established as to whether or not the act of using research tool patent as a tool for selecting a final (pharmaceutical) product in the pharmaceutical research and development process falls under “experiment/research” in Article 69, Paragraph 1 of Japanese Patent Law.
- Research tool patent should be widely and non-exclusively licensed under reasonable conditions so that pharmaceutical research and development activities will not be hindered even if such act is not interpreted to fall under “experiment/research” in Article 69, Paragraph 1 of Japanese Patent Law.
- Valid research tool patent should be respected in the above case, and persons who intend to use such patent should promptly notify the patent holder to obtain necessary license.

1. Effect of Proposal

- (1) In order to generate innovation in the new environment “knowledge economy” as a driving force of economic development, it is necessary to stimulate/activate intellectual creation, protect its outcome as intellectual property, and make use of such outcome effectively.
- (2) Patented invention of research tool is used to select a final pharmaceutical product in research and development process. If patent holders would not agree to license their patent rights or would seek an injunction to block use of their patent, research and development activity itself would be limited, and facilitation of intellectual creation especially in the pharmaceutical industry in Japan may especially be hindered.
- (3) Regarding the relationship between effect of patent right and experiment/research, Article 69, Paragraph 1 of Japanese Patent Law provides, “Effect of patent right does not extend to the execution of patent invention for experiment/research”. While the

scope of “experiment/research” is limited to the act such as studies on patent invention itself for its modification/development according to a dominant opinion, no precedent has been established.

- (4) If the provision is interpreted as in the dominant opinion without any countermeasure to be taken, research and development activities to select final (pharmaceutical) products by using research tool patent would be limited, opportunities to provide safer and more effective new drugs to Japanese people in a timely manner would decrease, and chances for generics to enter into the market would be reduced. Furthermore, our pharmaceutical research and development activities may be shifted to other countries where laws and regulations are streamlined so that research and development activities will not be hindered by research tool patent.
- (5) Under these circumstances, we, Intellectual Property Committee of Japan Pharmaceutical Manufacturers Association herein proposes a guideline for research tool patent licensing in order to improve the environment for drug innovation/development in Japan by promoting smooth utilization of research tool patent.

2. Definition of Research Tool Patent

Research tool patent in this guideline means a patent covering genes/proteins used as tools for selecting final (pharmaceutical) products in pharmaceutical research and development process as well as manufacturing, selection, and use of such genes/proteins (ex. marker proteins used in biochemical experiments and their coding genes, protein manufacturing procedures, gene selection, receptor proteins that may react to pharmaceutical molecules and their coding genes, drug screening methods, transgenic animals, vectors, and antibodies).

3. Scope of Application

- (1) This guideline shall be applied to pharmaceutical research and development activities in which research tool patent is used to select final (pharmaceutical) products.
- (2) This guideline shall not be applied to use of research tool patent in final (pharmaceutical) products or in manufacturing of final (pharmaceutical) products.