

Chapter 5 Collaborative IP Mechanisms' Applications: Exploring New Frontiers of Life Sciences

A. *Patent Pools and Biotechnology: Legal and Business Considerations*

A growing number of concerns have been raised about the impact of intellectual property rights on biomedical innovation.⁴³⁵ Even if there are no systematic empirical studies on this point, there is a certain anecdotal evidence of fragmented patent landscapes,⁴³⁶ echoing from highly focused public health cases such as malaria vaccine development.⁴³⁷ Indeed, it has often been suggested that cooperative agreements, as patent pools, where right holders agree to license their IP as a package, may well be an expedient to overcome the outlined problem.⁴³⁸ The rationale for such collaborative arrangements is quite simple: by clearing the way to freedom to operate in a given technological field and by reducing the number of necessary negotiations to be undertaken by prospective third party licensees, transaction costs can be lowered and technology transfers facilitated. Yet, despite their attractive potential and the success of patent pools in other sectors, notably consumer electronics, they remain largely untested in biotechnology. Therefore, this last part of our contribution will be dedicated to the understanding and evaluation of the actual feasibility and convenience of the implementation of patent pooling mechanisms in life sciences.

The motivations for cooperation lay at hand: as IP portfolios of flourishing biotechnology industries are taking shape, transactional costs of increasing technology transfer can begin to account for a non-affordable portion of an average company's precious research and development expenditures. In fact, expensive negotiations, and the threatening exposure to even higher potential litigation's fees, constitute a

435 For a valuable contribution to the debated issue of patentability of biotechnological inventions, see i.a.: Drexl J., "La Brevettabilità delle Biotecnologie", In: Sciso, Elena ed.: L'OMC 1995-2005 - Bilanci e prospettive. Rom, LUISS University Press, 2006, p. 37 *et seq.*; Straus J., "Stellungnahme zu den vom Rechtsausschuss gestellten Fragen zu dem Entwurf eines Gesetzes zur Umsetzung der Richtlinie über den rechtlichen Schutz biotechnologischer Erfindungen", In: BT-Drucksache 15/1024, Deutscher Bundestag, 15. Wahlperiode, Rechtsausschuss, Protokoll der 57. Sitzung am 29. September, 2004, p. 214 *et seq.*

436 Garlappi *et al.*, "Public Sector Science and the Strategy of the Commons", Best Paper Proceedings, Academy of Management, 2002.

437 Fedson D., "Preparing for Pandemic Vaccination: An International Policy Agenda for Vaccine Development", *Journal of Public Health Policy*, 2005, vol. 26, p. 4 *et seq.*

438 Grassler F. *et al.*, "Patent Pooling: Uncorking a Technology Transfer Bottleneck and Creating Value in the Biomedical Research Field", *Journal of Commercial Biotechnology*, 2003, vol. 9, p. 111 *et seq.*

serious economic inefficiency that may dislocate fundamental resources from the “core-business” of biotechnology.

Given the complex and evolving dynamics of biotechnology research and development, operating within an area of particularly dense patent production, the industry’s reliance on cooperative market-based technology transfer mechanisms, as embodied by patent pools or other private collective rights organizations, may be inevitable in the medium and long term. Having scrutinized the actual patent landscape as well as the prospective solutions, as diffusely outlined herein, the opportunities for future success may depend on the prompt acceptance and calibrated implementation of such collaborative IP strategies.

However, the successful stereotype that has emerged in the electronic and communication industries⁴³⁹ cannot be blindly transposed as “successful receipt” and implemented on a one-to-one basis in the biotechnology sector, because we ought to take into due consideration the specific peculiarities that distinguish the latter from the former. Indeed, a new, distinctive patent pool model may likely arise within the life sciences domain showing particular features that are reflecting the different business context. Hence, the question that remains to be answered is how the structure and organization of a biotechnology patent pool should differ from the general model.

B. Pilot Experiences

I. Cases at Hand

In an attempt to provide a satisfactorily answer to the questions as to what extent the patent pool mechanism can be applied to genetic inventions and whether such a model may lead to the expected benefits, some illustrative “first hand” experiences of patent pools, as recently undertaken - and have proven viable - in the field of life sciences, will be reported.

1. Golden Rice

A seemingly instructive case on collaborative IP patterns of protection and on successful negotiation through patent thickets emerged in the field of agricultural biotechnology.⁴⁴⁰ The Golden Rice Project was born out of an initiative of the Rock-

439 Aoki R. *et al.*, “Coalition Formation for a Consortium Standard through a Standard Body and a Patent Pool: Theory and Evidence from MPEG2, DVD and 3G”, Institute of Innovation Research Working Paper, 2005.

440 Stanley P. *et al.*, “Intellectual and Technical Property Components of Pro-Vitamin A Rice (Golden Rice): a Preliminary Freedom to Operate Review”, ISAAA Briefs No. 20, Ithaca, 2000, also available at: <http://www.isaaa.org>. For a more general discussion, see: Graff G. *et*