

In fact, the ability of patent pooling agreements to adapt themselves to different circumstances on a case-by-case basis may prove extremely valuable. Actually, as patent pools are characterized as voluntary IP mechanisms based on ongoing collaboration both among their members and with third licensees, they are typically amenable to any kind of arrangement, following the convenience and the peculiarity of the targeted market for the contracted product. Thus here, too, a patent pool solution is likely to prove very resourceful, if the business operators concerned seize the high potential benefits of such a collaborative approach.

II. Some Common Remarks

1. General Considerations

To draw some conclusions in the light of the “pilot experiences” that have been presented here, some fundamental issues have to be attentively addressed when further exploring whether the patent pool model, as we know it, may be amenable within the sphere of life sciences. In fact, a realistic implementation of such paradigm in life sciences should take into account the distinguishing features of the new economic environment in which a prospective consortium is to be shaped.

In this respect, the most noticeable traits characterizing the establishment of a biotechnology patent pool may be briefly outlined as follows:

- First of all, the life sciences industry is not as strongly conformed to technical standards,⁵³⁰ as those, most notably, defining the electronic and communication sectors. For some authors this point represents an obstacle to the inception of a patent pool in the first place,⁵³¹ although it has also been compellingly argued that “standards” might just need to be re-defined bearing in mind the scopes of the industry at issue, for example as a pre-determined set of genetic mutations recognized by the international community.
- Secondly, universities and public institutions, rather than for-profit firms, may well represent the typical licensors, often holding key biotechnology patents, given their major, active role as researchers and innovators in the field.⁵³² There-

http://www.genetests.org/servlet/access?prg=j&db=genetests&site=gt&id=8888891&fcn=c&qry=2622&res=nous&res=nointl&key=Q4npvENdATo2B&show_flag=

530 For a critical discussion on the interface between patent pools and standards in biotechnology, see: Eversible T., “Patent Pools and Standard Setting in Diagnostic Genetics”, *National Biotechnology*, 2005, 23, p. 937 *et seq.*

531 Aoki R. *et al.*, “The Consortium Standard and Patent Pools”, *The Economic Review*, 2004, vol. 55, p. 346 *et seq.*

532 This phenomenon is particularly visible in the American system, where the commercialization of knowledge is frequently nurtured by the input of universities and research institutions, where the start-up process takes place before finding its way in the business. In this sense and more specifically on the emergence of the so-called “triple helix” model, linking universities, industries and governments for the purpose of fostering innovation, see: Etzkowitz H.,

fore, a biotechnology patent pool should promote public-private collaboration and eventually also encourage said institutions to participate in the consortium.⁵³³ In this context, although more influential companies and government agencies may play a key role in launching and, possibly, partly financing the setting up of the initiative, it is important that the patent pool maintains its own character and independence, in terms of trustees and management. For this reason, it is fundamental that the consortium, once operating, may in the medium-long run rely on its own sources of auto-sustainment: concretely, the pool could be supported by contributions of its members, as consideration for the services provided, including an annual fee or, eventually, even a percentage of royalties received from the undertaken licensing activities - conceivably with an advantaged, discounted rate in order to facilitate the involvement of universities and public institutions that will likely play a minor role in the marketing and commercialization of the invention at issue.

- Finally, the end product incorporating the technologies contributed to the pool, characterized by a longer maturation cycle, may often not yet exist at the time of the consortium's creation, and rather be developed by the participating parties as a result of collaborative research and development's efforts.⁵³⁴

This last point is likely to make pool members more susceptible to the fear of a prospective antitrust scrutiny, because said longer product development phase, which is typically not yet initiated at the time of the pool establishment, renders the pre-assessment of the highly recommended "complementary" nature of the still to be patented technologies, which are to be eventually assembled, even more uncertain.⁵³⁵

As far as the premises for the establishment of a biotechnology pool are concerned, the necessary points to be checked may be summarized as follows:

- Multiple patent holders: pooling agreements are typically concluded to remove the "stacking" problem caused by a multitude of patents being owned by a variety of holders. Intuitively, the model therefore seems inappropriate when a

"The Triple Helix: University-Industry-Government - Innovation in Action", Business & Economics, 2008. For a wide assessment of public-private partnerships in a broad range of policy areas, see: Vaillancourt Rosenau P., "Public-Private Policy Partnerships", MIT Press, 2000.

533 For a legal and economic analysis of IP collaborative models in the context of life sciences, see i.a.: Schimmelpfennig D. et al., "Public-Private Collaboration in Agricultural Research: New Institutional Arrangements and Economic Implications", Wiley-Blackwell, 2000; Zilberman D. et al., "The Public-Private Structure of Intellectual Property Ownership in Agricultural Biotechnology", *Nature Biotechnology*, 2003, vol. 21, p. 989 *et seq.*

534 Gaulé P., "Towards Patent Pools in Biotechnology?", *Innovation Strategy Today*, April 2006, vol. 2, p. 123 *et seq.*

535 The need to avoid to pool "substitute" – as opposed to "complementary" – technologies is thoroughly analyzed when outlining the fundamental requirements prescribed by the patent pools guidelines in the different jurisdictions (i.e. EU, US and Japan) dealt with within the scope of this contribution.

single person or entity owns all the rights under a given technology, as for instance when one holder controls all patents relevant for the genetic testing for a particular disease.⁵³⁶ Coherently, the biotech cases discussed here all involve multiple patents in the hands of a plurality of owners.

In this perspective, given their high potential for solving stacking licenses, patent pools may prove particularly helpful in those areas of genetic testing characterized by diseases caused either by multiple defects in a single gene or by one or more defects in a multitude of genes, for which complex genetic associations have been discovered, thus a larger thicket is likely to take shape.

- Collaborative attitude: patent pools strongly rely on the voluntary commitment of all patent owners; therefore they cannot offer a viable solution in all those cases where the technology holders are not open to grant licenses on RAND terms or, even, they do not wish to grant any license at all in virtue of their statutory exclusive rights.⁵³⁷ Illustratively, in both the Golden Rice and the SARS instances, voluntary negotiations have been effectively undertaken and proven successful. Conversely, a “compulsory patent pool” - in which an administering body would seek a compulsory license for the essential technologies from all patent holders that do not voluntary engage in the pool - is in contradictions with the collaborative mechanisms that have emerged in the practice of those consortia.

In order to foster collaboration among different patent holders, a valuable incentive could be effectively provided by the emergence of standards for good practices in medical and laboratory genetics, which should be strongly encouraged. These standards are not the same as those conventionally defined within the electronic or the telecommunication sectors, but have instead to be understood, for instance when applied within the scope of genetic testing, either as a “set of mutations publicly recognized by the international scientific community” or “reflecting national and international best practice guidelines for genetic testing for a particular disease”.⁵³⁸

- Financial coverage: finally the ultimate incentive for attracting all parties into a patent pool is the likelihood of making profit; in fact, in order for a consortium to prove effective, the right balance has to be achieved between the costs for financing the establishment of the pool - which may be very high, especially in the initial phases -on the one hand and, on the other hand, the prospects of generating an overall adequate revenue by collecting royalties on the contracted

536 Mars J., *et al.*, “Diagnostic testing fails the test”, *Nature*, 2002, vol. 415, p. 577 *et seq.*

537 On the problem of deficient participation in patent pools, where it has been empirically demonstrated that between half and two-thirds of the eligible firms decide not to join the consortium, as conclusive founding, see more generally: Lerner J. *et al.*, “To Join or Not to Join: Examining Patent Pool Participation and Rent Sharing Rules”, January 2008, available through the Social Science Research Network at:

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=945189

538 Ebersole J., *et al.*, “Patent Pools and Standard Setting in Diagnostic Genetics”, *National Biotechnology*, 2005, 23, p. 937 *et seq.*

product. Under this aspect, it remains to be seen whether, for instance, diagnostic-gene consortia covering only one particular disease syndrome will reach such a balance. Ultimately, while, on the one hand, patent pools might constitute the ideal means for raising the visibility and accessibility of smaller genetic laboratories, thus increasing the amount of collected license fees and consequently bridging the gap between potential and actual revenue, on the other hand, it remains to be seen up to which extent small size patent pools will prove viable in the first place.

2. The Issue of Funding

This last point deserves particular consideration, as the perspective of gaining an economic and competitive edge is finally the drive for setting the whole pooling mechanism in going.⁵³⁹ However, while commercial solvency is at a time a prerequisite and, for good times, also an incentive for a patent pool to stay viable, this is not the only and primary goal pursued by such collaborative entities.

Indeed, good tailored patent pools in the biotechnology field could well serve societal public health purposes, as well. This is well illustrated by the Golden Rice case, where the end product, duly enriched with β-carotene, was transferred to developing countries at no cost in order to obviate nutritional deficiencies in those regions. That agreement was a superlative example of how private and public organizations dealt in a combined effort with the relevant patents by creating a non-profit humanitarian patent pool under a single licensing authority.⁵⁴⁰ The possible public goal beyond the creation of a consortium is, in fact, the reason why, besides the patent holders typically involved as shareholders and financiers of the pool, various governmental and non-governmental institutions - such as the already frequently mentioned WHO,⁵⁴¹ the OECD⁵⁴² or the HUGO,⁵⁴³ as well as professional entities, such as both the European and the American Society for Human Genetics⁵⁴⁴ - might eventually act to promote, by means of substantial support, the effective establishment of patent pools in the life sciences domain. In this respect, the need for public subsidies for comprehensive biotechnology projects, serving also the cause of de-

539 For a discussion on the issue, see: Krattinger A., "Financing the Bioindustry and Facilitating Technology Transfer", IP Strategy Today, 2004, vol. 8, p. 1 *et seq.*

540 On the topic, see: Graff G., *et al.*, "The Public-Private Structure of Intellectual Property Ownership in Agricultural Biotechnology", National Biotechnology, 2003, 21, p. 989 *et seq.*; and Parish R., "Using the Industry Model to Create Physical Science Patent Pools among Academic Institutions", Journal of the Association of University Technology Managers, 2003, 15, p. 65 *et seq.*

541 The World Health Organization: <http://www.who.int/en/>

542 The Organization for Economic Co-operation and Development: <http://www.oecd.org>

543 The Human Genome Organization: <http://www.hugo-international.org>

544 See respectively: <http://www.eshg.org> and <http://www.ashg.org/genetics/ashg/ashgmenu.htm>

veloping nations, was ultimately advocated in a report for the ICTSD⁵⁴⁵ on intellectual property and sustainable development issued in February 2007.⁵⁴⁶

From a practical angle, in order to fulfil the named public goals and to prevent the establishment of patent pools to become prohibitively expensive - especially for smaller and highly specialized entities and mainly as a result of the costly expertise required for the setting-up process - an appeal may be addressed to such public-profile and professional institutions to aid the creation of “key-patent pools”, encompassing essential innovations for a given biotechnological domain, to overcome patent access barriers which may impair “vital” innovation. In fact, funding from such organization, while typically remaining within the scopes of their institutional goals, would reward IP collaborative efforts and at the same time provide a substantial platform for the establishment of such practices, thus supporting and effectively encouraging collaboration in this delicate scientific field at the crossroad between life and technology.

Indeed, already in the context of the above-mentioned STS Forum,⁵⁴⁷ attention has been drawn on the fact that the benefits of science and technology are not reaching a major part of people in the world, where barriers to seizing the opportunities for using innovative solutions to solve global problems need to be removed. As it has been properly highlighted, because today problems are becoming increasingly complex against the backdrop of globalisation and international competition, they are beyond the control of any single country or of the scientific community alone, since for many issues an actual solution can only be found through changes in the social systems and mutual cooperation. Within this composite setting, the view is taken that funding by socially committed institutions, such as governmental agencies or non-profit foundations, may well represent an important catalyser for collaborative IP approaches, backing the establishment of said consortia particularly in those technological domains where public concerns priorities may become an issue.

In fact, whereas research and development itself is already a traditional area for investments, patent pooling mechanisms involved in the realization of innovative solutions still do not receive the same kind of consideration. Nevertheless, science, as a branch of knowledge, is inherently linked to its practical implementation in the marketplace, thus, in order to remove barriers to technology access, investments should also cover collaborative frameworks established to foster dialogue and exchange between firms and research institutions concurrently involved in specific technological endeavours.

545 The International Centre for Trade and Sustainable Development: <http://www.ictsd.org>

546 Barton J., “New Trends in Technology Transfer: Implications for National and International Policy”, ICTSD Program on IPRs and Sustainable Development, February 2007, Issue Paper no. 18, p. 16, also available at:

<http://www.iprsonline.org/resources/docs/Barton%20-%20New%20Trends%20Technology%20Transfer%200207.pdf>

547 Science and Technology in Society Forum, “Lights and Shadows - Fundamental Concepts”, available at: <http://www.stsforum.org/fp.htm>

This is a less explored area for funding that, all the same, seems to present a great potential not only to encourage a more constructive cooperative spirit among patent holders, but also to promote the dissemination of scientific applications to ultimately benefit the public at large, through centrally managed collaborative IP mechanisms providing for standardized, fair and non-discriminatory conditions of access to the pooled technologies. Seemingly in accordance with these views, the STS Forum has expressed the need for “major investment in infrastructure”,⁵⁴⁸ as a concrete, institutional premise for effective, international cooperation. Therefore, investments for the progress of sciences should extend to embrace the operative, managerial framework, as constituted by the establishment of consortia, needed to optimise and spread technological achievements, eventually making innovative solutions not only possible, but also widely accessible.

From a wider perspective, the concrete prospects of implementing collaborative IP mechanisms have eventually brought into the limelight the potential for new rewarding opportunities. In fact, overcoming some traditional hostility⁵⁴⁹ and acknowledging the economic and strategic importance won by collaborative IP licensing models, nowadays patent pools and collective rights management mechanisms have been attracting more and more interest also within the international arena, being addressed as possible solutions to the problem of highly fragmented patent rights, characterizing vast areas of the actual biotechnology landscape.

Indeed, the patent pool formula was explicitly mentioned as offering viable solutions also within the domain of life sciences, as affirmed at different formal occurrences by high-profile institutions such as the United States Patent and Trademark Office (USPTO) in 2000,⁵⁵⁰ the Federal Trade Commission (FTC) in 2003⁵⁵¹ and the World Health Organization (WHO) both in 2005⁵⁵² and 2006.⁵⁵³ On this latter occasion, in particular, the WHO suggestively concluded that: “patent pools of upstream technologies may be useful in some circumstances to promote innovation relevant to developing countries. WHO and WIPO should consider playing a bigger role in promoting such arrangements”. Thereby, the opportunity of committing public funds

548 Atlas R., Speech at the Plenary Session “Emerging Infectious Diseases Requiring Global Solutions”, Third Annual Meeting of the STS Forum, September 11, 2006, Kyoto, Japan, available at: http://www.stsforum.org/session_pdf/PL204-RonaldAtlas.pdf

549 In particular, referring to the old antitrust suspicion of arising anti-competitive concerns as a consequence of the aggregation of multiple rights, as examined more in general in the Introduction, when dealing with the interface between IP rights and antitrust law.

550 USPTO, “Patent Pools: a Solution to the Problem of Access to Biotechnology Patents?”, United States Patent and Trademark Office, December 2000.

551 Federal Trade Commission, “To Promote Innovation: the Proper Balance of Competition and Patent Law”, Report, October 2003, Executive Summary, available at: <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>

552 WHO, “Genetics, Genomics and the Patenting of DNA: Review of Potential Implications for Health in Developing Countries”, World Health Organization, Genetic Program, 2005.

553 WHO, “Public Health, Innovation and IP Rights”, Report of the Commission on IP Rights, Innovation and Public Health, World Health Organization, 2006.

for promoting access to key-technologies, namely by setting up collaborative IP models, was also called upon.

In fact, obstacles to the freedom to operate within the delicate sphere of life science, and the consequent drag on vital innovations, need a quick response, especially when involving major public health cases, i.a. pandemics such as SARS⁵⁵⁴ or swine influenza⁵⁵⁵. In this respect, the Organisation for Economic Co-operation and Development (OECD)⁵⁵⁶ provides an influential forum to deal with such issues: in fact, within the OECD the governments of the leading market democracies work together to address the economic, social and governance challenges of globalisation, as well as to exploit its opportunities, by offering a setting to compare policy experiences, seek answers to common problems, identify good practice and co-ordinate domestic and international policies.⁵⁵⁷

In such setting, a workshop dedicated to “Genetic Inventions, IP rights and Licensing Practices” was hosted in Berlin at the beginning of 2002: here substantial consideration was given to whether clearing house-type mechanisms may be an appropriate solution to facilitate patent access and whether they may be also successfully applied to the life sciences field, with a view to the feasibility and challenges of such an undertaking.⁵⁵⁸ Indeed, the central question addressed was whether and to which extent patent pool and similar models could be applied to genetic inventions, and subsequently whether such collaborative IP schemes may lead to the expected benefits, in view of optimising the resources available within a particular industry.

In an attempt to fully address the issue, the OECD subsequently hosted a workshop specifically dedicated to collaborative models to ensure IP access, with a particular focus on the role of patent pools, patent clearinghouses and other collaborative schemes in the field of biotechnology and human health.⁵⁵⁹ Taking steps from

554 Simon J., *et al.*, “Managing severe acute respiratory syndrome (SARS) intellectual property rights: the possible role of patent pooling”, Bulletin of the World Health Organization 83, 2005, p. 707 *et seq.*, also available at: <http://www.who.int/bulletin/volumes/83/9/707.pdf>

555 For an outline of the recent outbreak, see i.a.: Centers for Disease Control and Prevention, “CDC Health Update: Swine Influenza A (H1N1) Update: New Interim Recommendations and Guidance for Health Directors about Strategic National Stockpile Materiel”, Health Alert Network, April 2009, also available at: <http://www.cdc.gov/swineflu/HAN/042609.htm>; for an overview, see: http://en.wikipedia.org/wiki/Swine_influenza

556 For the OECD homepage see: <http://www.oecd.org>

557 Twenty countries originally signed the Convention on the Organization for Economic Co-operation and Development on 14 December 1960. Since then a further ten countries have become members of the Organization. The Member countries of the Organization and the dates on which they deposited their instruments of ratification can be found at: http://www.oecd.org/document/58/0,2340,en_2649_201185_1889402_1_1_1,1,00.html

558 Organization for Economic Co-Operation and Development (OECD), “Genetic Inventions, Intellectual Property Rights and Licensing Practices”, Report of a workshop organized by the OECD Working Party on Biotechnology, Berlin, January 24-25, 2002, available at: <http://www.oecd.org/dataoecd/42/21/2491084.pdf>

559 International Workshop on “Collaborative Mechanisms: Ensuring Access”, Washington D.C., December 8-9, 2005. For an outline of the discussions arisen, see: http://www.oecd.org/document/9/0,3343,en_2649_34537_39406921_1_1_1,1,00.html

the experience of patent pools in fields other than life sciences, the convening parties closely focused on the potential of establishing positive technology pooling practices in the field of biotechnology, particularly for genomic and genetic applications. In this respect, in order to ultimately ascertain how access to biotechnological innovations may be facilitated, the viability of collaborative IP models in life sciences has been closely scrutinized and their positive potential for implementation has been eventually acknowledged.⁵⁶⁰

Finally, in alignment with the view expressed by such internationally representative institutions, the belief is shared that companies positioned at the forefront of this rising collaborative IP trend, shall they prove able to strategically implement said cooperative strategies in compliance with the expected competitive standards, are going to shape the next era of commercial developments, hence paving the way towards new, inspiring opportunities. Undoubtedly, opportunities also come along with challenges, but based on the learning and good practices established in this domain, as partly outlined through this contribution, this shall be a path worthy to follow.

560 The conclusions endorsed by the OECD about the positive potential of such collaborative IP mechanisms may be placed on the same line with those already reached through a previous workshop: Organization for Economic Co-Operation and Development (OECD), “Genetic Inventions, Intellectual Property Rights and Licensing Practices”, Report of a workshop organized by the OECD Working Party on Biotechnology, Berlin, January 24-25, 2002, available at: <http://www.oecd.org/dataoecd/42/21/2491084.pdf>