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 industries[439] 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*

efeller Foundation, based on a widely recognised need for a sustainable biofortification program to solve the scourge of micronutrient deficiencies worldwide.[441] It was this project that brought together Prof. Ingo Potrykus, from the Institute of Plant Sciences at the Swiss Federal Institute of Technology (ETH-Zurich), and Prof. Peter Beyer, from the University of Freiburg, who in an exemplary collaboration created "Golden Rice" to help mitigate the problem of vitamin A deficiency in the world.[442]

In fact, they succeeded in genetically enriching rice grains with ß-carotene, the actual precursor of vitamin A, giving them the characteristic yellow colour that indeed lead to the name "Golden Rice".[443] Carotenoids (including beta-carotene) are natural plant pigments and are widely found in coloured fruits, carrots, and green vegetables. Plants do not contain Vitamin A, but only its precursor, pro-vitamin A (beta-carotene). Animals, including man, synthesise Vitamin A from carotenoids ingested through their diet. Hence, animal meat products contain Vitamin A. People living on a poor diet are at risk of becoming vitamin A deficient, which can lead to life-threatening illnesses. Indeed, only some carotenoids have pro-vitamin A activity and beta-carotene is the most common and important among them. Rice is the most important staple food for hundreds of millions of people in developing countries. Hence, delivery of beta-carotene with the help of Golden Rice could contribute to the reduction of chronic health problems caused by vitamin A deficiency (VAD). VAD is widely recognized to cause blindness, but more importantly, VAD exacerbates infections, including HIV-AIDS, measles, and other childhood diseases. This leads to an increased mortality rate, especially among children. UNICEF has estimated that 124 million children in the world are deficient in vitamin A.[444]

al., "Towards an Intellectual Property Clearinghouse for Agricultural Biotechnology", Agricultural Biodiversity and Biotechnology in Economic Development", May 2006, vol. 27, p. 387 *et seq.*

441 The project at issue has been followed by a big publicity and Golden Rice's properties were highly praised by: Time Magazine, "This Rice Could Save a Million Kids a Year", July 2000, vol. 156, no. 5
The Rockefeller Foundation has been widely acknowledge for its efforts of promoting access to key patented technologies, *i.a.*, ultimately in a report for the ICTSD (The International Centre for Trade and Sustainable Development) by: 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. 15, also available at: http://www.iprsonline.org/resources/docs/Barton%20-%20New%20Trends%20Technology%20Transfer%200207.pdf

442 Beyer P. *et al.*, "Golden Rice: Introducing the Pro-vitamin A Biosynthesis Pathway into Rice Endosperm", Science, vol. 287, p. 303 *et seq.*

443 Beyer P., *et al.*, "Why is Golden Rice Golden (Yellow) Instead of Red?", Plant Physiology, 2005, vol. 138, p. 441 *et seq.*

444 UNICEF Statistics, "Vitamin A Deficiency", available at: http://childinfo.org/areas/vitamina; For more information about the issue, see: http://www.goldenrice.org/Content3-Why/why3_FAQ.html

The process applied in Golden Rice production has become technically possible since the 1980s, when the techniques required to introduce, by means of transformation, and express genes in plants were developed. Regeneration of monocots, i.e. the group of plants that includes cereals, grasses, lilies etc, was harder to obtain than that of their dicot counterparts and was achieved by the end of the decade. However most of the science required to engineer the carotenoid pathway in the rice grain was developed only later in the 1990s.[445] Finally in 1999 the project entered into the operative phase of product development and the procedure for regulatory approval, required for the release of genetically modified plants into the environment, was undertaken. At the time when the scientific details of the rice were first published in 2000,[446] Golden Rice was considered a real breakthrough in biotechnology, as the researchers had engineered an entire biosynthetic pathway.

The fundamental step the promoters of the "Golden Rice" project had in mind was to transfer the product obtained for the benefit of developing countries for further breeding,[447] so that the new trait could be eventually introduced into the local varieties consumed. However, a "freedom to operate" survey, appropriately undertaken in order to get hold of the "status quo" of the technology market concerned under an IP perspective, already initially unveiled as many as approximately seventy patents, belonging to thirty-two different companies and research institutions, which could be embedded in the Golden Rice's technique.[448] Indeed, the promoters of the project found themselves facing a typical "patent thicket" situation, where overlapping IP rights are a common ground and multiple technology owners need to be addressed to obtain licenses.

In this case, the six key-patent holders were eventually approached to enter into a "sui generis",[449] i.e. non profit, technology pooling agreement, involving the crea-

445 For the history of the Golden Rice project see: http://www.goldenrice.org/Content1-Who/who2_history.html

446 Ye *et al.*, "Engineering the Provitamin A (beta-carotene) Biosynthetic Pathway into (carotenoid-free) Rice Endosperm", Science, 2000, vol. 287, p. 303 *et seq.*

447 For a wider, comparative perspective on the problem of breeder's access to protected biomaterial, see i.a.: Straus J., "Access to Patented Plant Material for Plant Breeders - The Problem and the German Solution, Recent Development of the Academic Disputes on the Intellectual Property Laws and the Competition Law", In: Japan Institute of Invention and Innovation, (Eds.): Publication of Articles in Commemoration of the 70th Birthday of Professor Dr. Monya, 2006, p. 1310 *et seq.*; Straus J., "Measures Necessary for the Balanced Co-Existence of Patents and Plants Breeders' Rights - A Predominantly European View", In: WIPO, UPOV (Eds.): Compilation of the 2002&2003 Joint Symposia Documents of the World Intellectual Property Organization (WIPO) and the International Union for the Protection of New Varieties of Plants (UPOV), Gen. 2005, p. 77 *et seq.*

448 Stanley P. *et al.*, "Intellectual and Technical Property Components of Pro-Vitamin A Rice (Golden Ricee): a Preliminary Freedom to Operate Review", ISAAA Briefs No. 20, Ithaca, 2000, also available at: http://www.isaaa.org

449 See: Parish R. and Jargons R., "Using the industry model to create physical science patent pools among academic institutions", Journal of the Association of University Technology Managers, 2003, p. 65 *et seq.*

tion of a private-public partnership between the inventors and the company Syngenta Seeds AG,[450] thereby allowing the "Golden Rice" promoters to grant licenses, free of charge, to the benefit of the targeted developing countries, even including the right of sub-license for the latter, in order to promote economic growth in those regions.[451]

In other words, Syngenta Seeds AG was able to negotiate access to all involved essential technologies for humanitarian purposes, consequently providing the Golden Rice Humanitarian Board with the right to sub-license breeding institutions in developing countries free of charge.[452] While the key technology for Golden Rice production was donated by the inventors, Prof. Potrykus and Prof. Beyer, the package of ancillary technologies licensed from Syngenta and required to engineer the trait into rice came from humanitarian donations by companies such as Bayer AG, Monsanto Co, Orynova BV, and Zeneca Mogen BV.

A humanitarian board, composed of internationally recognised experts from reputed institutions,[453] was established in the form of a voluntary association. The Humanitarian Project was sponsored by HarvestPlus (which in turn was funded by the Bill & Melinda Gates Foundation and the World Bank), the Swiss Development and Collaboration Agency and the Syngenta Foundation, together with local research institutes and several non-governmental organizations (NGOs) including the Rockefeller Foundation and the International Rice Research Institute (IRRI). This consulting body took over the strategic guidance of the project, with the purpose of assisting in the associated governance and decision-making process, as well as of helping the Golden Rice association to fulfil its major aim, namely reaching small farmers in the targeted developing countries. So far, approximately twenty master licenses have been granted to institutions mainly in developing Asian countries.

In practice, breeding institutions in developing countries may obtain a licence from the Humanitarian Board (so called "Humanitarian Use Licenses"). The consortium, in fact, had to define a cut-off between what is to fall under "humanitarian" versus "commercial" use: this figure was set at $10.000. Therefore, royalties shall be paid only in so far as a farmer or subsequent user of Golden Rice genetics makes more than $10.000 per year. Conversely, there is no fee demanded for the humanita-

450 Graff G. *et al.*, "The Public–Private Structure of Intellectual Property Ownership in Agricultural Biotechnology", Nat. Biotechnol., 2003, vol. 21, p. 989 *et seq*.

451 The initial research of Potrykus and Beyer was financially supported by the Rockefeller Foundation, together with the EU, the Swiss Federal Office for Education and Science (1996-2000), and the Swiss Federal Institute of Technology. Syngenta (formerly Zeneca) scientists contributed to the EU carotenoid research programme of which Golden Rice had been a part since 1996. Syngenta itself has supported the project with research and facilities since 2000. More recently funds also have also come from USAID, the Syngenta Foundation, HarvestPlus, and the Bill & Melinda Gates Foundation.

452 Syngenta Media Release, "Syngenta to Donate Golden Rice to Humanitarian Board", Oct. 2004, available at: www.syngenta.com

453 For a short biography of the Humanitarian Board's members, see: http://www.goldenrice.org/Content1-Who/who1_humbo.html

rian use of Golden Rice, where farmers are permitted to keep and replant seed.[454] Applications should be based on a breeding program as part of which the Golden trait is to be crossed in with conventional breeding into local varieties. Should no bio-safety regulations be in place in the target country, consideration must be given to an implementation strategy of a regulatory framework that would allow release of Golden Rice varieties in due time. In such a situation, it may be observed that even in the face of human misery that could be alleviated with a transgenic plant,[455] developing countries are still struggling with a political situation, which makes access to the needed technology very burdensome.[456]

For actual reference, access to IP rights was achieved for Golden Rice in the year 2000 and involved approximately six months of negotiations.[457] Subsequently, the required material transfer agreements (MTAs) were signed in 2001. The first Golden Rice field trial in the world was harvested in September 2004 and was carried out in collaboration with Louisiana State University,[458] as the USA is one of the few countries where field trials with transgenic plants can in principle be carried out if complying with an acceptable, well-defined amount of regulatory requirements. Preliminary results from the field tests, allowing a more accurate measurement of the nutritional value, have shown that field grown Golden rice produces three to four times more beta-carotene than Golden rice grown under greenhouse conditions.[459] Nevertheless, since targeted developing countries did not have bio-safety regulations in place, many years went by before Golden Rice could be finally planted in a field plot. In fact, a necessary condition attached to the main agreement with Golden Rice[460] licensees was that no field releases should take place in the absence of such a regulatory framework, causing a substantial delay for developing countries in most of the cases.

454 Golden Rice Project's details are available at: http://www.goldenrice.org

455 For a broader, deeper discussion on the legal protection accorded to transgenic plants from a European perspective, see i.a.: Straus J., "The Scope of Protection Conferred By European Patents on Transgenic Plants and on Methods for Their Production", In: Bakardjieva-Engelbrekt, A. / P.J. Nordell (Eds.): Festskrift in Honour of Marianne Levin, Stockholm, 2007, p. 639 *et seq*.

456 For a discussion on the policy implications, see: Lubbock A.C., "Public goods and public policy for agricultural biotechnology", 7th ICABR International Conference, Ravalli (Italy), June 29 to July 3, 2003.

457 Press releases on 16 May 2000; 22 January 2001; and 14 October 2004; also available at: http://www.syngentia.com

458 LSU Agricultural Center Communications, "Golden Rice Could Help Reduce Malnutrition", October 2004, available at: http://www.lsuagcenter.com/news_archive/2004/October/Headline+News/Golden+Rice+Could+Help+Malnutrition.htm

459 Reference available at: http://www.goldenrice.org/Content2-How/how8_tests.html

460 For more information about licensing Golden Rice, see: http://www.goldenrice.org/Content1-Who/who4_IP.html

In fact, critics of genetically modified crops, such as Greenpeace,[461] as well as environmental and anti-globalization activists, raised various concerns, objecting both to the general suitability and effectiveness of Golden Rice.[462]

In particular, one of the critical points raised in connection with Golden Rice was its inherent deception: it was indeed argued that Golden Rice is a "Trojan horse"[463] that would eventually open the door to more widespread use of genetically modified organisms (GMOs),[464] by exploiting a public health issue, ultimately to gain wider acceptance for the latter. In this respect, it has been claimed that Golden Rice is merely a marketing event serving the needs of profit-driven biotechnology firms attempting to consolidate their hegemony in the food market, providing for a much needed public relations boost at a time when genetic engineering is apparently under siege in Europe, Japan, Brazil and various developing countries.[465]

Here we ought to distinguish primarily between two quite closely connected, but different issues: the first regards the ownership of new biotechnologies in the hands of dominant firms, which could eventually create dependencies on the part of farmers or small, medium sized companies cultivating their lands; the second, on the contrary, involves the science of genetic engineering itself. However, with the advancement of knowledge and the development of new applications comes the danger of exploitation, as history may remind us. Nevertheless, this persistent problem, which certainly needs serious consideration with view to a resolution, also beyond the case of biotechnology, has to remain separate from the underlying science, as the implementation of genetic engineering, in our instance, does not necessarily imply the emergence of market monopolies.[466]

Therefore, blind anti-science propaganda might eventually divert the focus from the truly important task of ensuring that the effective advantages of genetically modified crops in adverse agricultural areas are not diminished by a neo-colonial exploitation of those in most urgent need of the technology, which shall instead represent

461 For the official website, see: http://www.greenpeace.org/international

462 See for all: Greenpeace, "All that Glitters is not Gold: The False Hope of Golden Rice", May 2005, also available at: http://www.greenpeace.org/raw/content/international/press/reports/all-that-glitters-is-not-gold.pdf

463 Erosion, Technology and Concentration Group (ECT, formerly RAFI), "Golden Rice and Trojan Trade Reps: A Case Study in the Public Sector's Mismanagement of Intellectual Property", RAFI Communiqué, September/October 2000, no. 65.

464 Shiva V., "The Golden Rice Hoax - When Public Relations Replaces Science", Norfolk Genetic Information Network, October 2000, available at: http://ngin.tripod.com/11.htm

465 The environmental risks reportedly inherent to genetically modified organisms and applying to Golden Rice relate to out-crossing and are described in: Chen L. J., *et al.*, "Gene Flow from Cultivated Rice to its Weedy and Wild Relatives", Annals of Botany, 2004, vol. 93, p. 67 *et seq.*; Chen J., *et al.*, " Can Transgenic Rice Cause Ecological Risks through Transgene Escape?", Progress in Natural Science, 2003, vol. 13, p. 17 *et seq.*; Kleter G., *et al.*, "Assessment of the Food Safety Issues Related to Genetically Modified Foods", Plant Journal, 2001, vol. 27, p. 503 *et seq.*

466 Social Issues Research Centre (SIRC), "A Rice Dilemma", February 2001, available at: http://www.sirc.org/articles/rice_dilemma.shtml

the main issue of concern.[467] Consequently, the view is taken that the moral crusade against genetically modified organisms shall not override primary public policy considerations. Indeed, it is the Greenpeace international coordinator on genetic engineering himself, Mr. Benedikt Haerlin, to have pointed to a distinct change of direction by stating that: "Golden Rice is a moral challenge to our position. It is true there is a different moral context, whether you have an insecticidal or pesticide-resistant GM, or whether you have a GM product that serves a good purpose".[468] Although this may not reflect the views of some of the most persistent Greenpeace's activists,[469] it is significant to note that this was actually the first time that the organization has publicly recognized that GM crops can indeed also serve a constructive cause.

Finally, it is believed that the balance to be drawn is a positive one, as the Golden Rice project may ultimately be regarded as a quite promising example of how both private and public organizations, in a combined effort, may find a constructive way out of the "patent thicket", overcoming the legal and operative uncertainty of overlapping IP rights, in order to attain a scope that goes beyond the economically oriented interests of the participating companies,[470] thus making further steps in the direction of addressing compelling nutritional shortages in developing countries.

Although it is still too early to assess the practical benefits of Golden Rice - since, as has been recalled, through the delays of the proper nutritional testing, the crop is not yet available for human consumption - this case definitely represents an outstanding illustration of a how a non-profit, humanitarian, and therefore "atypical" patent pool, acting through a single licensing authority in the framework of a collaborative IP mechanism, is pursuing, as we have considered, the main objective of ensuring and promoting free technological access to a quite promising product ad-

467 For a thorough legal discussion on the broader issue of patent protection of biomaterial and its actual global impact, see i.a.: Straus J., "Patents on Biomaterial - A New Colonialism or a Means for Technology Transfer and Benefit-Sharing?", In: Thiele, F. and Ashcroft R. (Eds.): "Bioethics in a Small World", Heidelberg, Springer ed., 2005, p. 45 *et seq.*

468 Steve C., "Greenpeace Promises Not to Halt Trials of GM Vitamin Rice" - Letter to the Editor by Harlein B., The Independent, February 2001, p. 2 *et seq.*, also available at: http://environment.independent.co.uk/article252062.ece

469 Although Greenpeace has never been comfortable with the charge that its food campaigns, led primarily by relatively well-fed people in the West, represent an elitist disregard for genuine suffering and malnutrition in less fortunate parts of the world. It has tried to fend off such challenges by describing them as nothing more than cynical PR for the multinational biotech companies – those who stand to profit very substantially from widespread acceptance of the GM crops, which they have developed. But the Golden Rice issue has always been different, primarily because it has arisen out of research by a charitable foundation, which has placed the technology at issue to the free disposal of poorer farmers. For the reference, see: Social Issues Research Centre (SIRC), "A Rice Dilemma", February 2001, available at: http://www.sirc.org/articles/rice_dilemma.shtml

470 Reminding that Golden Rice can still be licensed for a consideration to firms and individuals making commercial use of it raising above the defined threshold of USD $10.000 turnover per year.

dressing the needs of those regions where the economical and social conditions are more critical. Certainly, the Golden Rice case has been surrounded by a significant, even though to some extent controversial, deep public interest, which, in any event, may ultimately raise just the much-needed publicity that such types of collaborative mechanisms deserve.

2. SNPs

The acronym SNPs stands for single nucleotide polymorphisms,[471] which are DNA sequence variations that occur when a single nucleotide in the genome is altered.[472] SNPs are evolutionarily stable, i.e. not changing much from generation to generation, making them easier to track in population studies.[473] In fact, it is interesting to note that any two unrelated persons are the same to about 99,9% of their DNA sequences, where accordingly only the remaining 0,1% is important because it contains the genetic variants, which may eventually influence how people differ in their risk of disease, as well as their response to drugs[474] or other therapies.[475] Indeed, SNPs do not cause disease, but they can help determine the "likelihood" that someone will develop a particular disease, without wanting to minimize the concurrent role eventually played by environmental factors.

This makes SNPs of great value for biomedical research and for developing pharmaceutical products or medical diagnostics, as scientists believe that tracking SNPs maps will help them identify the multiple genes associated with such complex diseases as cancer, diabetes and some forms of mental illness such as depression. For instance, it is considered that said variations in the human genome can help catalogue the unique sets of changes involved in different cancers, making SNPs valuable research tools for improving cancer diagnostic and treatment planning.[476]

For this reason, several groups worked on finding SNPs sequences and ultimately created various SNP maps of the human genome. Among these were the US Human Genome Project (HGP)[477] and a large group of pharmaceutical companies, which

471 For reference, see the "SNP Fact Sheet", available at: http://www.ornl.gov/sci/techresources/Human_Genome/faq/snps.shtml

472 For example a SNP might change the DNA sequence AAGGCTAA to ATGGCTAA.

473 However, for a variation to be considered SNP relevant, it shall occur in at least 1% of the population.

474 Bentley D. *et al.*, "The HapMap Project and its Application to Genetic Studies of Drug Response", Pharmacogenomics Journal, vol. 4 (2), p. 88 *et seq.*

475 Even if scientists believe that others could predispose people to diseases or influence their response to a drug, it is known that many SNPs have no effect on cell function.

476 For more related information, see: US National Institutes of Health - National Cancer Institute, "Understanding Cancer Series: Genetic Variation (SNPs)", available at: http://nci.nih.gov/cancertopics/understandingcancer/geneticvariation

477 The National Human Genome Research Institute (NHGRI) led the National Institutes of Health's (NIH's) contribution to the International Human Genome Project. The first phase of

eventually established the so-called SNP Consortium.[478] In fact, it is not surprising that companies invested concurrent efforts in the tracking of SNPs because, on the one hand, the potential payoff for further research was high, and, on the other hand, the actual likelihood of duplication among the groups was small because of the great estimated number of about 3 million SNPs.[479] Indeed, these endeavours often took place within a collaborative setting, given the frequent interaction and the overall common goals of the institutions and research centres involved.[480] Some key systematic steps towards the attainment of the defined SNPs mapping goals may be summarized as follows:

- The Human Genome Project:[481] in 1998, as part of their five-year political plan, the US Department of Energy (DOE)[482] and the National Institutes of Health (NIH)[483] Human Genome Program established the first major institutional setting to identify and map SNPs human sequences, fundamentally aiming at cataloguing common variants in the coding regions of the most identified genes in order to create public resources of DNA samples and cell lines.
- The SNP Consortium:[484] in April 1999, ten large pharmaceutical companies and the U.K. Welcome Trust philanthropy announced the establishment of a consortium,[485] headed by Arthur L. Holden, to find and map approximately 300.000 common SNPs. The goal was to generate an extensive, publicly available map using SNPs as markers evenly distributed throughout the human genome. Two years later, a total number of 1,4 million SNPs, much more than originally planned, were discovered and released in the public domain at the end of

this project, which had as its primary goal the sequencing of the three thousand million base pairs that make up human genome, was successfully completed in April 2003. For more information, refer to the NHGRI official website at: http://www.genome.gov

478 These efforts have ultimately converged into the so called International HapMap Project, whose official website is available at: http://www.hapmap.org

479 International HapMap Consortium, "A Haplotype Map of the Human Genome", Nature, 2005, vol. 27, p. 1299 *et seq*.

480 See, for instance: Human Genome Project (HGP), "SNP Consortium Collaborates with HGP, Publishes First Progress Reports", Human Genome News, November 2000, vol. 11, n. 1-2, also available at: http://www.ornl.gov/sci/techresources/Human_Genome/publicat/hgn/v11n1/10snp.shtml

481 International Human Genome Sequencing Consortium, "Initial Sequencing and Analysis of the Human Genome", Nature, 2001, vol. 409, p. 860 *et seq.*; For more information, "All About The Human Genome Project (HGP)" is available at: http://www.genome.gov/10001772

482 For the official Department of Energy (DOE) website, see: http://www.energy.gov

483 For the official National Institutes of Health (NIH) website, see: http://www.nih.gov

484 For the SNP Consortium official website, see: http://snp.cshl.org (which precisely corresponds to the HapMap Project's website, which eventually took over the latter's goals, available at: http://www.hapmap.org)

485 The international member companies, which together committed at least $30 million, are APBiotech, AstraZeneca Group PLC, Aventis, Bayer Group AG, Bristol-Myers Squibb Co., F. Hoffmann-La Roche, Glaxo Wellcome PLC, IBM, Motorola, Novartis AG, Pfizer Inc., Searle, and SmithKline Beecham PLC. The Welcome Trust contributed at least $14 million.

2001.[486] As the initial SNP discovery phase of the TSC project was completed, the emphasis shifted to studying SNPs in populations to determine shared variants. Ultimately, the SNP consortium views its map as a way to make available an essential research tool that will spark innovative work throughout the research and industrial communities by enhancing the understanding of disease processes, thus facilitating the development of more effective medications.

- The HapMap Project:[487] in October 2002 endeavours to carry on SNP mapping goals were revivified and resumed by the inception of the newly named HapMap Project. Thanks to support provided by public funding a hundred million dollars of public-private international research effort were also built up accumulated.[488] The new venture aimed at speeding up the discovery of genes related to common diseases, such as asthma, cancer or diabetes, by comparing genetic differences between individuals. In particular, consortium members intend to compare groups of people with the targeted disease to groups of people without that disease in order to identify chromosome regions where the two groups differ in their haplotypes[489] that might contain genes affecting the personal predisposition for a given disease, by eventually developing a "haplotype map" of the human genome[490] (from which the name "HapMap Project" actually derives) describing

486 The International SNP Map Working Group, "A Map of Human Genome Sequence Variation Containing 1,42 million Single Nucleotide Polymorphisms (SNP)", Nature, 2001, 409, p. 928 *et seq.*

487 International HapMap Consortium, "The International HapMap Project", Nature, 2003, vol. 18, p. 789 *et seq.*; For the official HapMap project website, see: http://www.hapmap.org

488 Public funding for the effort will be provided by the Japanese Ministry of Education, Culture, Sports, Science and Technology in Tokyo; Genome Canada in Ottawa and Genome Quebec in Montreal; the Chinese Academy of Sciences, the Chinese Ministry of Science and Technology, and the Natural Science Foundation of China, all in Beijing. For the reference, see: National Institutes of Health News Advisory, "International Consortium Launches Genetic Variation Mapping Project - HapMap Will Help Identify Genetic Contributions to Common Diseases", Washington, October 2002, available at: http://genome.gov/10005336

489 A haplotype is a series of consecutive alleles on a particular region of a chromosome. Haplotypes are broken down every generation by a mechanism called recombination. However, it was observed that haplotypes in a population are longer than expected because recombination occurs preferentially in specific regions, thus creating "recombination hotspots" and "recombination cold spots", better known as haplotype blocks. Because alleles are correlated with each other in a haplotype block, knowing these structures in a population would enable researchers to infer unknown alleles without genotyping all of the SNPs. On the point see: Farkas D., "DNA from A to Z", American Association for Clinical Chemistry (AACC) Press, 2004, p. 58.

490 To create the HapMap, DNA will be taken from blood samples collected by researchers by regions of different population, i.e. in Nigeria, Japan China and the United States. The samples will be processed and then stored at the Coriell Institute for Medical Research in Camden, N.J., a non-profit biomedical research center that specializes in storing living cells and making them available to scientists for further study. See on the point: Sio-Iong Ao, "Data Mining and Applications in Genomics", Springer ed., 2008, p. 43.

relevant DNA sequence variations.[491] All data and relevant scientific information generated by the project will be released in the public domain, soon after they have been produced, without IP restrictions,[492] so that any researcher can access and freely use them for their scientific endeavours.

On balance, on the one side, it has been objected that, in general, SNPs mapping projects may raise some ethical issues that shall not be undermined.[493] Although the collected samples include no personal identifiers and the privacy risks connected to individual donors are minimal,[494] the fact that each sample is labelled by population and characterized based on respective haplotype frequencies, in order to allow comparisons, could raise risks of group stigmatization and consequent discrimination, should a higher frequency of a disease-associated variant be found in a population over-generalized to all or most of its members.[495] However, it is argued that the same statement might in fact be invoked for all statistical studies and should be no reason for refraining from pursuing research efforts, but rather for inducing to better regulate their actual implementation.

On the other side, SNPs mapping projects and data collection provide the scientific community with an effective "shortcut" to a great wealth of information, representing their prompt availability a huge saving in the studies of complex diseases. Besides, the collaborative endeavours catalyzed by the undertaking have fostered an open exchange of valuable research tools among scientists and institutions, ultimately providing the foundations and institutional support on which further innovation is based.[496]

In fact, although biotechnology companies have the reputation of being quite fiercely competitive, SNP mapping efforts represent a praiseworthy example of the

491 For more details, see: Altshuler D., "The Structure of Haplotype Blocks in the Human Genome", Science. 2002, 296, p. 2225 *et seq.*

492 Except that users have to agree on their turn not to reduce others' access to the data and to eventually share it only with interested parties agreeing on the same term, to preserve the project data remain within the public domain. For the terms of the HapMap project, see: http://hapmap.org/abouthapmap.html

493 International HapMap Consortium, "Integrating Ethics and Science in the International HapMap Project", Nature Reviews Genetics, vol. 5 (6), p. 467 *et seq.*

494 OECD, "Creation and Governance of Human Genetic Research Databases", OECD - Organisation for Economic Co-operation and Development, 2006, p. 43.

495 For supporting, see i.a.: Donovan A. et al., "The Human Genome Project in College Curriculum: Ethical Issues and Practical Strategies", Science, 2008, p. 71 *et seq.*; Knoppers B., "Populations and Genetics: Legal and Socio-Ethical Perspectives", Medical Genetics, Martinus Nijhoff Publishers, 2003, p. 92 *et seq.*

496 In this regard, TSC chairman Arthur Holden has publicly stated that: "We are very positive about the chance to work collaboratively with the HapMap effort to support the informatics aspects of the program, as well as to ensure that the resulting HapMap will be useful in both disease and pharmaco-genomic research", In: Press Release, "International Consortium Launches Genetic Variation Mapping Project - HapMap Will Help Identify Genetic Contributions to Common Diseases", NIH News Advisory, October 2002, available at: http://www.genome.gov/10005336

existing cooperative spirit typically preceding the formation of a patent pool.[497] Indeed, all parties working with SNPs for research, diagnostic or therapeutic purposes understood that they would all need access to a considerable number of said DNA sequence variations, as they represent essential research tools for their scientific endeavours. Thus, in order to avoid licensing problems related to acquiring rights to thousands of SNPs, firms and institutions involved decided to work together to form a consortium, thereby foregoing exclusive rights on human SNPs and placing all of their data in a public database, eventually undercutting future patenting efforts.[498]

On these grounds, it has been objected that the established SNPs Consortium, as well as its succeeding International HapMap Project,[499] could not be properly defined as a patent pool, but might be better characterized as an "anti-patent pool".[500] Nevertheless, independently of legal systematizations, the very fact that the consortium exists and that it is well established certainly indicates that also private firms from the field of biotechnology can work together to overcome licensing problems, pointing to positive chances for a mutually beneficial collaboration, showing in the case at issue that substantial economic benefits can be reaped from a cooperative strategy.

Anyway, we shall admit that even if the SNP Consortium is an outstanding evidence of the benefits of cooperation in life sciences, it cannot be generalized as a typical appropriate model for biotechnology patent pools. In fact, SNP patents - unlike patents on genes that code for useful proteins or genes that can be used in diagnosis - have very little practical value on their own, since said DNA sequence variations derive most of their value and usefulness from their ability to serve as research tools. Indeed, scientists need to use a quite big number of SNPs to make meaningful comparisons between genomes, thus requiring access to hundreds or even thousands of them.[501] The companies that formed the SNP consortium realized that they would benefit very little from exclusive control over a few SNPs, while they might reap far greater advantages from having non-exclusive access to thousands of DNA sequences.[502] Thus, the SNP consortium shows how self-interest and cooperation may

497 For supporting the point, see: Resnik D., "A Biotechnology Patent Pool: An Idea Whose Time Has Come?", Journal of Philosophy, Science and Law, January 2003, vol 3, p. 12-13.

498 Marshall E., "Drug Firms to Create Database of Genetic Mutations", Science, 1999, 284, p. 406 *et seq.*

499 For the official website, see: http://www.hapmap.org (previously: http://snp.cshl.org).

500 The assertion comes from: Resnik D., "A Biotechnology Patent Pool: An Idea Whose Time Has Come?", Journal of Philosophy, Science and Law, January 2003, vol 3, p. 12.

501 For an overview, see: Straus J., "Intellectual Property Rights in Human Genome Research Results - The US and European Approach - Common Problems, Different Solutions?", German-American Academic Council Foundation (GAAC) (Ed.), GAAC 4th Public Symposium "The Changing Character, Use and Protection of Intellectual Property", Washington, DC, December 3-4, 1998, Washington, D.C. 1999, pp. 85 *et seq.*

502 International HapMap Consortium, "A Haplotype Map of the Human Genome", Nature, 2005, vol. 27, p. 1299 *et seq.*; Venter J.C. *et al.*, "The Sequence of the Human Genome", Science, 2001, vol. 291, p. 1304 *et seq.*

well coexist under mutually advantageous terms, also within the traditionally highly competitive biotechnology sector.

Indeed, analysing the collective efforts developed around SNPs from a strategic perspective, it may be observed that the choice of joining a biotechnology patent pool might be compared to a business decision made in the context of a cooperative game:[503] right holders would enter into a consortium, if they think that the benefits of belonging to the pool will outweigh the risks in the long run. Still, some objective considerations may keep the candidate parties from taking that step: for instance, a company with patents related to a valuable protein is not likely to place it into the pool, because it would find it more economically convenient to exert its exclusive rights to gain more edge on the marketplace and, eventually, to cut out competitors, than to license it together with other patent holders retaining rights on complementary technologies. Therefore, it may be predictable that companies and universities might place some of their less worthy patents into the pool, while maintaining control over their more valuable IP assets.

Nonetheless, these factors are not automatically going to make the pool idea obsolete, because even under the given circumstances, the consortium could still play a beneficial role as long as the participating parties still contribute enough patents to serve a well-defined, comprehensive scope - possibly aiming at a particular niche of the market at issue or, more in general, like in the given case, enabling "freedom to operate", thus clearing the way to further innovations in a certain scientific field - while providing enough cooperative advantages, so as to maximize technology access and minimize transaction costs, as a means of self-sustainment or, eventually, for attracting prospective licensees.[504] In practice, if there are many patent holders that do not find it convenient to join together, the pool cannot represent a one-stop shopping entity with the related savings; therefore it may not constitute a particularly efficient licensing solution, because third parties may still need to negotiate with individual patent holders outside of the pool. For the considerations exposed, we may argue that the biggest challenge to forming and keeping a biotechnology patent pool going is in the first place economic, rather than legal, as the parties, when confronted with the choice of whether joining into a consortium, should be able to ascertain and foresee their long-term financial interests.

503 Harsanyi J., "Rational Behaviour and Bargaining Equilibrium in Games and Social Situations", Cambridge University Press, 1977.

504 Resnik D., *supra*, fn. 497, p. 13.

3. SARS

Another area in which the emergence of a "patent thicket" has been recently observed,[505] causing a certain level of alert, and in which the a patent pool solution has been advanced, relates to the biomedical field and, more specifically, to the severe acute respiratory syndrome (SARS) corona virus, where overlapping IP rights may dangerously lead to a "dead-end" situation.[506]

In the late months of 2002 an outbreak of severe atypical pneumonia was reported in patients from China's Guangdong province. Soon after that the disease, later known as the severe acute respiratory syndrome (SARS), spread to other Asian countries, Europe and North America, having a notoriously dramatic impact on people and economies worldwide.[507]

In March 2003, in response to the threatening outbreak of SARS, the World Health Organization (WHO)[508] invested its resources in setting up a network of laboratories and research institutions in order to contain the worldwide spreading of the feared disease by identifying its etiological agent. The undertaken efforts finally led to the isolation of the causative virus,[509] as well as the sequencing of its genome.[510]

The containment of SARS is a good example of the effectiveness of active scientific collaboration in isolating and containing such a disease outbreak. The WHO deserves much credit for achieving this, as it played a fundamental role in organizing the SARS network, as well as in disseminating clinical samples and ultimately defeating the outbreak.[511] As a result of these combined efforts, in July 2003 they announced that SARS had been finally dominated; in the following just a few isolated cases occurred, which in fact could be traced back to the exposure of laboratory personnel to the virus.

However, the potential grounds for a conflict arose following the contextual accreditation to two different research groups for respectively discovering the SARS genome independently from each other.[512] Besides, raising the likelihood of disputes about the respective IP legal boundaries even more, several of the contributing la-

505 Simon J. *et al.*, "Managing Severe Acute Respiratory Syndrome (SARS) Intellectual Property Rights: The Possible Role of Patent Pooling", Bulletin of the World Health Oranization, 2005, vol. 83, p. 707 *et seq.*

506 Gold R., "SARS Genome Patent: Sympton or Disease", The Lancet, 2003, vol. 361.

507 World Health Organization, "Severe acute respiratory syndrome (SARS)", Weekly Epidemiological record, 78, 2003, p. 81 *et seq.*

508 For the official website, see: http://www.who.int/en

509 Peiris J., *et al.*, "Coronavirus as a Possible Cause of Severe Acute Respiratory Syndrome", Lancet, 361, 2003, p. 1319 *et seq.*

510 Marra M., *et al.*, "The Genome Sequence of the SARS-Associated Coronavirus", Science, 300, 2003, p. 1399 *et seq.*

511 Simon J., *et al.*, *supra*, fn. 505, p. 707.

512 Rota P.A., *et al.*, "Characterization of a Novel Corona Virus Associated with Severe Acute Respiratory Syndrome", Science, 300, 2003, p. 1394 *et seq.*

boratories also filed patent applications embedding SARS genomic sequence data. Ultimately, further research led to the consequent filing of additional patent applications by a multitude of private and public sector entities operating in that biomedical field.

In particular, among the institutions, which were simultaneously involved in the research, we find the Bernhardt-Nocht institute (BNI), the British Columbia Cancer Agency (BCCA), the Centers for Disease Control and Prevention (CDC), the Erasmus Medical Centre (EMC) and the Hong Kong University (HKU). The involvement of multiple parties resulted in a fragmentation of patent rights incorporating the SARS genomic sequence across the different groups, creating a complex situation when it comes to sorting out the confines of the different contributions, which may eventually require the costly and time consuming intervention of the law courts. Just to give an idea of the dimension of the phenomenon, more than 160 hits have been displayed in a recent research database after feeding it with a request for SARS patent applications.[513]

To make the point: here numerous patent applications incorporating the genomic sequence of the severe acute respiratory syndrome, resulting in a fragmentation of IP rights, are in turn likely to adversely affect the development of products, in primis vaccines, to combat the disease.[514] Placing these patent rights in a pool to be licensed on a non-exclusive basis may be the way to overcome this impasse and set a good precedent for employing this type of collaborative IP mechanisms in other areas of health care, which is likely to lead to consistent benefits for the public health.

The economic conclusions that may be drawn from the legal uncertainty that results from the interface of overlapping IP rights do not leave much space for optimism: potential licensees of the SARS patents, who may wish to develop vaccines to protect the population against the disease, are likely to be discouraged from investing resources in that field. In fact, blurry legal boundaries concerning patent rights make investments risky, because in such a situation it is neither possible to predetermine the future cost of licensing the patent rights nor to make out whether there is going to be the effective possibility of licensing, as all necessary patents may not be available, if a subsequently identified right holder refuses to collaborate or grant a licence at a reasonable royalty rate.

In the case at issue, should for instance a single essential patent for vaccines against SARS be licensed only on an exclusive basis, the licensee with the right of exclusivity would be able to exclude other parties from selling their SARS vaccines, thus not only hampering competition, but also putting public health at risk. There-

513 Simon J., *et al.*, "Managing Severe Acute Respiratory Syndrome (SARS) Intellectual Property Rights: the Possible Role of Patent Pooling"- "Impact of Patent Applications on Stakeholders", Bulletin of the World Health Organization 83, 2005, p. 708 *et seq.*, also available at: http://www.who.int/bulletin/volumes/83/9/707.pdf

514 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.*

fore, the counter-incentive for SARS vaccines producers is to postpone the decision on whether to invest in that domain, at least until the nebulous legal situation surrounding the patent rights concerned is cleared.[515]

Facing the problem, the World Health Organization set up a SARS consultation group in charge of identifying all relevant parties to be targeted, mostly institutions and research entities owning the essential patents, and of developing a strategy, in close collaboration with stakeholders, to address potential SARS related IP issues.[516]

Currently, the relevant parties to be involved in the IP collaborative scheme have been all identified and a gross agreement on the main issues at stake has been reached. At present, signing "letters of intent" has finally formalized the ongoing cooperation with highly qualified technical and legal experts assisting the parties during the chain of negotiations. Recalling the above-mentioned steps in the formation of a patent pool, at this point we may go back to the time immediately preceding the more thorough evaluation of patents - when the pre-set portions of royalties to be re-distributed within the pool are determined - on which the consensus of all parties has to be met, leading to the signing of the final patent pool consortium agreement. If the parties finally conclude a full agreement,[517] the resulting pool will be set up in the USA, possibly followed by attempts to also set up similar consortia elsewhere.

A pool comprising patents incorporating the genomic sequence of SARS, licensed out on a non-exclusive basis, would enable wide access to the development of vaccines and safeguard public health from possible future outbreaks of the disease. In fact, ensuring broad access under a given technology is one of the characterizing traits of a patent pool,[518] distinguishing it from bilateral negotiations, which are traditionally more limited in scope.

Indeed, the health care sector is not the only one facing fragmentation of IP rights, and lessons may certainly be learned from observing how other industries have solved similar problems, as positive experiences may be transposed into the field of biotechnology. In fact, patent pools have been dealing with such fragmentations, i.e. "patent thickets", for the past century and a half, offering a more flexible and voluntary mechanism, based on collaboration, as opposed to compulsory licensing, or similar "public use" provisions, ensuring access through government intervention. Practical examples of this latter are not unknown in the domain of life sciences: in October 2001 the US government publicly considered use of its powers

515 Gold R., "SARS genome patent: symptom or disease?", Lancet, 2003, p. 423 *et seq*.

516 Friedman Y., "Best Practices in Biotechnology Business Development", Logos Press, 2008, p. 134-135.

517 Takenaka T., "Patent Law: A Handbook of Contemporary Research Patent Law: A Handbook of Contemporary Research" -"Preemptive Pools" Edward Elgar Publishing, 2008, p. 715-716.

518 Clark J. *et al.*, "Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?", White Paper commissioned by Q. Todd Dickinson, the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, December 2000, also available at:
http://www.uspto.gov/web/offices/pac/dapp/opla/patent- pool.pdf

in the wake of the anthrax attacks. In the end drastic solutions could be avoided, as an agreement with Bayer for the use of its antibiotic Cipro was reached through cooperative negotiations.[519]

In the case at issue, the formation of a patent pool - as the next step in the cooperation reached through the signing of letters of intent - would send a powerful signal to potential licensees, i.e. vaccines manufacturers, that patent owners intend to make their IP rights available at reasonable, standard rates, reducing IP risks and in turn encouraging earlier investments in the patented technology in the field of product development.

The "net effect" generated by such a patent pool would be of great value for public health, not only for the diffusion of vaccines against SARS, but also for setting an influential precedent that may encourage the formation of analogous collaborative IP models in other big areas of life sciences which face similar issues of public concerns, such as avian influenza, malaria or tuberculosis, thus leading to increased dissemination of key technologies to combat these diseases.

In fact, the SARS case is an ideal one to set a precedent, also because of its relative simplicity. In particular, the characteristic traits of such cooperation may be currently highlighted as follows: [520]

- The technologies involved are at a similar, early stage of realization, i.e. patent applications, so that the prospective formation of a pool would not be complicated by old issued IP rights that are already entangled in parallel third-party agreements.
- Among the current patent applications, only a few are known to incorporate essential technologies for the purpose of the pool, thus leading to a relatively limited, contained and easily identifiable number of parties to be eventually involved in the cooperative scheme. The major parties to be addressed would in fact be four: the Centers for Disease Control and Prevention (CDC); Health Canada - holding the British Columbia Cancer Agency (BCCA)'s application; Versitech Ltd. - the technology transfer office of the Hong Kong University (HKU); CoroNovative BV - a spun out company of Erasmus Medical Centre (EMC).
- The identified parties are either public organizations or institutions with strong public vocations, i.e. pursuing general collective interests, therefore public health implications of SARS certainly give them a strong incentive to move forward.

It is noteworthy that collaborative steps actually undertaken in the SARS case have gained considerable public support. In particular, both the World Health Or-

519 Resnik D., "Bioterrorism and patent rights: compulsory licensure and the case of Cipro", The American Journal of Bioethics, 2002, p. 2 *et seq.*

520 Simon J., *et al.*, "Managing severe acute respiratory syndrome (SARS) intellectual property rights: the possible role of patent pooling"- "The case for using acute respiratory syndrome as a key precedent in health care", Bulletin of the World Health Organization 83, 2005, p. 709 *et seq.*, also available at: http://www.who.int/bulletin/volumes/83/9/707.pdf

ganization and the National Institutes of Health Office of Technology Transfer in the U.S[521] have positively assisted such cooperation: the former has issued a formal recommendation[522] for developing the SARS collaborative model further, the latter is backing the formation of such consortium and helping to develop an operative platform for the establishment of a pool.

Furthermore, two major law firms[523] expressed their support for the creation of such patent pool and, most importantly, are providing a pro bono service to evaluate the suitability of each patent application for incorporation into the consortium, as well as engaging into discussions with antitrust authorities and regulatory agencies to test the viability of such pooling agreement from a legal perspective.

4. HNPCC

Another peculiar case, which has raised great interest as to the possibility of adopting a collaborative IP scheme and in which the establishment of a patent pool is deemed to introduce considerable benefits for life sciences, is the one of the genetic disease known as hereditary non-polyposis colorectal cancer (HNPCC).[524] For this reason - although concrete steps for entering into an operative phases have not yet been undertaken - we will now turn our attention to this specific genetic disease and to the characteristics that make it particularly eligible for patent pool considerations, as they may be well applied by analogy when confronting similar diseases.

As we have already considered for the SNP[525] case in a more general way, genetic diseases are due to mutations in genes: in particular, such diseases can be either caused by a variety of mutations in one single gene, which is actually the case with

521 For the National Institutes of Health Office of Technology Transfer, see: http://ott.od.nih.gov/

522 For the whole text of the WHO SARS Consultation Group's Recommendation, see: http://www.who.int/vaccine_research/diseases/sars/events/2003/11/recommendations/en/

Note in particular under Point 6, Intellectual Property (IP) Considerations:

"Given the successful worldwide collaboration initiated by the WHO on the identification and control of the SARS CoV, the SARS consultation group has addressed the possible impact of SARS CoV-related IP issues on the further progress of this process. The SARS consultation group proposed that a strategy be developed, in consultation with stakeholders, to address potential SARS CoV-related IP issues and thus enhance development of intervention approaches. This strategy should aim to achieve consensus on SARS CoV IP issues for the benefit of public health".

523 The law firms involved are: Drinker Biddle & Reath LLP and Morgan Lewis & Bockius LLP. See: Simon J., *et al.*, *supra*, fn. 520, p. 710, also available at: http://www.who.int/bulletin/volumes/83/9/707.pdf

524 Van Overwalle G., *et al.*, "Patent Pools and Diagnostic Testing", "HNPCC Patent Pool: A Test for Diagnostic Testing?", TRENDS in Biotechnology, vol. 24, no. 3, 2006, p. 118 *et seq.*

525 Acronym for Single Nucleotide Polymorphisms (SNP). See the official website at: http://www.hapmap.org. The case, which presents significant similarities with the one now at issue, is dealt in greater depth is previous n. (2) of the hereby-reported pilot experiences for biotechnology patent pool.

HNPCC, or by one or more mutations in several genes. As far as HNPCC is concerned, its diagnosis in a particular family is partly based on molecular genetic testing for germline mutations in one of the mismatch-repair (MMR) genes; typically, patients are being tested for mutations in two or more out of some candidate genes. Nevertheless, other genes involved in the MMR pathway have been reported to be associated with HNPCC, and, most importantly, the number of genes identified as being involved in familiar colorectal cancer is expected to grow.[526]

The point here is that some of these newly identified genes might soon be included on the shortlist for routine testing;[527] consequently, as various patents have been filed, it is likely that genetic data necessary for testing HNPCC will be hindered by the presence of overlapping IP rights,[528] where legal boundaries are increasingly difficult to ascertain. As a patent thicket is manifestly arising, an HNPCC patent pool encompassing essential genomic patents may certainly help to overcome this impasse, thus making proprietary genomic data more accessible for clinical use.

The considerations introduced hereby, strongly advocating the creation of an HNPCC patent pool, may suggest that such a cooperation takes the form of a "dynamic model", with regard to both size and operating purpose, i.e. content of the pool, differing and remaining flexible over time: to be more specific, additional essential patents - e.g. relating to other genes with a role in the same pathology and on particular mutations of those genes - are to be included in the pool as they are granted; on the contrary, other expired or no longer essential patent rights shall not be maintained within the consortium.

Furthermore, the granting of licenses to a subset of patents is also recommendable: while some genetic laboratories offering testing for the clinical condition as a whole may be interested in the entire set of technologies offered by the pool, other more specialized research units may only desire to acquire a license to a subset of patents in the pool, typically corresponding to a specific subset of disease genes or mutations, which may be of particular interest in view of the geographical heterogeneity related to the distribution of different mutations. Besides, some smaller laboratories may want specifically to license only a particular gene or even a particular mutation for the purpose of the development of an antibody or another therapeutic or research tool, thus further restricting the field of operative interest to those delimited patent applications.[529]

526 For more details on the HNPCC disease, see: http://www.genetests.org/servlet/access?db=geneclinics&site=gt&id=8888891&key=Q4npyENdaTo2B&gry=&fcn=y&fw=S9X0&filename=/profiles/hnpcc/index.html

527 Knoppers B. et al., "Human DNA: Law and Policy : International and Comparative Perspectives"- "Predictive Genetic Testing in HNPCC", Martinus Nijhoff Publishers, 1997, p. 183 *et seq.*

528 Van Overwalle G., *et al.*, "Patent Pools and Diagnostic Testing", "HNPCC Patent Pool: A Test for Diagnostic Testing?", TRENDS in Biotechnology, vol. 24, no. 3, 2006, p. 118-119.

529 For an overview or the clinical laboratories involved in HNPCC testing and their different roles, see:

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=Q4npyENdaTo2B&show_flag=c

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.,