



**SHORT SUMMARY REPORT OF THE WORKSHOP ON
GENETIC INVENTIONS, INTELLECTUAL PROPERTY
RIGHTS AND LICENSING PRACTICES**

Held in Berlin, Germany – 24 and 25 January 2002

I. The Berlin Experts Workshop

On January 24-25, 2002 the Working Party on Biotechnology held an Experts' Workshop on "Genetic Inventions, IPRs, and Licensing Practices." The Workshop was hosted by the German Federal Ministry for Education and Research in Berlin and opened by Minister Edelgard Bulmahn of that Ministry. Over 100 public and private sector experts from 18 OECD countries attended. Speakers and participants reviewed the empirical evidence demonstrating the impacts of current patenting and licensing practices on access to technology by researchers, companies and within healthcare systems. The Workshop also discussed the possible policy implications of current licensing practices for genetic inventions.

The Workshop found that contrary to fears that the recent growth in the number and complexity of biotechnology patents would cause a breakdown in the patent system and so prevent access to inventions by researchers and health service providers, in fact patents and licenses for genetic inventions seem to stimulate research, knowledge flows, and the entry of new technology into markets. However, most participants agreed that continued vigilance was necessary to ensure that this remains the case internationally. In particular, participants noted that improvements in the current arrangements for the licensing of genetic tests could enable even more effective use of new technologies by health care systems. A rapporteur's report of the Workshop deliberations is expected to be published in late 2002.

II. Summary of the Discussions at Berlin

Minister Bulmahn opened the Workshop. She emphasised Germany's objective that researchers not be hampered by overly broad patents and be assured appropriate access to genetic information in their pursuit of new diagnostics and treatments. At the same time, Germany also wants to maintain strong incentives for private sector investment in R&D. The 1998 European Directive on the protection of biotechnology inventions (EC/98/44), which specifies that patents should only be granted if a specific gene function is identified, would be an important step in establishing this balance across Europe. Minister Bulmahn underlined the need for further information gathering about how the patenting and licensing of inventions actually works in order to address remaining questions on the appropriate breadth of patent claims, the scope of protection offered, and the effects of patent crowding. Only fact-based discussions, such as those in the OECD Workshop, can lead to specific recommendations for action for policymakers.

The first session of the Workshop focused on how genetic inventions are protected under the present intellectual property regimes of OECD countries. Two introductory speakers discussed the legal criteria for patentability of genetic inventions, the rights that patents confer and how those rights are limited, as well as the need for non-IP (Intellectual Property) regulatory structures in pursuing national policy objectives. Biological materials and processes have for decades been recognised by patent authorities as patentable. The sequence or partial sequence of a gene is patentable subject matter at the major patent offices even if the structure of the claimed element is identical to its structure in nature.¹ Patent applications for such "genetic inventions" are on the rise. The European Patent Office, for one, has received around 30 000 biotechnology patent applications since 1998, of which about 10 000 pertain to "mutations or genetic engineering." About 40% of the latter are for micro-organisms, plants and/or animals and 60% relate to human or animal DNA sequences. Despite their patentability and popularity, debates remain about what constitutes an inventive step and about sufficient disclosure of function for genetic inventions. Experts are also debating whether to limit the claims of patents for genetic invention only to the functions disclosed in the patents. However, speakers noted that while some of the fine-tuning of the patent system will be done

1. The European Patent Office (EPO), the US Patent and Trademark Office (US PTO), and the Japanese Patent Office (JPO) all concur on this point.

statutorily and through case law, the applicants themselves, patent offices and third parties can better use the present IP regime in establishing a fair balance between the broad scope of claims and the public interest.

The second session introduced three recent surveys of the patenting and licensing practices of firms and research organisations with regard to genetic inventions. The German ministry for education and research commissioned a study to be presented to the OECD Workshop from Professor Joseph Straus of the Max Planck Institute for Foreign and International Patent, Copyright and Competition Law. The second study was conducted by John Walsh, Wes Cohen, and Ashish Arora for the Science, Technology and Economic Policy Board of the US National Academy of Sciences. Finally Professor Fabio Pammolli presented results from an ongoing project on the markets for technology in biopharmaceuticals. A number of findings were consistent across the three studies. For example, patenting activity is high and increasing both in firms and public research bodies, as is the number of technology transfer transactions (*e.g.* licensing). Patents appear to make knowledge a more tradable commodity which both encourages the circulation of new information and promotes a division of labour. Some theoretical problems with patents on genetic inventions in practice seem not to have occurred: two studies confirmed that patents on research tools are rarely enforced, and that in general firms do not pursue public research bodies for infringement. Also, while researchers sometimes avoid pursuing particular areas of research due to broad blocking patents or patent thickets requiring multiple licenses, most of the time firms find “working solutions.” It is very rare for research projects to be halted due to patent issues. Nevertheless, the studies flagged attention to the effect of patents and licensing on delays in research, higher transaction costs, and shifts in research agendas.

The third session turned to public research organisations (PROs) and the impact of licensing practices for genetic inventions on their research activities. The speakers noted that patents are an important element of technology transfer in the public sector. Many public research organisations in the US, and the NIH in particular, have developed patenting and licensing strategies to balance their commercial interests and public research missions, including such principles as not engaging in defensive patenting, avoiding exclusive licensing or refusing secrecy clauses. But professional technology transfer organisations are key in developing and implementing such policies. The US National Institutes of Health, because of its central role in funding US bio-medical research, has originated and disseminated such good licensing practices (*e.g.* the standardised Material Transfer Agreements). In Europe, however, public research organisations are fragmented and coherent policies at a national level are rare. A more professional cadre of IP managers in the public sector will be important if countries are to maintain adequate access by public research bodies to patented inventions.

The fourth session explored the impacts of patenting and licensing practices on the development of new products by the private sector. The protection of genetic inventions has led to a fragmentation of rights and an increase in transaction costs for companies integrating these rights in the development of new products and processes. Industry speakers felt that patent thickets, royalty stacking and reach-through rights are all legitimate concerns, but none seriously threaten innovation in biotechnology. Speakers felt that “working solutions” such as changes in the types of contracts negotiated or collective actions such as the formation of the Single Nucleotide Polymorphisms (SNPs) consortium and possibly patent pools are already emerging to overcome transaction costs associated with a more complex patent environment. These do not necessarily require affirmative government intervention. Nevertheless two important issues were flagged for attention. First, the situation for the private sector is likely to become even more complex and challenging as IP protection in biotechnology will increasingly include not just biochemical patents but database protection, copyrights and patents for software, reflecting both the chemical and informational nature of the inventions. Second, companies felt that reach-through claims in patents and the definition of non-infringement for research were a source of commercial uncertainty and need to be clarified.

The fifth session on human health and technology uptake focused primarily on patents for genetic tests. Two recent studies of laboratory directors in the United States, conducted by Mildred Cho and colleagues, showed that when patents issued on genetic tests, 25% of the labs that had been offering the test said that the patent owner or licensee prevented the lab from continuing its testing service and 53% of the laboratories who were considering the test opted not to offer it. Laboratory directors believe that patents and licenses have had a negative impact on access, cost and quality of the testing offered. Several OECD public health authorities have concurred. There are tools available to address some of the social concerns related to patents (*e.g.* access and affordability) which may not unduly lessen private incentives to innovate. The use of exclusions permitted in Trade Related Intellectual Property Rights (TRIPS), higher patent standards to be used in examination procedures, opposition procedures, and the threat of compulsory licenses are perceived as means of limiting patent owner licensing actions. The private sector stressed, however, that other solutions for improving clinical access might be preferable because they would be less arbitrary, probably less costly for all, and neither discriminatory nor a misuse of patent rights. These alternatives include: creating patent pools or clearing-houses to make it easier for laboratories to obtain licenses for patented genetic inventions thus reducing transaction costs; increased pressure on licensors in negotiation by large providers or through public pressure; and antitrust solutions.

III. Workshop Lessons and Future Challenges

Patents and effective licensing regimes make technology available and are essential for the successful development of new therapeutic applications of biotechnology. There is much private sector good practice in the licensing of genetic inventions, even as firms experiment with new solutions to the challenge of an increasingly complex IP environment. However, a large gap exists between the concerns of the public and the actual problems identified by experts and documented by surveys. This gap very much needs to be narrowed.

In some cases, however, the present system does fall short of public and private sector goals for the utilisation of new biotechnology by health care systems. Of most immediate concern are the difficulties of licensing patents related to genetic tests. Clinical laboratories often fall shy of concluding licensing agreements with holders of such patents, though the defining reasons for this remain to be clarified. The conference heard of a number of potential tools that might be available to improve access and market penetration without undermining the patent system and within the confines of member-country health service budgets. However, further detailed analysis by the private and public sectors and international organisations is necessary to determine what approaches might work best.

The Workshop also heard that most if not all OECD countries operate formal or informal research exemptions that work reasonably well in most cases. However, the transition between “research” and “commercial” use and subsequent requirements for licensing agreements needs to be clarified. Unclear definitions of exemptions could have a chilling effect on the progress of basic science.

Participants emphasised the need for improved international harmonisation of patent and licensing practices for genetic inventions and identified implementation of the European Directive on the protection of biotechnological inventions as being instrumental in helping achieve this.

In summary, while issues of patentability are still being discussed in public fora, experts stressed that licensing practices for genetic inventions are rapidly becoming the more contentious problem. The Working Party on Biotechnology will consider two possible themes for its future work programme. First, the WPB could develop “Best Practice Guidelines for the Licensing of Genetic Inventions,” focussing on how to facilitate access to and diffusion of technologies for the public good and on the identification of acceptable licensing practices. Second, the Working Party might explore the development

of indicators to better monitor the economic, research, and clinical impacts of licenses to genetic inventions. Measures of transaction costs, royalty stacking, and time to technology uptake, for example, could be applied to particular technologies or fields of activity (*e.g.* genetic tests), in order to document the concerns related to access and diffusion of genetic inventions across several countries.