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Conference on Research Use of Patented Inventions

Madrid, 18-19 May 2006

Summary Report

With the support of

Foreword

The conference on Research Use of Patented Inventions examined a key issue at the intersection of innovation policy and intellectual property rights: how to ensure access to inventions for follow-on research without weakening the incentive that patent protection provides to original inventors. This topic was discussed by Ministers responsible for science and technology policy at an OECD meeting in January 2004, at which they invited the OECD to examine the role of patent systems in fostering innovation, knowledge diffusion and competition and to assess the effect of national policies on exemptions for research use of patented inventions on the conduct of scientific research.

The conference, held in Madrid on 18-19 May 2006, was organised jointly by the Organisation for Economic Co-operation and Development (OECD), the Spanish National Research Council (CSIC) and the Spanish Patent and Trademark Office (OEPM), with the support of the European Patent Office (EPO) via its European Patent Academy and with a contribution from the Japanese government. It attracted 159 registered participants from a large number of OECD countries and diverse professional backgrounds (research, technology transfer, business, legal, policy). Speakers included internationally renowned legal scholars, business executives, government officials, scientists and economic researchers, as well as high-level representatives of the co-organising and supporting institutions.

Presentations made at the conference are available at:

www.oecd.org/sti/ipr

and

www.oepm.es

This report was prepared and co-ordinated by Catalina Martínez, with assistance from Jerry Sheehan and Dominique Guellec. Individual session summaries were written by Yann Ménière and Nicolas van Zeebroeck, conference rapporteurs, drawing on the presentations and discussions of the conference speakers and chairs, whose excellent contributions and subsequent comments are hereby acknowledged. Gerardo Penas was responsible for the printed edition of this report issued by OEPM.

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The views expressed in this report are those of the individual speakers and contributors and should not be attributed to the organising and supporting institutions.

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Executive Summary

This report summarises the presentations and discussions from the Conference on Research Use of Patented Inventions held in Madrid on 18-19 May 2006 and jointly organised by the by the Organisation for Economic Co-operation and Development (OECD), the Spanish National Research Council (CSIC) and the Spanish Patent and Trademark Office (OEPM), with the support of the European Patent Office (EPO) via its European Patent Academy. The main conclusions are set out below.

At present, there is no empirical evidence of a widespread problem in accessing patented inventions for research; concerns are confined mostly to specific fields of research and countries.

- Existing concerns are limited primarily to research in pharmaceuticals and biotechnology and are most pronounced in the burgeoning area of research tools in genomics and biotechnology. Many of the issues of concern are related to threats of litigation and are more worrisome in countries with traditionally high levels of litigation, such as the United States.

- Available empirical evidence indicates that issues of access to intellectual property are not as significant as issues of access to material research inputs, owing to competition between research laboratories, among other factors. Existing evidence, however, is based on isolated surveys that tend to be limited to United States and to the life sciences. The situation may differ in other countries and fields of research.

- More and better empirical evidence is needed to reach more robust conclusions. Limited information is available on research use of patented inventions in most OECD countries. The forthcoming results from the international survey undertaken by the American Association for the Advancement of Science in the framework of its Project on Science and Intellectual Property in the Public Interest (AAAS-SIPPI) will be a first step in remedying this situation, as it will be based on responses from researchers in all scientific fields and four different countries (United States, Japan, United Kingdom and Germany). Preliminary results for the United States are consistent with previous surveys limited to specific areas.

Nevertheless, concerns over research use could expand to other important areas of research and industrial development and to other countries.

- There are no signs of an extended slowdown in patent filings in OECD countries, and future scientific research is unlikely to take place in patent-free zones. Patent portfolios are likely to be built (in the public and private sectors) as a way to guarantee freedom to operate and co-operate in research.

- At the same time, alternative protection mechanisms are leading to the creation of informal co-operative communities (*e.g.* open licensing schemes, patent pools for defensive purposes) that will spread and co-exist with traditional means of IP protection.

- New science-based technologies will proliferate and gain increasing economic importance. Some of the issues raised in the biotechnology sector are likely to be amplified in nanotechnology and other fields.

- The ongoing trend towards more multidisciplinary research also heightens prospects for greater litigation over research uses. Such work brings together not only researchers from different disciplines, but also different approaches to and traditions in IPR management (*i.e.* biotechnology

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and information technology in bio-informatics). The current situation of benign neglect and mutual forbearance may not be an optimal or enduring option in such an environment.

A balanced patent system should facilitate inventions that build on earlier findings, but the line may be difficult to draw, especially for patented research tools.

- Most patent systems have research exemptions either written into their laws (statutory) or adopted in their jurisprudence in the form of research use defences (common law). Statutory research exemptions generally allow research *on* the subject matter but not *with* it, so that use of unlicensed research tools is not exempt from infringement. Such statutory research exemptions provide clarity and security (especially when they are accompanied by statutory bans on contractual clauses undermining the scope of the exemption). Common law defences, in contrast, provide greater flexibility but less certainty, as the interpretation of the law may change over time subject to court decisions.

- Uncertainty and international differences as regards the scope of research exemptions in patent systems may hinder firms and other research organisations that perform R&D globally from benefiting from research exemptions given potential litigation risks.

- The balance between providing sufficient incentives to initial and follow-on inventors is greatly facilitated by the granting of high-quality patents characterised by a sufficient level of inventiveness and an appropriate level of protection relative to their contribution to the state of the art (*e.g.* claims granted only for disclosed specific uses).

Alternative mechanisms to facilitate access to inventions for research purposes are also available.

- Other government policies can also facilitate access. Competition policy can be used to guarantee affordable and widespread licensing of foundational inventions and essential research tools protected by patents by monitoring the behaviour of licensors. Governments often retain the right to inventions developed with government funding or can require compulsory licensing in certain situations.

- Other models of intellectual property management are also gaining ground and seek to create communities of users and foster collaborative innovation among them via improved sharing of patented inventions. The Open Invention Network, for example, acquires patents related to open source software and makes them available royalty-free to others who agree not to assert related patents. The Science Commons Licensing Project explores how standard open agreements can facilitate licensing of intellectual property and exchange of materials.

Further studies are needed to better understand emerging issues related to research access to patented inventions and identify good practices for promoting it across different industry sectors and countries.

- Despite the considerable progress made in recent years, more work needs to be done to better define, measure and delineate the problem of research use of patented inventions. Studies could focus on specific issues in the research tools industry or on emerging problems in interdisciplinary fields. Of particular interest would be efforts to determine how different legislative and regulatory environments affect innovation, economic growth and the location of R&D activities.

- There is also need to identify good practices for facilitating access to patented inventions, for example, as regards research tools in biotechnology, as well as patented inventions based on publicly funded research results.

- Theoretical and empirical research for the assessment, determinants and impacts of patent quality would also be important to better address the issues raised in this area.

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Summary of Conference Sessions

Opening Session

The conference was opened by high-level officials of the three organising institutions and of the European Patent Office: José Manuel Fernández De Labastida from the Spanish National Research Council (CSIC), Mª Teresa Mogín from the Spanish Patent Office (OEPM), Nobuo Tanaka from the OECD, and Bruno van Pottelsberghe de la Potterie from the European Patent Office (EPO).

In his opening speech, ***José Manuel Fernández De Labastida***, Vice President of the Spanish National Research Council (CSIC), underlined the critical importance of the conference's topic to an institution such as the CSIC. The largest public research body in Spain, with more than 12 000 staff from tenured scientists to technicians, administrative staff and research fellows, CSIC is also the third largest research institute in Europe, behind the CNRS in France and the Fraunhofer Institute in Germany, federating 125 institutes all over the country. Public research organisations such as the CSIC must contribute to the creation of knowledge but also to social and economic wealth. In order to fulfil its mission, CSIC needs to perform outstanding competitive research, which requires optimal communication of results among scientists in order to enable incremental inventions. In this context patents are the best way, and in many cases the only way, to make knowledge dissemination compatible with industrial use of the results obtained. However, the system needs major improvements. All research organisations are looking for mechanisms to valorise their creation and diffusion of knowledge. For public institutes the creation of spin-offs is the most efficient way to bring inventions to the market and give value to their IP portfolios. To increase the creation of spin-offs from its research results, CSIC needs to provide them with appropriate tools to develop and in particular to ensure their freedom to operate and to do research. The aim of this conference is precisely to initiate a debate with policy makers to discuss the future of the patent system and the rules under which research organisations will be doing their job tomorrow.

To ***Mª Teresa Mogín***, Director of the Spanish Patent Office (OEPM), the participation of her office in this conference is important as it may contribute to the establishment of partnerships between patents and science. The OEPM wants to develop a supporting framework for scientific activities. This may be facilitated by a number of improvements to the patent system, such as regulations clarifying the ownership of university inventions and the establishment of provisions on research exemptions, taking into account the financial issues they may raise for universities. The participation of the Spanish Patent and Trademark Office in seminars like this one aimed at improving understanding and ties between research institutions and patent offices is a crucial element of its endeavour.

The subject is equally of great importance to OECD countries, as noted by ***Nobuo Tanaka***, Director for Science, Technology and Industry at OECD, since we live in a knowledge-based economy in which innovation policies and the utilisation of IP assets are of key importance. This importance is illustrated by the OECD's recently published report on IP assets and value creation, which shows that investments in knowledge (including R&D) are growing faster than investments in machinery and equipment, and hence that intellectual assets are becoming more important than tangible ones. However, innovation is becoming more complex, open and collaborative, with more, and more intensive, cross-border and cross-sector collaboration. In such a context, what is the best way to ensure that the patent system continues to enhance both the creation and protection of inventions? The OECD believes that a balanced patent system is critical. Licensing is becoming increasingly complex, with high transaction costs. Hence, some countries have instated exemptions for certain research activities for which potential infringement is not an issue. However, several countries are now re-examining their exemptions to make sure that they still foster innovation and provide researchers with access to patented inventions in a properly balanced way. These concerns about the research use of patented inventions are shared by OECD member states' ministers and require gathering and analysing data on

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the links between research, IP rights and economic performance as well as providing ways of improving research use while maintaining sufficient incentives to innovate.

Patent offices are facing many challenges in the current economic context, as highlighted by ***Bruno van Pottelsberghe***, Chief Economist at the European Patent Office (EPO). The EPO has experienced a nine-fold surge in patent filings over the past two decades, especially in the information and communication technology (ICT) and biotechnology sectors and increasingly from Asia. At the same time, the complexity of filings, as measured by the number of claims, has doubled – although not homogenously across sectors – and multiplied the EPO's workload by about 20. This has put increasing pressure on the quality of the granting process. To ensure that it will continue to deliver high-quality patents, the EPO is committed to granting patents only for significant inventions; to providing applications with an extended search report in order to stop poor applications earlier in the process; and to increasing legal certainty by reducing the time to grant (as of January 2006, about half of the patent applications received in 2002 were pending and 40% of those received in 2001), and by increasing the quality of the information produced and the clarity of the patents granted. This EPO's attention to quality is illustrated by the fact that around 30% of applications are withdrawn after a communication from EPO examiners, more than 50% of them due to EPO actions such as search reports and communications.

The increasing number and complexity of patent filings show the strategic role played by patents in the business sector. At the same time, regulations similar to the Bayh-Dole Act have spread across Europe, leading universities and public research institutes to become new players in the patent field. The need for further integration and harmonisation of the European Patent System is clear and should become even more attractive owing to the London Protocol, the European Patent Litigation Agreement (EPLA), and the Community Patent and the Technology Transfer Block Exemption (TTBE). In a context lacking any sign of a slowdown in patent filings, key questions from the EPO's viewpoint are whether patents are really the enemy of open science, whether they can hinder the timeliness and quality of academic research, and how frequently patent issues block academic research projects.

Keynote I: Science and the patent system

The first keynote speech was given by ***John Barton***, Professor of Law Emeritus at Stanford Law School. He explored possible conflicts that may arise between the scientific and patent systems as regards research tools. He also considered different policy solutions to overcome these conflicts.

The science and patent systems are comparable in many respects. Both rely on a system of rewards – namely recognition and patent monopoly – which creates incentives to innovate. The rewards are conditional on the fulfilment of parallel requirements relating to the novelty, inventive step and publication of innovative works. Still, several differences complicate the coexistence of these systems. Researchers may be more reluctant to share information about their ongoing work under the patent system and it may also be more difficult to verify earlier findings or to build upon prior findings; under the scientific system they are only required to give academic credit.

Conflicts between the scientific and patent systems are especially likely to occur for research tools. These can be defined as inventions or discoveries that enable the development of other inventions or discoveries. They cover a wide range of innovations, from the telescope as a research tool for astronomy to gene sequencing as a research tool for contemporary medicine and biology. Policies geared towards research tools should pursue two distinct goals in order to ensure good articulation between the scientific and patent systems:

- First, they should set an appropriate balance between the incentives for innovators who develop and patent new research tools, and the conditions of access for other researchers who use these tools for their own research. This balance should ensure that appropriate conditions for innovation are preserved at both stages.

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- Second, inventors of research tools should not have control over subsequent inventions developed thanks to this tool, even though they are entitled to receive a fair monetary reward from them. Otherwise valuable inventions may not be developed because the owner of the research tool lacks the capacity or lucidity to recognise their potential.

Addressing these two policy goals is difficult because several factors increase the variety of the development and use patterns of research tools. On the one hand, patents are not the only way to create incentives to innovate. In some cases the development of research tools is supported by public or non-profit funding, so that patent protection may be redundant. On the other hand, access to research tools may be compromised if university researchers do not have a budget for licensing fees and therefore cannot afford the research tools, even when these are licensed at a reasonable cost and on a non-discriminatory basis. A similar issue can arise for inventions whose physical transfer is costly. Finally the true question may not necessarily be how to ensure access to patented inventions but whether the invention should be patented at all. Some of the more contemporary examples involve initial inventions of contested patentability. For example, in the US Supreme Court's decision in *Brenner v. Manson* (1966), the Court stated that patent claims should be "reduced to production of a product shown to be useful".

The available evidence on the impact of patented research tools makes it possible to identify where policy measures may actually be needed and indicates that university research is not significantly impeded by patents on research tools, although this may be due to the fact that university researchers ignore such patents. In contrast, industries such as the pharmaceutical industry may be more exposed to problems of access to patented research tools. Patents on research tools may also be more likely to hinder innovation in fields such as agriculture or genomics. As research processes become more complex, new fields may be concerned in the future.

According to Barton, empirical evidence points to the existence of an imbalance in the patent system that could be addressed by three different policy measures.

A first policy measure would consist in better controlling the patentable subject matter of inventions. Two distinctions are worth being considered:

- The first opposes inventions and discoveries. Despite statutory limitations, patentability has progressively extended to the latter, especially in genomics. However, this evolution is problematic when the patented invention affects a large research area, and when it is necessary to use several such inventions to carry out new research.
- The second distinction opposes information and tangible inventions. It applies especially to computer science, where innovation is intangible. This has raised difficulties in the United States and the European Union. The patentability of software has an impact in biotechnology, an area that increasingly uses it as a research tool.

Research exemptions to patent law for experimental use constitute another policy lever for facilitating the use of research tools. Such exemptions can be articulated in terms of three principles, namely:

- Exceptions to patent law for uses that are non-commercial or motivated solely by scientific curiosity.
- Exceptions for use to understand and improve the innovation (*i.e.* research "on" the patented invention), in contrast to use of the innovation for the research purpose for which it was intended (*i.e.* research "with" the patented invention);
- Bolar-type exceptions relating to securing approval for generic medical products.

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According to Barton, the first principle is probably unnecessary and is difficult to apply to real cases as the distinction between commercial and non-commercial research evaporates, while the third principle applies only in specific contexts. The second principle is more reasonable and has a wider scope of application.

Regulation of licensing behaviour is a third possible policy lever. In particular, a refusal to license an invention widely could be overcome by using, when possible, the antitrust patent misuse and essential facilities doctrines. Barton argued that a licensing principle could be formulated to avoid exclusive licensing when broad licensing would be socially desirable. He identified three cases in which applying such a principle would foster innovation: when many different applications seem likely; when research would benefit from work by many different teams; and when many inventions have to be combined for subsequent research.

Besides the application of antitrust law, non-exclusive licensing can also be promoted by research donors. They can impose conditions on the use of patents that benefit from their funding and thus solve some access problems. The NIH licensing guidelines, the Rockefeller Foundation support to open-source biology, and the patent pool created by the SNP consortium are examples of such commitments. There are also however examples of research donors that impose restrictions on the licensing of sponsored research results.

As a reality check, Barton compared the three levers he had identified by looking at whether they could apply to seven recent US court cases involving biotechnology research tools: *i)* PCR-Roche; *ii)* transgenic research mice – DuPont; *iii)* Cre-lox – DuPont/BMS; *iv)* Genomes – Celera, Incyte; *v)* Stem cells – WARF/Geron; *vi)* BRCA – Myriad; *vii)* Array – (Affymetrix). He concluded that none of these remedies could have addressed the problems raised in the PCR and Cre-lox cases. In contrast, the limitation of patent scope would have been an effective way to facilitate access in the other five cases, while the research exemption and licensing levers could only have been applied in three (Genome, BRCA, Array), and with more uncertain results.

Session I: How does patenting affect access to inventions for research purposes?

The effect of patents on innovation is uncertain when patented inventions are used for research purposes. On the one hand, patents are necessary to enable upstream inventors to derive a profit from their research investments. On the other hand, there is a risk that patent exclusivity will limit excessively the access of other researchers to the invention. A “tragedy of the anti-commons” is especially likely when researchers need access to several patented inputs. The session aimed at pooling empirical evidence on this problem. The results of three surveys on the reality and causes of limited access to patented inventions for research purposes were presented.

Biomedical research tools are typically the kind of inventions that can generate tensions between the rewards of patentees and diffusion to other researchers. ***John Walsh***, Professor in Sociology at the University of Illinois, presented the results of a survey of 414 academic biomedical researchers working in US universities and non-profit and government labs. Even though 22% of the researchers in the sample had filed patents in the past two years and 35% of them had some business activity (start-up, negotiations, licensing, commercialisation of discovery), they generally appeared to be weakly aware of patents on research inputs because of a lack of information and interest. Only 8% of respondents believed they needed knowledge or information covered by patents. Even fewer check regularly for patents and their proportion did not increase significantly after the US research exemption was removed in 2002 following *Madey v Duke*. Although researchers are now given instructions to improve patent awareness more frequently, no change in behaviour has been perceived.

The fact that research inputs are patented impedes academic research very little. In this matter two categories of research inputs can be contrasted. On the one hand, there are “knowledge” or “intangible” research inputs, which can be qualified as “pure” intellectual property featuring disembodied knowledge that can be easily accessed by other researchers. On the other hand, there are

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"tangible" research inputs that require physical delivery by the patent owner, as it is the case of cloned genes, organisms or cell lines. Access to "pure" intellectual property raises very few problems for academic research projects. No project has been abandoned because of "pure" patents and only 1% of respondents had either to delay their project beyond one month or to modify it. The share is higher when the sample is limited to academics who find that a particular patent is relevant to their research: 16% suffered delays in their research; and 13% had to modify their research.

Academic researchers face more difficulties for accessing "tangible" research inputs, but this is mainly due to factors other than patents. Researchers frequently request access to "tangible" inputs. About 75% of the academic respondents in the sample had requested access to tangible research inputs (mostly to other academics) during the two years prior to the study, 19% of whom had not received the last input requested. Moreover, the share of requests that go unanswered in academic to academic exchanges in the field of genomics seems to have increased in recent years as compared with results of previous surveys. Difficulties in accessing tangible inputs also seems to have a significant effect on the timing of research projects, with at least 8% of requests leading to delays of more than one month in academic research projects, but to delays of only 1% for problems related to "pure" intellectual property. The main predictor of refusals to provide materials is competition between research labs, which erodes the norms of open science. The time and effort required to deliver an input, and the prior involvement of researchers in a business activity such as a start-up, licensing or the commercialisation of a discovery, are other important factors. In contrast the fact that the research is funded by industry has no serious impact on the sharing of tangible inputs. The survey also addressed the impact of particular terms (reach-through, royalties, publication restriction, co-authorship), and found that demanding publication review or royalties reduces the likelihood of completing the transfer.

Even rare results may have major social welfare impacts if they affect an important technology. To probe this, Walsh presented the results of case studies in three fields of high scientific importance, patenting and commercial activity (with drugs either in the market or in clinical trials). These case studies show that the impact of pure intellectual property (IP) is still small in high-risk areas (3% compared to 1% in the general survey) while the impact of withholding tangible property is significant and greater than in other areas (26-32%, compared to 19% in the general survey).

So, if there is a problem, Walsh concluded, it is one of access to tangible rather than intellectual property, and the constraints on access turn more on cost, effort, scientific competition and commercial activity than on intellectual property *per se*. Reforming patent law would thus not be relevant. Policy initiatives to facilitate access to research inputs should instead aim at promoting more co-operative behaviour among academic researchers, in order to balance laws such as the Bayh-Dole Act which are entirely geared to commercial activities. Solutions should be tied to problems and facilitating tangible input sharing to reduce cost and effort might be important.

Jana Asher, Senior Program Associate for the Project on Science and Intellectual Property in the Public Interest (SIPPI) at the American Association for the Advancement of Science (AAAS) compared the results of two large surveys on researchers' experiences with and practices regarding intellectual property in a wide range of scientific fields. A first pilot survey carried out on an international sample of AAAS members focused on researchers' experiences since 2001 regarding the acquisition of protected technologies and methods of legal protection of their own created IP. The sample comprised 843 relevant respondents from academia, public research institutions and industry (out of a sample size of 4 000). A second survey, currently in progress, extends the pilot exercise to a sample of members of scientific organizations based in four different countries and focuses on experiences since 2002. As that survey is not yet completed, Asher's presentation was based on first results from the US sample, which comprises 2 157 respondents (out of a sample size of 8 000). In contrast with the pilot survey, the US sample in the international survey has substantially more respondents from the medical and health sciences (about three times more than in the pilot survey) and biological sciences (around seven times more than in the pilot survey). It also has more respondents from industry (about four times more than in the pilot survey) and academia (about twice as many) which may explain some of the differences in results. Some of the discrepancies between the results of

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the survey presented by Walsh and those of the AAAS pilot study disappear when considering this more recent and extended US survey.

In both surveys the acquisition of protected technologies by researchers is more frequent in the life sciences, the medical/health sciences and the biological sciences (at least 30% in the pilot and around 40% on average in the US survey). Engineering, computer sciences and chemistry are the fields in which acquisition of protected technologies also appears to happen more frequently than in other areas (above 20%), with engineering ranking higher in the US survey than in the pilot (second after life sciences, with 40% compared to less than 25% in the pilot).

Material transfer agreements and licences (exclusive and non-exclusive) are the most popular methods of acquisition. Among the respondents who obtained intellectual property (32% in the US survey, 24% in the pilot), a large share reported difficulties, although fewer in the US survey (32% of those obtaining IP) than in the pilot (40%). Difficulties principally result in additional delays (delays were reported by around 40% of scientists facing difficulties), especially when licences are exclusive. But they may also lead to changing or even abandoning projects. The abandonment of research projects was nevertheless the least reported effect, around 1% of all respondents to the US survey (or 9% of those reporting difficulties).

Concerning the protection of research results, between 46% (pilot survey) and 52% (US survey) of respondents reported having created intellectual property during the last four years. The shares are larger in industry than in academia whatever the scientific field. Patenting is by far the main method of protection.

Asher concluded by reminding participants that more insight into the results of the SIPPI-AAAS survey by scientific field and across countries will be available in a full report to be released after all phases of the survey have been completed. The UK and the US phases are complete and the German and Japanese phases are in progress.

Sadao Nagaoka, Director and Professor at the Institute of Innovation and Research of Hitotsubashi University, presented three empirical studies on the patenting and licensing of research tools: *i*) patents for key research tools in life sciences; *ii*) licensing conditions for research tools, as disclosed mainly by US biotechnology firms; *iii*) access problems as seen by Japanese pharmaceutical and biotechnology firms.

The first study focuses on 47 inventions identified by the Japanese Patent Office (JPO) as foundational in the life sciences (*e.g.* the recombinant DNA technology developed by Cohen and Boyer). More than 45% of these inventions can be considered solely as research tools, and an additional 35% can have a dual use as research tools and final products.[1] The study highlights two important trends. The first is a shift from the public to the private sector as regards the ownership of patented research tools (covering key inventions with both unique and dual use as research tools). Until the mid-1980s, most belonged to research laboratories and universities, and the government had an interest in half of the university patents. Since then, biotechnology and pharmaceutical companies lead. The study also reveals a trend towards the globalisation of patent applications, with 60% of key inventions being applied in the three major patent offices (JPO, USPTO and EPO).

The second study explores licensing conditions for research tools in contracts included in the RecapIP licensing database in the life sciences which covers more than 800 contracts mainly disclosed by US

[1] Nagaoka, Sadao and Reiko Aoki, 2006, "Economics of Research Exemption", Hitotsubashi University, Working Paper 06-04 of the Institute of Innovation Research of Hitotsubashi University (http://www.iir.hit-u.ac.jp)

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biotechnology firms either as licensees or licensors.[2] Contracts with exclusivity provisions and/or a high level of royalties appear to be less frequent at the discovery stage than at the downstream stage and when they concern research tools rather than product technology. In both cases this may be due to the higher risk and R&D costs that the licensee will incur in order to commercialise the innovation. Exclusivity provisions are more frequent when licensing takes place *ex ante*, before the licensee makes any investment. Such *ex ante* contracts can be interpreted as a way for the licensee to reduce the risk of being unable to appropriate the benefit of its innovation. According to Nagaoka, strong patent protection of research tools could thus foster *ex post* licensing by reducing the risk perceived by the patent holder. Finally universities appear to impose exclusivity more frequently than private companies when they license their innovations *ex post*, which may reflect their financial constraints.

The analysis of the results of a survey implemented in January 2004 on access to patented research tools by 68 Japanese pharmaceutical and biotechnology firms (36 of them users of research tools) complemented the first two studies,[3] Firms seldom abandon a research project after having discovered the existence of a patent on a research tool. They most often buy a license either immediately or after continuing their research without a licence until they have obtained some results. Otherwise they use alternative methods, challenge the validity of the patent or simply ignore it. When they decide to buy a licence, they frequently find the licensing conditions unreasonable, although licensing deals are finally struck in most cases.

Based on these three studies, Nagaoka's preliminary conclusions were that patent protection would stimulate the development of research tools and might also facilitate *ex post* rather than *ex ante* licensing, which is often exclusive, as long as it meets clear patentability standards. For the efficient use of research tools, he recommended that royalty stacking due to multiple licensing should be avoided and that cost-based or free non-exclusive licences should be used for government-supported research tools, unless exclusivity is necessary to develop the inventions.

Other empirical studies were mentioned by ***Stephen Merrill***, Executive Director for Science, Technology and Economic Policy at the National Academies.[4] They identify negative effects of patent grants on citations to corresponding articles in biotechnology, which seems to confirm a weakening of open science in the academic world. Perhaps citations are more affected by patents than subsequent research. Further research is needed to reconcile these results with the other evidence presented in the session.

Session II: Perspectives from the private and public research sector

The importance and strategic use of patents varies widely across industrial sectors. Practices in terms of research use of patented inventions may also vary from industry to industry and have different consequences for private and public research activities. In this session, four speakers provided different perspectives and considered some practical applications in different settings.

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[2] Nakamura, Kenta and Sadao Nagaoka, 2006, "Licensing Agreements for Upstream Inventions: A Contract-Based Analysis of Pharmaceutical Industry", based on the research project report on *patent protection of upstream inventions* supported by the JPO, forthcoming as a Working Paper of the Institute of Innovation Research, Hitotsubashi University

[3] Koichiro Onishi and Sadao Nagaoka, 2006, "Structural characteristics of key inventions in the life science area", based on the research project report on patent protection of upstream inventions supported by the JPO, forthcoming as a Working Paper of the Institute of Innovation Research, Hitotsubashi University.

[4] Sampat, B.N. (2004), "Patents on Academic Genomic Discoveries: Effects on Biomedical Research", Working Paper, University of Michigan Department of Health Management; Murray, F. and S. Stern (2004), "Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis", (unpublished manuscript); Pressman, L. *et al.* (2006), "The Licensing of DNA Patents by US Academic Institutions: An Empirical Survey", *Nature Biotechnology*, 34:1, January 2006, pp. 1-9.

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José Luis De Miguel, Director of the Technology Transfer Office at the Spanish National Research Council (CSIC), proposed a public research organisation's view of the research use of patented inventions. CSIC is a multidisciplinary institution that is active throughout Spain and plays a key role in the articulation of science and technology. With 2 400 scientists and a budget of EUR 530 million, CSIC represents 6% of Spanish R&D efforts and is responsible for 20% of Spain's international scientific publications and 50% of the Spanish public sector's papers in prestigious journals. Patents are obviously essential to an organisation such as CSIC, which is currently the leader in Spain in terms of Patent Convention Treaty (PCT) patent applications. They will become even more important as the CSIC intends to double the disclosure and diffusion of its inventions and to increase the creation of spin-offs by 50%. Achieving this objective requires high-quality research and a market for technology dissemination.

Patenting by public research organisations encourages the communication of results, a powerful vector of progress in science, even though publications remain main source of recognition. Moreover, CSIC's experience shows that patents do not affect the use of inventions for research purposes, perhaps because most researchers are unaware of the possible limitations imposed by patents and are not used to exploiting them. However, if patents are taken into account by researchers and appear to place limitations on their research, public organisations and scientists will have to change how they perform research and interact with each other. Whether this new way of doing research would be better or worse is a question for experts. But if an invention presents any economic value, it is CSIC's role to patent, exploit and leverage it.

A major difficulty research organisations currently face with respect to patents is the conflict between protection and publication. Nowadays, researchers need to publish as fast as possible but patent applications generate delays in the publication of results. This faces research organisations with a difficult choice between delayed publication and absence of protection. For De Miguel, implementing a grace period in Europe would not only solve this issue, but would also make the patent system better adapted to public research dynamics and would reduce the amount of industrially useful knowledge that is being lost by public research institutes for lack of protection.

IP Counsel at IBM Research in Zurich, ***Peter M. Klett*** first stressed the importance of patents to IBM. With research centres all over the world, IBM Research is a major source of IBM's patented knowledge. Its activities are product-oriented and focused on servers, storage and software, with a particular interest in exploring areas such as nanotechnology, photonics or microscopy, which involve basic research. According to the traditional research paradigm, researchers are keen to collect information, collaborate and communicate with others. But these activities constitute major sources of legal risks. Patents as competitive instruments offer many benefits to companies: they offer protection, good publicity and efficient defence tools when companies are attacked; their publication is a useful source of knowledge for researchers who can use patent databases to learn about what is being done; they provide an indicator of usability, especially in the United States where the best way to use the invention must be disclosed; they offer an indicator for business value; and they reveal competitors' activities.

Nevertheless, patents can be frustrating. They tell researchers how to do something but prevent them from doing it. Is a research exemption therefore needed? Nowadays, research exemptions are not harmonised throughout the world, and multinationals cannot rely on research being limited to one jurisdiction. Moreover, it may be difficult to draw the boundary between research activities and commercial exploitation, and it is an illusion to think that research can be done in a patent-free world since patents are always involved at some point. However, companies may rely on other safeguard mechanisms. In particular, in the research phase, infringement is difficult to detect and the patent holder would receive minimal licensing or litigation revenues (the threat of patent trolls is also reduced). Therefore, provided that the research process is lengthy, companies may enjoy a long time frame in which they are reasonably safe. Many researchers probably live in this grey zone, supposedly without knowing it, although it would be hazardous to try to define the scope of such a "safe zone". The willingness of researchers to collaborate acts as a stabilising glue that binds the research

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community together. Consequently, international research activities are generally free *de facto* (at least free from litigation if not from infringement), but this freedom is generated by the nature of research rather than by law.

Obviously, it is always advisable to patent some inventions. Other protection mechanisms exist as well, such as secrecy (powerful but quite risky), defensive publications and even co-operation agreements. When companies are involved in bilateral co-operation, contracts set the terms and liabilities of their sharing of knowledge. The EU framework programmes are also worth mentioning as they require several parties to team up in a research project, the contractual rules of which are set forth by the European Commission, ensuring that all parties grant each other freedom to do research and exploit and disseminate the results.
Open standards also create platforms of knowledge based on IP protection. They are the source of the necessary building blocks for collaborative innovation (*e.g.* if the TCP/IP protocol had not been opened, the Internet would probably never have emerged). Standards reflect the need for harmonised markets in order to make progress, and this may ultimately lead companies to use patents at the appropriate level to boost value creation while granting each other freedom to operate. Collaborative innovation relies on a shared foundation of proprietary and open innovation. A well-managed IP portfolio allows companies to differentiate themselves and generate revenue, whereas open innovation acts as a regulatory device based on standardisation.

In conclusion, a new research paradigm is emerging, in which research is still using, generating and sharing knowledge, is still embedded in a framework with or without a research exemption, but is now more and more collaborative and more and more open.

As explained by ***Miguel Ángel Flores***, Research Scientist, RepsolYPF does not aim to license its 100 patents and utility models for chemical technologies, but focuses on protecting its inventions and ensuring its freedom to operate. A regionally integrated oil and gas company operating in 28 countries, RepsolYPF is the leader in Spain and Argentina, with a refining capacity of over 1.2 million barrels a day. RepsolYPF dedicates 16% of its R&D budget to collaborations, notably with 200 R&D contracts with academic institutions. To the best of RepsolYPF's knowledge, research use of patented inventions has never raised particular concerns or conflicts in the petrochemical industry. It nevertheless considers the research exemption, which covers the improvement of existing inventions for whatever purpose, a basic condition of scientific progress.

A key issue relates to difficulties – not exclusively legal – in accessing inventions protected by patents and to the use made of the patent system by the academic community to search, assess or publish scientific information. For industry, patents contain mainly technological information along with some scientific content, determine the scope and development line of a research project, and can be used by scientists as a source of ideas. To universities, patents look unreliable and difficult to understand, are not valued in academic CVs or in scientific citation indexes, and induce delays in the publication of scientific papers; they are rarely used as a source of knowledge despite some similarities in content and structure between patents and scientific papers. Since industry-university collaboration is increasingly encouraged and realised, there is a real need to avoid the delays induced by patent applications for scientific publication, to improve the perception of patents within universities, and to promote patents as valuable scientific achievements in the academic community.

Neil Thomas, Director of Intellectual Property of the Madrid-based Genetrix Group, points out that in the biotechnology industry, research use of patented inventions is a much more sensitive issue than in other industries. Genetrix is engaged in the promotion of biopharmaceutical business initiatives, so far leading the formation of a group of seven biotechnology companies specialising in biomedicine and life science technologies. Over the past four years, Genetrix has taken academic institute and in-house generated IP rights and transformed them into 68 jobs and over EUR 20 million in capital. Its aim is to develop and commercially exploit these intellectual assets, which it did through in-licensing from academic research entities in its start-up phase.

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Patents have both positive and negative effects on small biotechnology firms. On the one hand, they are an easily accessible source of information functioning as a window onto new research ideas or as a filter to avoid wasteful reinvention of existing technologies. Patents are usually published after 18 months, sometimes delaying dissemination of the technology to the public, but they must disclose the claimed invention in a repeatable way and even include the best mode known to the inventor at the time of filing (at least in the United States), requirements that have equivalents in most international laws. On the other hand, patents expose the research aims of a company and possibly give information on early stage activities to its competitors. In addition, patents generate various obstacles to research. Firstly, researchers are more inclined to publish their inventions first in scientific journals perhaps due to an underappreciation of the recognition inventorship on patents brings and/or lack of interest in the commercial exploitation of their research. Secondly, in most countries basic research is legally exempted only as long as it consists of research "on" and not "with" a patented technology. Hence research may be hampered by patents on research tools, especially those held by large firms. Finally, there remains some uncertainty as to the exemption of clinical research as demonstrated in the United States by *Merck v. Integra*.[5]

Patents also allow firms to build fortifications against competitors. New inventions may be protected by patents and are often licensed out when they are considered to be outside the firm's core activity. However, as patents on new tools and know-how can be sometimes difficult to enforce or license, companies may prefer to protect them by trade secret, which is vulnerable to leakage, especially by ex-employees or prevent anyone else from creating a blocking patent situation by making defensive publications, though this carries the risk of generating blocking prior art for their own future inventions. Finally, patents can build bridges in that they can help a company raise capital and form R&D partnerships by securing know-how assets in a recognisable and reassuring form. Indeed, when setting up R&D projects with academics, patents crystallise the subject matter and clearly indicate who owns what to any third party (though attention should be paid to regulations similar to those of the Bayh-Dole Act). Academic publications prior to patent filing, as often occur in such collaborations, is a risk to patent protection in those territories without inventor grace periods, thus education and monitoring of the collaborators should be a priority. In this way, small and medium-sized enterprises (SMEs) can outsource R&D to academic institutions and then license in the resulting technology, so as to transform science into potential products. Additionally, SMEs can out-license their own patents to other companies in order to share R&D expenditures.

In view of these pros and cons, alternative strategies that biotechnology SMEs wishing to protect their inventions might consider include: *i*) the first mover advantage obtained by being first to market approval; *ii*) orphan drug status exclusivity; *iii*) investment in specialised production capabilities such as GMP (good manufacturing process) facilities; or even *iv*) open source models inspired from the ICT industry or the Human Genome Project. In any case, the huge investment needed to bring a drug to market is very unlikely to be recouped in the absence of a 20-year long (or more) patent-based exclusivity period, so patent protection remains the optimal solution in this sector.

In concluding the session, it appears first of all that the question of the research exemption varies widely in importance from industry to industry. Highly sensitive for biotechnology SMEs, especially for patents on research tools, the issue seems almost nonexistent in the petrochemical industry and it has taken a completely different form in the information technology (IT) industry with the emergence of new open and collaborative innovation models and standards. What is more, as highlighted by ***Richard Johnson***, Vice-Chairman of the Technology Committee of the Business and Industry Advisory Committee to the OECD (BIAC), if the innovation process becomes less linear but more iterative, collaborative and complex, there will be a need for more open tools to preserve access to new technologies for research use, from basic research to development, bearing in mind these divergences across sectors and between different types of actors.

[5] In 2005, the Supreme Court in *Merck v Integra* held that the regulatory review defence applies to pre-clinical research, but left open to the question of how much further back upstream in drug discovery.

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Session III: How effective are research exemptions in patent law?

From a legal standpoint, exemptions that provide access to patented inventions for research purposes can take various forms and vary in scope, and this is reflected in their heterogeneity across OECD countries. The purpose of this session was to highlight different national approaches to research exemptions and to evaluate their respective effectiveness. Trevor Cook provided a general overview of the problem in different legal systems. Professor Straus described the cases already resolved by the German courts on this issue. Finally, Andrew Christie and Nikolaus Thumm referred to the discussions and problems raised for considering the introduction of a so-called research use exemption in the legislation of Australia and Switzerland, where it does not yet exist.

In his introductory remarks, Professor ***Alberto Bercovitz***, founder of the Madrid-based law firm Estudio Jurídico, suggested reconsidering the title of the session as it is extremely dubious that the experimental use of a patented invention entails an exception in patent law. Instead, the experimental use of patented inventions is a general principle of patent law, and as such, the right of the patent holder to prevent or limit that use (which would be an exception) needs to be interpreted restrictively. Experiments on a patented invention would not affect any exclusive rights unless directly aimed at marketing the patented object or at using it in a company's production process. However, problems may nevertheless arise in the face of the proliferation of patents, many of which are of a low inventive level, if the number of (possibly unfounded) lawsuits against researchers increases in the future. In addition, national differences with respect to the right to investigate using patented inventions might result in research being performed in certain countries depending on the more or less favourable existing legislation or jurisprudence.

Trevor Cook, partner in the Intellectual Property Department of the London-based law firm Bird & Bird explained that effective and balanced experimental exemptions for patented research tools and gene patents can be derived from statutory research exemptions. The statutory defence for "use for experimental purpose relating to the subject matter of the invention" exists in most European countries. Countries like Australia, Canada and Switzerland are contemplating introducing them. The main exception is the United States, where experimental exemptions for patented research tools and gene patents would be possible only through a broad interpretation of the regulatory review defence for medicinal products. Yet the validity of such an interpretation is still ambiguous despite a Supreme Court decision in 2005 (*Merck v Integra*).

Most European case law on statutory exemptions concerns late-stage efficacy and safety trials of medicinal and other products to which a regulatory review defence could also have applied. Although in most of these cases the analysis tends to focus on whether the use of the patented inventions was "experimental", it is also possible to derive clear principles concerning the "subject matter of the invention" that could apply to early-stage research. Following these principles, the defence can be applied to patents on research tools and gene patents if they are the object of the experimentation or, put differently, if the experimentation is undertaken "on" them. In contrast, the defence does not apply if the patented invention is used as a means for experimentation or, in other terms, if the experimentation is undertaken "with" the patented invention. This principle seems economically sound since it eliminates barriers to the improvement of innovations, while ensuring a return on investment to the inventors of research tools. Cook thus recommended that it be preserved as such, and that no initiative be taken to introduce special provisions for "research tools" or "gene patents".

His review of national research exemptions for experimentation led Cook to shed light on two particular issues:

- Patents on genetic sequences raise a specific problem for plant breeders. Although it is technically possible, they may not be allowed to breed a new variety that does not infringe any patent from an initial variety that embodies a patented gene sequence. As this problem stems from an overlap between plant variety rights and patent regimes, it does not fall within the

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scope of experimental use defence and would therefore justify introducing a specific defence as has been done in Germany.

- Directive 2004/27/EC introduced a new statutory defence for regulatory review in Europe. This defence applies to studies and trials undertaken with a view to securing the approval of generic medical products. Cook argued that it could be extended to tests and trials conducted with a view to securing a marketing authorisation for medicinal products other than generics. However it should not be formulated as an instance of the experimental use defence as in the Italian and Spanish transpositions of the Directive, because the scope of the experimental use defence might then be reinterpreted in unexpected ways.

Germany is currently one of the countries where research exemptions are broadest. ***Joseph Straus***, Director of the Max Planck Institute for Intellectual Property, Competition and Tax Law in Munich, presented the recent developments that led to this situation. Since the adoption in the German Patent Act of the research exemption for "acts done for experimental purposes relating to the subject matter of the patented invention" as formulated in the 1975 Community Patent Convention, three changes have taken place in German law:

- The German Federal Supreme Court and the German Federal Constitutional Court clarified the scope of the experimental use exemption respectively in the mid-1990s and in 2000. It now covers all experiments aimed at acquiring knowledge on the subject matter of the patented invention, independent of the purpose for which such knowledge is intended. This includes tests aimed at verifying the novelty or functioning of inventions, at comparing the invention with other products, or at discovering new applications for the invention.
- In 2005, an amendment of the German Patent Act created a special statutory exemption in favour of plant breeders. They can now use patented biological material for the purpose of "breeding, discovery and development of new varieties of plants".
- In 2005, the transposition of the Directive 2004/27/EC led to the adoption of another amendment to the German Patent Act. It extends the experimental exemption to "studies and trials… necessary for obtaining pharmaceutical marketing authorisation". It therefore goes further than the initial scope of the Directive, which was limited to generic drugs.

Straus observed that the German research exemptions, although broad, do not apply to the use of patented research tools for experimentation. This is necessary to preserve a balanced system in which incentives to develop new research tools are maintained. So far no problem of access to research tools has occurred, and whether it happens in the future will depend on how patent holders behave *vis-à-vis* academic researchers. Litigation is unlikely since the use of research tools in laboratories is difficult to detect, and because there is little profit to be expected from suing academic researchers.

So far Australia does not have any statutory research exemption, and the existence of a non-statutory exemption is uncertain. There is moreover no evidence of a problem of access to patented inventions, although this is not a reason to conclude that there is none. ***Andrew Christie***, Professor of Intellectual Property Law at the University of Melbourne Law School, described how Australia has addressed the question of whether to introduce a new research exemption in this context.

Several policy options that would allow the introduction of a research exemption have been identified. The principal ones are:

- Limitation of the scope of patent claims to the disclosed utility.
- Limitation of patent exclusivity by a paid statutory licence for experimental acts.
- Introduction of a specific exemption limited either to specified purposes, or to research "on" the patented invention in contrast to research "with" the invention.

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- Introduction of an exemption whose conditions of applications would be defined in more general or inclusive terms.

The problem of choosing between these options can be addressed by assessing them according to four complementary criteria:

- The research exemption should maximise the disclosure of knowledge while minimising the negative impact on incentives to invest.
- The research exemption should be in harmony with exemptions in other countries, in order to minimise transaction costs for researchers and companies that operate internationally.
- The exemption should balance certainty and flexibility. Expressing a statutory exemption primarily aims at reducing uncertainty, but it should not result in an excessively rigid legal framework.
- The research exemption should be TRIPs-compliant. Article 30 of TRIPs states that exceptions to patent law must be limited and that they should neither unreasonably conflict with normal exploitation of patents nor unreasonably prejudice legitimate interests of patent owners.

The inclusive formulation of the research exemption matches the harmony and balance requirements, and it can be compatible with TRIPs if it is not applied to research tools. It has therefore been adopted for the Australian proposal on research exemption. According to this proposal, acts done for experimental purpose do not infringe a patent "if they [relate] to the subject matter of the invention" (as in Europe) and if they "do not unreasonably conflict with the normal exploitation of a patent" (in order to comply with TRIPs). The proposal states that acts done for experimental purposes relating to the subject matter of the invention are explicitly included in the exemption and include: *i)* determining how the invention works; *ii)* determining the scope of the invention; *iii)* determining the validity of the claims; and *iv)* seeking an improvement to the invention. Yet the inclusive formulation preserves the possibility that other acts fall within the scope of the exemption.

Switzerland does not yet have a statutory research exemption, but it is on the way to introducing one in the context of a broader revision of its patent law. ***Nikolaus Thumm***, Senior Economic Counsellor at the Swiss Federal Institute of Intellectual Property, presented the Swiss proposal for a research exemption developed mainly as a response to a perceived economic imbalance in the patent system in the field of biotechnology. Beyond a certain level of protection, patents indeed create more impediments than incentives for future innovators, according to the 53 Swiss biotechnology entities surveyed in 2002. Respondents to the survey complained that gene patents create dependencies and hinder or block access to technologies. They identified a broad research exemption and the limitation of protection to the concrete disclosure functions of DNA as possible remedies. Regarding genetic tests, respondents considered that patents create abusive monopoly positions and increase the cost of genetic testing. They mentioned clinical use exemptions and non-exclusive licences granted on reasonable terms to clinical laboratories as possible remedies.

Following up on these results, a broad research exemption, to a large extent modelled on that of Germany, has been proposed for the revision of the Swiss patent law. The proposal foresees several general exemptions for:

- Private use and non-commercial purposes.
- Use of the invention for teaching purposes.
- Use of biological material for the purpose of breeding or for developing a plant variety.
- Research and trials in which the invention is the object of research.

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The last of the general exemptions is inspired by the European exemption. It concerns non-commercial and commercial research aimed at gaining new knowledge about the subject matter of the invention. It also applies to use of the patented invention with a view to securing a marketing authorisation for pharmaceutical products. Although there is no statutory exemption for research undertaken with patented research tools, the Swiss proposal differs from other statutory exemptions in that it guarantees access to research tools through legal "non-reach-through" licences. If the parties cannot reach an arrangement, the fees for such licences should be fixed by a court. It is however expected that the intervention of courts will not be necessary in practice and will constitute a negotiation baseline that facilitates market solutions.

The main difficulty of the various approaches considered in OECD countries for implementing legal exemptions for research use of patented inventions lies in the definition of the scope of the exemption. Allowing research "on" a patented invention versus research "with" it seems to be the most appropriate way of defining the research exemption. Nevertheless, specific industries, especially in the biotechnology and pharmaceutical areas, are expressing concerns about accessing patented material for research purposes that may not have been explicitly addressed yet by national patent regimes.

Keynote II: From molecular biology to biotechnology

In her keynote speech, ***Margarita Salas***, Research Professor at the Spanish National Research Council (CSIC), showed, with an example of her own work, how basic research in molecular biology can lead to biotechnological applications.

For the last 40 years, Salas has worked with small bacteria or viruses. Her team identified a certain phage with very interesting size and genetic properties. At the time, almost nothing was known about it, and Spain had to establish a working group that did not include many competencies from abroad to study this phage. By using temperature-sensitive properties, the team constructed a linear genetic map and identified four main genes involved in the replication process. In fact, the replication mechanism of the identified phage showed extremely interesting properties, and made it possible to observe a uni-length DNA. Thanks to its properties, a molecule can be synthesised without some factors usually required with another phage. These properties of processivity, transitivity and nucleus activity led Salas's team to issue a patent for this so-called phi-29 polymerase. A chemical company was interested and bought a licence on the patent before being taken over by Amersham and then GE Healthcare. Additional proteins that allowed the initiation of the replication, were then studied. In an *in vitro* system, they allowed amplification of DNA up to one gram with a high degree of fidelity. In 2001, the team published an amplification key with throughput amplification, allowing the amplification of over 1 million (a thousand times better than the initial key). Amersham Biosciences later provided another amplification key for linear generic DNA. This resulted into two amplification keys: "rolling circle amplification" (from 1 picogram to 2-3 micrograms) and "linear genomic DNA amplification" (from 1 nanogram to 2-3 micrograms).

This initial basic discovery provides a very enlightening example of how basic research from which no practical results are expected can lead to concrete industrial applications, in this case a DNA polymerase with excellent properties that make it an excellent tool for DNA amplification.

Session IV: Facilitating access to inventions for research purposes

Traditionally, the patent system has been a way to bring knowledge to the public. But what happens then? How well is this knowledge brought to the public and what use does the public make of patented inventions? Patent holders need to enforce their rights to profit from their inventions, and researchers need to preserve their freedom to do research in a world full of patent rights. Research exemptions, statutory or not, have been put in place in most industrialised countries to establish a proper balance between these conflicting interests. The four speakers of this last session shed more light on what is working and what is not.

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From the observation made by John Walsh that very few American researchers in biomedical research suffer from significant delays in their work due to blocking patents, ***Rebecca Eisenberg***, Professor of Law at the University of Michigan Law School, stressed that researchers seem unaware of and unconcerned about existing patents. Nevertheless, difficulties were frequently reported in gaining access to "tangible" materials. Certainly, there have been examples of patents being used by their owners to restrict access to their inventions by universities or to negotiate deals, such as the huge transaction costs associated with DuPont's oncomouse licences. At the root of such controversial cases are the costs or practical impossibility for users to reproduce the patented product or tool on their own, which leaves them with no choice but to ask the patent holder for an instance of the subject matter, then to wait and negotiate the terms before doing any research. In such situations, access to patents and tangible materials converge. What matters then is not whether the subject matter is tangible or not, or patented or not, but whether researchers can access at an affordable price the knowledge or technology they need. Therefore, shouldn't the debate focus on facilitating access to tangibles rather than on patents and research exemptions?

For resources that are costly to reproduce, the burden indeed rests on the researcher who seeks access, whereas for patented technologies, researchers seem to act as if there were no patents and the burden is then on the one who wants to stop the infringing activities. In such a case, the patent holder would first need to detect the infringement – an all but easy exercise – and then to enforce her rights, except that the expected returns would not justify the cost of enforcement. This explains why litigation against universities is exceptional, as if patents did not apply to them. However, the fact that enforcement and litigation against researchers is very rare does not mean that it is impossible and will never happen. Actually, academic research may become an attractive target for litigation in certain circumstances, for instance in cases of co-operation with industries. It then depends on the user and the owner, each of whom is exposed to some risk of enforcement from the other. In addition, cases in which faculty members file patents and then sue their (former) home university are becoming increasingly important, especially when professors leave their institution under unhappy circumstances. Finally, universities may some day be targeted by patent speculators – an emerging form of maverick entrepreneur who owns and enforces patented technology against others – as universities are increasingly using the patents of such speculators, especially in biotechnology, and then publish their infringing work in scientific papers.

Consequently, it appears very important to care about research patents and research exemptions, not only because researchers and especially universities might be forced to care about patents sooner or later, but even more so because one could not possibly accept a system whose equilibrium relies on complete disrespect of the patent system, or it would be the end of it.

Jerry Rosenthal, CEO of the Open Invention Network, evoked different potential uses of inventions by universities from different contexts. Traditionally, especially in industry, inventions were made in isolated laboratories on a one-on-one basis. Since the beginning of the 21st century, innovative activities have taken more collaborative forms, particularly in the ICT sector. The outcome of such collaborative research projects is a question of great interest, in terms of ownership, generation of IP rights and actual use by the industry. In particular, there has not been a lot of patenting in such collaborative environments (*e.g.* the development in open source of the Linux operating system). This may betray some inadequacies in the patent system with respect to these new forms of innovation. Innovation protection systems have long been conceived and deployed to allow inventors and inventing institutions to exclude competitors. Selective licensing of certain intellectual assets to competitors nevertheless creates a marketplace that increases the innovator's commercial and financial leverage and enables incremental innovations. But the social value of inventions might actually become even larger as they are included in an industry standard. In this respect, open licensing encourages a broad adoption of new technologies and gives rise to a self-regulated ecosystem of users.

Initially, Internet and Linux inventions were not really protected. This put these open communities in danger of having private companies claim rights to their inventions. This forced open communities to protect themselves against companies that were also trying to protect themselves in the same field. In

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other words, open communities needed to develop patent portfolios for the benefit of their members. Open Invention Network (OIN) was created precisely for the purpose of developing a patent portfolio to benefit and protect the Linux environment. OIN acquires or receives patents useful to the Linux environment and similar technology spaces, which are then licensed at no cost to the entire open community against the formal commitment of the users not to assert their own patents against the Linux community. Should anyone charge the Linux environment with patent infringement, OIN would help the attacked party to defend itself on the grounds of OIN's IP rights. By exploiting the patent system in the interest of this open and collaborative innovation framework, OIN contributes to building the Linux ecosystem.

Open innovation not only needs to defend itself against attacks from the outside but also needs very efficient diffusion of knowledge. This is the main objective of the creative and science commons discussed by ***Brian Fitzgerald***, Head of Queensland University of Technology's School of Law. The sense of the word "open" is that the permission to use, copy, access or reuse a technology is free, whether "to all" or "to a secured (defined contract-base) community".

Creative commons are information communities that manage intellectual property rights and copyrights in particular. They rely on four main protocols:

i) Attribution, so that the anyone has the right to use, modify and distribute the work as long as the original author is given credit.

ii) Non-commercial, meaning that the use, modification and distribution of a work are restricted to non-commercial purposes.

iii) No derivatives, in the sense that other people may not modify the work to create derivative works.

iv) Share alike, which allows the distribution of derivatives (provided they are allowed), but on the condition that these are made available to other people on the same licence terms.

Based on these principles, electronic platforms have been developed which allow authors to publish their work and distribute it at no cost on the basis of the above principles or otherwise for a fee. The principles can be applied to various artistic forms (photos, music, text, etc.) and also to public sector information, such as publicly funded research or government copyright material. The aim of the creative commons is in fact to make copyright more alive, active and accessible and to make sharing possible.

The objective of the science commons is to stimulate and support the creation of areas of access and inquiry using standardised licences and other means. Like the creative commons, the science commons use intellectual property (copyright, patents and data-related rights) as a funding platform and are based on the willingness of researchers to innovate, collaborate and share their results. They include open access publishing (open licences for scientific publications), licensing of scientific materials (a standard, open framework for managing material transfer), access to scientific data (licensing approaches to database-related rights) and the creation of standards and more fluent knowledge communities. Instances of science commons, such as the neurocommons and the MTA project for the transfer of biological materials, have demonstrated their capacity to simplify scientific access by answering key questions: the rights to commercially exploit the material, academic attribution for research generated from the material, ownership of the risk of damages from the transfer and the use of the material and of the IP associated with the material and its derivatives. The same ideas were applied notably to open source biotechnology and its "free-revealing" principle. Its ambition is to maximise the use value of biotechnologies through free revealing (the value of a tool to its user is higher if the user understands how it works) and translating the increased use value into economic value thanks to efficiency gains and cost savings on the user's side and provision of alternative services (training, consulting, etc.) with additional market benefits on the technology

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owner's side. Projects being undertaken by Cambia implementing an open patent licensing model and an interactive patent database called a Patent Lens are interesting examples of what is being done.[6]

In conclusion, open and collaborative (cumulative) innovation on technologically enhanced networks is leading the push for greater access and negotiability within the parameters of copyright, data and patent law. The next generation of scientists who grow up under this new system of access to knowledge is likely to increase the demand for openness.

In the United States, a wide variety of provisions and practices currently rule research use of patented inventions. ***Sean O'Connor***, Associate Director of the Center for Advanced Study and Research on Intellectual Property (CASRIP) at University of Washington School of Law, proposed a practical overview of these *de facto* research use exemptions in the context of public-private partnerships.

An interesting case is Thomson's patents on stem cell research. In the 1990s, the US Public Health Service (PHS) funded a research project at University of Wisconsin which led in 1998 to the first Thomson patent. It was governed by the Bayh-Dole Act and assigned to the Wisconsin Alumni Research Foundation (WARF), which licensed the Thomson patent, and follow on patents, to WiCell Research Institute. WARF also allowed WiCell to administer the approved stem cell lines derived by Thomson, under material transfer agreements (MTAs) governed by state contract law. One year later, WARF further granted an exclusive licence to Geron for R&D in therapeutic and diagnostic fields under a standard technology transfer deal. Thanks to these deals, WARF enjoyed some upfront payments in spite of the very lengthy development phase before any commercialisation could be considered.

As in any federal funding agreement, government rights in the first Thomson patent include a mandatory worldwide non-exclusive licence "to practice or have practiced [the invention] for or on behalf of the United States". Therefore, in 2001, WiCell and PHS executed a Memorandum of Understanding to set out the mechanism by which future PHS extramural researchers would request samples of Thomson stem cell lines, including the agreement that PHS researchers can practise the Thomson patents directly under the PHS funded non-exclusive license. As a result, combined with the Bush Order of 2001, these rights and exclusive licences tightly controlled the stem cell research field. However, Bayh-Dole Act requirements, the fact that the approved stem cell lines were derived without federal funding, and the fact that the Bush Order sharply reduces the amount of research that could have operated within the government licence zone all drove stem cell research towards private and state funding arrangements outside of federal control.

From this particular case a *de facto* exemption for research use of federally funded research results can be drawn. Indeed, if the research leading to a patent was at least partially funded by any federal agency – *i.e.* governed by the Bayh-Dole Act – and if any federal agency at least partially funds new projects so that other researchers now practise the patented invention on behalf of the US government, that latter agency can authorise researchers to practice the patented inventions on behalf of the government under the Bayh-Dole government licence. Thus, in a particular field in which the government has such licenses, federal agencies can establish a protected zone of research in public and private labs that receive federal research funding. Even outside of the Bayh-Dole government license, a second *de facto* exemption exists whereby state agencies such as many state universities enjoy protection under the doctrine of sovereign immunity. Because no one can use the federal courts to sue individual states, except in certain prescribed circumstances, and as patent suits are limited by law to federal courts, patent owners can never sue states for infringement. Thus, universities that are truly state agencies (and not just state funded) can infringe patents and leave patent owners with no recourse. A third *de facto* exemption arises under 28 USC Sec. 1498 which gives government agencies the power to authorise infringement of privately owned patents by either the agency's own workers, or an external contractor working on the government's behalf. The patent owner may not sue either the government

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or the contractor in a regular patent infringement suit. Instead, the owner's only remedy is to seek compensation from the government for the unauthorised use in the federal Court of Claims.

This shows that the United States avoids compulsory licences, particularly those that would allow commercial entities to compete with the patent owner in the marketplace, but has more tolerance for government (funded) (research) use and activities. Universities may increasingly be considered commercial competitors, but a combination of the Bayh-Dole Act license and recent Supreme Court interpretations of the scope of the regulatory review exemption under the Hatch-Waxman Act (35 U.S.C. Sec 271(e)) in the case of *Merck v. Integra* may have the effect of giving continuous coverage from public basic research through private R&D for commercialisation. Ultimately, research exemptions in the United States are currently limited to government use (by or on behalf of a government agency) and regulatory review (clinical testing).

As these different speeches show, in many industries and many countries, nature has filled the vacuum with *de facto* exemptions in spite or for lack of appropriate regulations. In particular, it would appear that researchers tend to advance blindly and pay no attention to patents, as if they crossed the street without heeding the appropriate signals. One may wonder why inventors incur the costs to file and obtain patents if they do not enforce their rights. It presumably is because these applicants intend to enforce their patents against companies, and in fact many of them have a tacit policy not to sue universities. As a matter of fact, the difficulty of detecting infringement at the research stage makes pure research patents very difficult to enforce and be used to make money. Therefore, patent holders usually try to draft their claims so as to protect final products and pay little attention to illicit research use, although this is surely no reason to encourage such behaviour. As ***Alison Brimelow***, President-elect of the EPO observed, not too many people are killed jaywalking, but is this the optimal way to cross the streets? Policy makers should bear this in mind and take action.

Roundtable discussion

The Conference ended with a forward-looking roundtable discussion chaired by ***Nobuo Tanaka***, Director for Science, Technology and Industry at OECD. ***Sadao Nagaoka***, Director and Professor at the Institute of Innovation and Research of Hitotsubashi University, ***John Raubitschek***, Patent Counsel for the US Department of Commerce, ***Elizabeth Thouret-Lemaître***, Vice President and Head of Patent Operations of the Sanofi-Aventis pharmaceutical Group, and ***Alain Gallochat***, advisor at the French Ministry of Research, participated in the roundtable and answered questions from the audience.

Nobuo Tanaka observed that following up on the previous presentations, the first question to be addressed was about the reality and nature of the issues raised by the research use of patented inventions. The issues seem to be limited to specific fields such as biotechnology, pharmaceuticals and agriculture. They also appear to be more acute in the United States than in the rest of the world, and to concern industry rather than academia. Sadao Nagaoka argued that there is a real problem since the emergence of new businesses is jeopardised when research processes require access to numerous patented inputs. He also noted that the licensing behaviour of universities and government-funded research institutions could generate inefficiencies in the future by raising the cost of access to technology for industry. Elisabeth Thouret-Lemaître stressed that there is no access issue opposing the biotechnology and pharmaceutical industries since both patent research tools. She argued that research tools must remain patentable to preserve a balance between incentives and disclosure. She explained that companies seldom sue infringers, because they do not know early enough whether their patent applications will result in actual patent grants, and because the cost of litigation is high. In this context she confirmed that the problems of access principally concern tangible inventions, and for other reasons than patents.

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Nobuo Tanaka recalled that the problems relating to research use of patented inventions could be addressed in different ways, from statutory exemptions for experimental use to behavioural solutions such as good licensing practices or mere ignorance of patents by researchers. Yet the long-term efficiency of the latter solution seems dubious. Researchers' lack of knowledge of the patent system and the research exemptions in vigour is a source of uncertainty that could undermine the functioning of the patent system and threaten innovation in the long run. Therefore efforts towards raising the awareness and consciousness of researchers are necessary.

The effectiveness of research exemptions was also discussed. John Raubitschek noted that unexpected interpretations of statutory exemptions by the courts may generate additional uncertainty. In this respect, one can understand the ambiguity maintained by the US Supreme Court as a way to preserve a *de facto* balance between protection and access, until new problems arise that would justify the intervention of policy makers. In contrast Alain Gallochat explained that recent French Court decisions and a draft law implementing the EU Directive 2004-27 have clarified the scope of the research exemption in France. He also argued that compulsory licences should be used as a complement to the research exemption, which the TRIPs agreement allows. Elisabeth Thouret-Lemaître expressed her scepticism *vis-à-vis* any statutory measure aimed at facilitating the research use of patented inventions. Like John Raubitschek, she argued that making sure that only strong and valid patents are granted is the best way to facilitate access to research tools and inventions.

The participants reached a consensus on the need to improve international harmonisation, but also on the difficulty of achieving this goal. Elisabeth Thouret-Lemaître explained that the variety of research exemptions in Europe is a factor of uncertainty for the industry. She observed that the uncertainty has increased after the divergent implementations of the new EU Directive (Directive 2004/27/EC). Alain Gallochat also recalled that discussions at WIPO (the World Intellectual Property Organisation) on worldwide harmonisation through a Substantive Patent Law Treaty have not yet made it possible to reach agreement on international harmonisation of a number of issues relevant to the grant of patents, such as the grace period.

Nobuo Tanaka finally asked the participants whether the OECD should undertake new initiatives relating to research use of patented inventions. The participants' main recommendations concern the production of guidelines and the improvement of information about the different national systems and their respective economic efficiency. Elisabeth Thouret-Lemaître insisted that non-binding guidelines would be more appropriate than new laws. According to Sadao Nagaoka, such guidelines should principally concern the efficient licensing of research tools and perhaps science commons mechanisms. Sadao Nagaoka and Alain Gallochat agreed that they should primarily target universities and publicly funded research. John Raubitschek noticed that they would anyway have little effect on the behaviour of companies.

OECD could also produce more information on national patent systems in order to give advice to governments. It could collect empirical data on the effect of the different regulations and systems in place and identify working solutions. Alain Gallochat noted that compulsory licensing issues should be taken into consideration on this occasion and argued that both guidelines and new empirical data would provide a good framework for future negotiations. Elisabeth Thouret-Lemaître similarly recommended that the OECD organise and foster harmonisation by clarifying definitions as a first step.

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Agenda

Conference on Research Use of Patented Inventions
CSIC Headquarters, Madrid (Spain)
18-19 May 2006

Opening session
- José Manuel FERNÁNDEZ DE LABASTIDA, Vice-president for Scientific and Technical Research, Spanish Research Council (CSIC)
- Mª Teresa MOGÍN, Director, Spanish Patent Office (OEPM)
- Nobuo TANAKA, Director for Science, Technology and Industry, OECD
- Bruno van POTTELSBERGHE, Chief Economist, European Patent Office (EPO)

Keynote Speech I
- John BARTON, Professor of Law, Emeritus, Stanford Law School

Session 1: **How does patenting affect access to inventions for research purposes?**
Chair and discussant: Stephen MERRILL, Executive Director, Science, Technology, and Economic Policy, The National Academies

- John WALSH, Associate Professor of Sociology, University of Illinois at Chicago
- Jana ASHER, Senior Programme Associate, Project on Science and Intellectual Property in the Public Interest, American Association for the Advancement of Science (AAAS)
- Sadao NAGAOKA, Professor of Economics, Institute of Innovation Research, Hitotsubashi University

Session 2: **Perspectives from the private and public research sectors**
Chair and discussant: Richard JOHNSON, Arnold and Porter, Vice-Chairman, BIAC Technology Committee

- José Luis de MIGUEL, Director, Technology Transfer Office, Spanish Research Council (CSIC)
- Peter M. KLETT, IP Counsel, IBM Research GmbH, Zurich Research Laboratory
- Miguel Angel FLORES, Research Scientist, RepsolYPF
- Neil THOMAS, Intellectual Property Director, Genetrix, Madrid
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Session 3: **How effective are research exemptions in patent law?**
Chair and discussant: Alberto BERCOVITZ, Universidad Nacional de Educación a Distancia (UNED) and Estudio Jurídico Alberto Bercovitz

- Trevor COOK, Partner, Bird & Bird, United Kingdom
- Joseph STRAUS, Director, Max Planck Institute for Intellectual Property, Competition and Tax Law
- Andrew CHRISTIE, Director, Intellectual Property Research Institute of Australia (IPRIA)
- Nikolaus THUMM, Senior Economic Counsellor, Swiss Federal Institute of Intellectual Property

Keynote Speech II
- Margarita SALAS, Research Professor, Spanish Research Council (CSIC)

Session 4: **Facilitating access to inventions for research purposes**
Chair and discussant: Alison BRIMELOW, President Elect European Patent Office (EPO).

- Rebecca EISENBERG, Professor of Law, University of Michigan Law School
- Jerry ROSENTHAL, CEO, Open Invention Network
- Brian FITZGERALD, Head, School of Law, Queensland University of Technology
- Sean O'CONNOR, Associate Director, Center for Advanced Study and Research on Intellectual Property (CASRIP)

Roundtable: **Looking to the future**
Chair: Nobuo TANAKA, Director for Science, Technology and Industry, OECD

- Sadao NAGAOKA, Professor of Economics, Institute of Innovation Research, Hitotsubashi University
- John H. RAUBITSCHEK, Patent Counsel, Office of the Chief Counsel for Technology, US Department of Commerce
- Elisabeth THOURET-LEMAITRE, Head of IP Department, Sanofi-Aventis
- Alain GALLOCHAT, IP Counsel, French Ministry of Research
- José Luis de MIGUEL, Director, Technology Transfer Office, Spanish Research Council (CSIC)

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Biographies of Speakers and Chairs

José M. Fernández de Labastida
José M. Fernández de Labastida holds a Ph.D. in Physics from the State University of New York at Stony Brook (United States). Since 2004, he is Vice-president of the Spanish National Research Council (CSIC). From 2001 to 2004, he was Deputy Director General for Research Programmes in the Ministry of Science and Technology of Spain. He has been Professor of Theoretical Physics, University de Santiago de Compostela, since 1991 (on leave), where he has held various management positions, such as Director of the Particle Physics Department (1991-94); Dean of the Faculty of Physics (1994-97) and Director of the Graduate School (1999-2001). His research fields are Quantum Field Theory, String Theory, Knot Theory and Topological Quantum Field Theory; he has authored and co-authored more than 80 scientific publications, led five national and European research projects and advised five Ph. D. theses. He has also been very active in several scientific societies; he has been President of the Theoretical Physics Group of the Royal Spanish Society of Physics (1998-2001), Vice-president of the Royal Spanish Society of Physics (2001-05) and Member of the Council of the European Physical Society (2000-04).

Maria Teresa Mogín Barquín
Maria Teresa Mogín Barquín is civil servant in the Superior Body of Civil Administrators of the State. She has a degree in Economics from the Autónoma University of Madrid. She has held several jobs in the Commerce Ministry as well as in the INFE (nowadays ICEX, Institute for Foreign Commerce). In 1988 she was nominated as General Director in the *Función Pública* of the Spanish Administration, Ministry of Public Administrations (body in charge of all issues relating to the development of civil servant careers). She served as General Director (1993-96) for Social Affairs in the Ministry of Labour and Social Affairs, General Director (1996-Oct. 2002) of Children and Family Social Affaires in the Ministry of Labour and Social Affairs, Vocal Adviser (2002-03) in the Ministry of Economy and Treasury and in the AECI (body in charge of Spanish co-operation with Latin America) in the Ministry of Foreign Affairs and General Director (2004 onwards) in the OEPM (Spanish Patent and Trademark Office) in the Ministry of Industry, Tourism and Commerce.

Nobuo Tanaka
Nobuo Tanaka has been Director for Science, Technology and Industry at the Paris-based Organisation for Economic Co-operation and Development (OECD) since 16 August 2004, with responsibility for a broad range of issues including science policy, information and communication technologies, economic and statistical analyses, biosciences, and sectoral issues. Mr. Tanaka heads the internal OECD Steering Group of the Centre for Entrepreneurship. Mr. Tanaka has a degree in Economics from the University of Tokyo and an MBA from Case Western Reserve University, Cleveland, Ohio. In 1973, Mr. Tanaka began his career with the Ministry of Economy, Trade and Industry (METI) (formerly known as the Ministry of International Trade and Industry, MITI), in Tokyo. He has extensive national government and international experience within METI, the Embassy of Japan in Washington, DC (twice) and the OECD. Within METI, he has held a broad range of high-level posts, Deputy-Director of the General Affairs Division, Machinery and Information Industries Bureau, Personnel Division, Director of International Nuclear Energy Affairs of the Natural Resources and Energy Agency. He first joined the OECD in 1989 as Deputy Director of the Directorate for Science, Technology and Industry, and was promoted to Director in 1992. In 1995, he returned to METI as Director of the Industrial Finance Division. He has since worked in METI in high-ranking positions, the most recent being Director-General, Multilateral Trade System Department, Trade Policy Bureau. Mr. Tanaka, a Japanese national, is married with two children.

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Bruno van Pottelsberghe
Bruno van Pottelsberghe is Chief Economist of the European Patent Office (EPO) since December 2005. His task is to inform EPO policy on economic matters and to conduct studies and projects on economic aspects of patenting in Europe. He has been professor at Brussels University (ULB) since September 1999. As holder of the Solvay S.A. Chair of Innovation he teaches courses related to the economics and management of innovation and intellectual property. Until November 2005 he was Vice-president of the Solvay Business School, Director of its MBA programmes and of its International Exchange Programme. He has published several articles on S&T policy, the internationalisation of R&D activities, innovation competencies, entrepreneurship and intellectual property. In the past he worked for two years at the OECD (Directorate for Science, Technology and Industry), and spent several months as visiting researcher at the Columbia Business School (New York City) and at the Research Institute of the METI (Tokyo) and as Visiting Professor at the Institute of Innovation Research of Hitotsubashi University (Tokyo) and at the University of Stellenbosh Business School (Cape Town).

John H. Barton
John H. Barton is emeritus professor of Law at Stanford University, where he long taught on international and high technology issues. He has published extensively on biotechnology, technology transfer to developing nations, patent-antitrust tensions and patent law. He chaired the UK Commission on Intellectual Property Rights and Developing Countries (2001-02), and was a member of two working groups of the Commission on Macroeconomics and Health. He was also a member of the National Research Council committee on patent law which produced the 2003 report, *Patents in the Knowledge-Based Economy*, and of the Nuffield Council on Bioethics committee that produced the 2002 report, *The Ethics of Patenting DNA*. He has spoken previously at OECD meetings on patent-antitrust issues and on patents and developing nations, and is cofiler of a brief in the Metabolite case currently before the US Supreme Court, which deals with the scope of patentable subject matter. Prof. Barton went to Stanford to teach in 1969; he has also been a visiting scholar at the National Institutes of Health Department of Clinical Bioethics (2004-05), and a visiting professor at several prominent US universities. He is a fellow of the American Association for the Advancement of Science, and has been a member of the roster of trade experts for NAFTA dispute settlement. He is a member of the District of Columbia and Supreme Court Bars. His educational background includes a J.D. from Stanford University and a B.S. degree in philosophy and physics from Marquette.

Stephen Merrill
Stephen Merrill has been Executive Director of the National Academies' Board on Science, Technology, and Economic Policy (STEP) since its formation in 1991. With the sponsorship of numerous federal government agencies, foundations, multinational corporations and international institutions, the STEP programme has become an important discussion forum and authoritative voice on technical standards, trade, taxation, human resources and statistical as well as research and development policies. He has directed or co-directed several STEP projects and publications, including *A Patent System for the 21st Century* (2004) and *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property, Innovation, and Public Health* (2005). For his work on the former project he was named one of the 50 most influential people worldwide in the intellectual property field by the journal *Managing Intellectual Property* and earned the Academies' 2005 Distinguished Service Award. Previously, he was a Fellow in International Business at the Center for Strategic and International Studies (CSIS), where he specialised in technology trade issues. From 1975 to 1981 he served on various congressional staffs. He holds degrees in political science from Columbia University (B.A.), Oxford University (M. Phil.) and Yale University (M.A. and Ph.D.).

John P. Walsh
John P. Walsh is an Associate Professor of Sociology at the University of Illinois at Chicago. In the autumn, he will be joining the School of Public Policy at Georgia Institute of Technology. His research focuses on the relations among work, organisations, institutional context and innovation. Recent studies include the impact of patents on research inputs for biomedical research, the role of patents and other appropriability mechanisms for firm R&D in the United States and Japan, and

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university-industry linkages in Japan and the United States. His work has been published in *Science*, *Research Policy*, *Management Science* and *Social Studies of Science*. He received his Ph.D. in Sociology from Northwestern University. He has held visiting positions at Carnegie Mellon University, University of Tokyo, Hitotsubashi University, and Japan's National Institute of Science and Technology Policy.

Jana Asher
Jana Asher is a Senior Program Associate for the Science and Human Rights Program (SHR) and the Project on Science and Intellectual Property in the Public Interest (SIPPI) of the American Association for the Advancement of Science. Her past work has included the design and implementation of a national survey on human rights abuses in Sierra Leone, technical advice towards a national survey of human rights abuses in East Timor, design of the stratification and modelling for an analysis of data for Peru's Truth and Reconciliation Commission (CVR), co-authorship of the statistical appendix for the final report of the Sierra Leone Truth and Reconciliation Commission, and development of the statistical methods for estimating the death counts outlined in a report to the International Criminal Tribunal for the Former Yugoslavia. She also has served as an expert advisor for the Metagora project of the OECD. More recently, she co-authored the AAAS report, *The Effects of Patenting on the AAAS Scientific Community*, and is currently working on an international survey of scientists regarding their experiences with intellectual property protections.

Sadao Nagaoka
Sadao Nagaoka, a national of Japan, is the director and a professor at the Institute of Innovation Research of Hitotsubashi University (www.iir.hit-u.ac.jp/index_e.html). He has both an M.S. (Management) and a Ph.D. (Economics) from the Massachusetts Institute of Technology. He has work experiences in the Ministry of International Trade and Industry of Japan, the World Bank and the OECD. His current research interests cover the institution and policy of intellectual property, determinants of R&D productivity and profitability, compensation for innovators, and innovation policy. He has participated in a number of government committees and study groups on intellectual property rights, standards and competition policy.

Richard Johnson
Richard Johnson is a Senior Partner in the Washington, DC, office of Arnold & Porter LLP. He specialises in legal, regulatory and public policy issues related to fundamental research, technology innovation and strategic relationships for corporations, research universities and public research organisations – especially with respect to biotechnology and life sciences, nanotechnology and other emerging technologies. He formerly served as General Counsel for International Trade at the US Commerce Department, where he was responsible for trade policy and international technology issues. In addition to receiving a J.D. from the Yale Law School where he was Editor of the *Yale Law Journal*, he received an M.S. degree from the Massachusetts Institute of Technology where he was a National Science Foundation National Fellow. He received his A.B with Highest Honours from Brown University. He is a member of the MIT Corporation's Visiting Committee; several university and think tank advisory boards; the National Cancer Institute/NIH leadership roundtable; and participates on several National Academy of Science advisory panels. In OECD/BIAC matters, he serves as: Chairman of the Biotechnology Committee; Vice- Chairman of the OECD Technology and Innovation Committee; and Chairman of the BIAC Intellectual Property and Innovation Task Force. He is the former Co-Chairman of the American Society of International Law annual meeting and a member of its Executive Board.

Jose Luis de Miguel Antón
Jose Luis de Miguel Antón holds a Ph.D. in Physics from the Complutense University of Madrid. Since May 2005, he is director of the Technology Transfer Office of the Spanish National Research Council (CSIC). He previously held several managing positions at the Telecommunications Market Commission (the Spanish telecom and audiovisual regulator), which he joined at its creation in 1996. As Director of External and International Relations, then Director of Markets and then Director of Planning, Co-ordination and Control, he participated actively in initial design and development of the

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regulatory authority. Prior to that, he worked in Telefónica I+D (the R&D company of the Spanish incumbent telecom operator) for seven years. During that period, he acted as Project Leader in the Optoelectronics Division, Division Head of External Technical Relations, representative of Telefonica on the R&D Board of the Unisource Consortium, and Division Head of International Development. His received his Ph.D. at the Institute of Materials Physics of the CSIC and the Max Planck Institute for Solid State Physics. For three years, he worked as a postdoctoral fellow at Bellcore (the R&D company of the US local operators) and at AT&T Bell Labs in the United States. Later, he joined the National Center for Microelectronics of the CSIC as permanent staff.

Peter M. Klett
Peter M. Klett holds a Master's degree in electrotechnical engineering and information technology from the Technical University of Munich, Germany. After working for several years for the IP department of Robert Bosch GmbH in Stuttgart, Germany, he qualified as a European Patent Attorney and joined the Intellectual Property Law Department of the IBM Research Laboratory in Rüschlikon, Switzerland in 1995. In 1999 he graduated as Master of European and International Business Law (M.B.L.-HSG) from the University of St. Gallen, Switzerland. He then spent a year on an international assignment at the IBM Research Laboratory in Yorktown Heights, New York and at the IBM Intellectual Property & Licensing Headquarters in Armonk, New York. On his return to the Zurich Research Lab he became manager of its IP law department and founded the IBM European Center of Competence for EU-government funded projects. Since the restructuring of the European IP function in 2005 he has responsibility as IP Counsel for all of IBM Research's IP matters in Europe, Middle East, and Africa.

Miguel A. Flores
Miguel A. Flores obtained his B.A. degree in 1992 from the Universidad Autónoma de Barcelona and his Ph.D. degree in 1997 from the same University, although his research work in the area of homogeneous catalysis was done at the Materials Science Institute of Barcelona (ICMAB, CSIC) in the group of Prof. Teixidor. He spent one year as a RepsolYPF postdoctoral fellow at the Massachusetts Institute of Technology with Prof. Schrock, Nobel laureate in chemistry in 2005, where he worked in the area of olefin polymerization catalysis. He has worked as a research scientist in two companies: BASF AG (Ludwigshafen, Germany), where he worked on a project to develop homogeneous catalysts for the hydrocyanation of butadiene, and RepsolYPF, where he has spent most of his professional career, working on different projects concerning the development of metallocene catalysts for production of polyolefins.

Neil Thomas
Neil Thomas has a Bachelor of Science degree in Biological Sciences from the University of Birmingham, United Kingdom and a Ph.D. in Biochemistry and Molecular Biology from the University of Durham, United Kingdom. He joined Genetrix in February 2006 from Bioxell S.p.A. in Milan, Italy, where he was Director of Intellectual Property and Technology from 2002. Prior to this, he worked for over six years in London-based European patent attorney firms, advising academic and industrial clients in the biotechnology and pharmaceutical sectors. He has particular experience in the creation, management and strategic exploitation of patent portfolios in biotechnology SME environments and is a member of the Licensing Executives Society.

Alberto Bercovitz
Doctor. Law Faculty of the University of Madrid (1966). Commercial Law Professor (1970-78, University of Salamanca; 1978- State University for Distance Learning). Permanent Member of the General Codification Commission (Ministry of Justice) (1970-). Former President of the International Association for the Promotion, Teaching and Research in Intellectual Property (ATRIP) (1989-91). Former President of the Spanish Branches of the International Association for the Protection of Industrial Property (AIPPI) (1992-96) and of the International Literary and Artistic Association (ALAI) (1991-95). Member of Honour of the Spanish Groups of AIPPI and ALAI. Former President of the Spanish Association for Competition Law (Spanish Group of the League of Competition Law) (2001-05). Doctor *honoris causa* of the University of Lyon III "Jean Moulin" (France). Co-ordinator

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of the WIPO Academy for Latin America, held in Geneva in 1993 and 1994. Member of the Scientific Advisory Board of the Munich Intellectual Property Law Centre (appointed March 2004). Author of numerous publications in the fields of commercial law, industrial property, intellectual property and competition law. Practising attorney.

Trevor Cook
Trevor Cook joined Bird & Bird in 1974 with a degree in chemistry from Southampton University. He was admitted as a solicitor in 1977, joining the Intellectual Property Department of Bird & Bird, where he has been a partner since 1981. He is Treasurer of the UK Group of the AIPPI (The International Association for the Protection of Industrial Property), and a member of the Council of the Intellectual Property Institute, for which he has recently completed the study "A European Perspective on the Extent to Which Experimental Use, and Certain Other Defences as to Patent Infringement, Apply to Differing Types of Research"/ He authored *The Protection of Regulatory Data in the Pharmaceutical and Other Sectors* (Sweet & Maxwell, 2000) and *A User's Guide to Patents* (Butterworths. 2002; Tottel, 2006) and is working on a new edition of *Pharmaceuticals, Biotechnology and the Law* (Macmillan, 1991; LexisNexis Butterworths, 2006). He is one the general editors of *The Modern Law of Patents* (LexisNexis Butterworths, 2005). He has been involved in many significant patent cases in the English courts, in the last couple of years acting for the successful parties to Kirin-Amgen Inc v Transkaryotic Therapies Inc (2004, House of Lords) (erythropoietin) and Ranbaxy v Warner Lambert (2005, Patents Court) (atorvastatin).

Joseph Straus
Joseph Straus, Dr. jur., Professor of Law (University of Munich and University of Ljubljana); Dr. jur. *honoris causa* (h.c.), University of Ljubljana; Dr. jur. h.c., University of Kragujevac; Director MPI (www.ip.mpg.de), Munich; Chair Managing Board, MIPLC (www.miplc.de); Marshall B. Coyne Visiting Prof., GWU Law School (www.law.gwu.edu), Washington DC; Hon. Prof., Tongji University of Shanghai and Hon. Prof. Huazhong University of Wuhan; Distinguished Visiting Professor, Faculty of Law, University of Toronto (2005); Visiting Professor, Cornell University Law School, Ithaca, N.Y. (1989-1998). Dipl. in Law 1962 University of Ljubljana; Dr. jur. 1968, University of Munich; Habilitation (1986) University of Ljubljana. Private practice 1966-74, since then Max Planck Institute. More than 250 publications in the field of intellectual property law. Consultant to OECD, WIPO, UNCTAD, UNIDO, ECComm., World Bank, German Parliament and Government, European Parliament, the European Patent Organisation, the Swiss Government and the Swiss Federal Institute for Intellectual Property. Chair IP Rights Committee, HUGO; Chair Programme Committee AIPPI, former President ATRIP. Member Academia Europaea. Corresponding member, Slovenian Academy of Sciences and Arts. Science Award 2000 of the Foundation for German Science, Awarded Commander's Cross (*Grosses Verdienstkreuz*) of the Order of Merit of the Federal Republic of Germany (2005).

Andrew Christie
Andrew Christie is the Davies Collison Cave Professor of Intellectual Property at the University of Melbourne Law School. He is also the founding Director of the Intellectual Property Research Institute of Australia (IPRIA), a national centre for interdisciplinary research on the economics, law and management of intellectual property, based at the University of Melbourne. He holds a Bachelor's degrees in Science and in Law from the University of Melbourne, an LLM from the University of London, and a PhD from the University of Cambridge. He is admitted to legal practice in Australia and the United Kingdom, and worked for many years in the intellectual property departments of law firms in Melbourne and London. He is an active adviser to governments and intergovernmental organisations on intellectual property law and policy, and is a current member of the Australian government's Advisory Council on Intellectual Property. In July 2005 he was identified by the international magazine *Managing IP* as one of the world's 50 most influential people in intellectual property.

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Nikolaus Thumm
Nikolaus Thumm works as Senior Economic Counsellor at the Swiss Federal Institute of Intellectual Property. He is chairman of the United Nations Advisory Group on the Protection and Implementation of Intellectual Property Rights for Investment and acts as country representative in different expert groups with the European Commission, the OECD, and the World Intellectual Property Organisation (WIPO). A German industrial engineer by training, he holds a Ph.D. in economics and has published extensively in international journals on innovation systems and IPR protection.

Margarita Salas
Research Professor at the Spanish National Research Council (CSIC), Margarita Salas holds a doctorate in chemistry from the Complutense University in Madrid and completed further studies in the Biochemistry Department at New York University. During her career, Professor Salas has held several academic and research positions: Professor of Molecular Genetics at the Complutense University in Madrid (1967); Research Professor at CSIC (1974); Director of the Institute of Molecular Biology, CSIC (1988-91); Director of the Severo Ochoa Centre of Molecular Biology, CSIC and UAM (1992-93). Since 1993, she has been a member of the governing body of CSIC. She is the author and co-author of more than 300 works on molecular biology and has been awarded several prizes: Severo Ochoa Prize for Biomedical Research (1986); Rey Jaime I Prize for Scientific Research (1994); Mexico Prize for Science and Technology (1998); L'Oréal-UNESCO Prize for "Women in Science" (1999); Santiago Ramón y Cajal National Prize for Scientific Research (1999); Science and Research International Prize of the Cristóbal Gabarrón Foundation (2004). She has also been nominated Doctor *honoris causa* at Oviedo University (1996), Polytechnic University of Madrid (2000); Extremadura University (2002); Murcia University (2003) and Cádiz University (2004) and is member of the European Biology Molecular Organization (1980); the Royal Academy of Exact, Physical and Natural Sciences (1988); founding member of the Academia Europaea (1988); advisory committee of Juan March Foundation (1992-94); President of Instituto de España (1995-2003); Spanish Royal Academy (2003) and the American Academy of Arts and Sciences (2005).

Alison Brimelow
Alison Brimelow joined the Department of Trade and Industry in 1976. She worked in a variety of policy jobs, including the private office. She joined the Patent Office in 1991, where she became Head of the Trade Marks Registry. In 1997 she returned to DTI to work on European and international competition policy. She was appointed Chief Executive and Comptroller General of the Patent Office in March 1999. In 2003 she was elected President of the European Patent Office jointly with Professor Alain Pompidou of France. Her term of office begins on 1 July 2007. She resigned from the UK Civil Service on 31 December 2003. In November 2004 she was appointed Chair of the National Weights and Measures Laboratory's Steering Board. In February 2005 she was elected Associate Fellow of Templeton College, Oxford.

Rebecca Eisenberg
Rebecca S. Eisenberg is a graduate of Stanford University and Boalt Hall School of Law at the University of California, Berkeley, where she was articles editor of the *California Law Review*. Following law school she served as law clerk for Chief Judge Robert F. Peckham on the United States District Court for the Northern District of California and then practiced law as a litigator in San Francisco. She joined the University of Michigan Law School faculty in 1984. Professor Eisenberg regularly teaches courses in patent law, trademark law and FDA law, and runs workshops on intellectual property and student scholarship. She has taught courses on torts, legal regulation of science, and legal issues in biopharmaceutical research. She has written and lectured extensively on the role of intellectual property in biopharmaceutical research, publishing in scientific journals as well as law reviews. She spent the 1999-2000 academic year as a visiting professor of law, science and technology at Stanford Law School. She has received grants from the program on Ethical, Legal, and Social Implications of the Human Genome Project from the US Department of Energy Office of Biological and Environmental Research for her work on private appropriation and public dissemination of DNA sequence information. Professor Eisenberg has played an active role in public policy debates concerning the role of intellectual property in biopharmaceutical research. She is a

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member of the Advisory Committee to the Director of the National Institutes of Health, the Panel on Science, Technology and Law of the National Academies, and the Board of Directors of the Stem Cell Genomics and Therapeutics Network in Canada. Professor Eisenberg is the Robert and Barbara Luciano Professor of Law.

Jerry Rosenthal
Mr. Rosenthal is CEO of Open Invention Network, a company formed in 2005 to further innovation by acquiring patents on a royalty-free basis in order to protect and benefit the Linux environment. Mr. Rosenthal has more than 40 years of engineering and technology intellectual property management experience. Prior to becoming CEO of Open Invention Network, Mr. Rosenthal was the vice president of IBM's intellectual property and licensing business. Previously, he held senior and executive-level management positions around the world, supporting IBM's intellectual property licensing operations. Mr. Rosenthal began his 37-year career with IBM as a technical sales and marketing executive working with the medical systems engineering groups. Prior to IBM, he held engineering positions with the National Institutes of Health and United Aircraft. At the latter, he was part of the biomedical telemetry team that designed the space suites for the astronauts in the Apollo Space Program. He holds B.S. and M.S. degrees in electrical engineering from New York University. He also holds a J.D. degree from Pace University and is a member of the New York State Bar. Mr. Rosenthal is a frequent speaker at major IP conferences around the world. Additionally, he is a member of the Licensing Executive Society.

Brian Fitzgerald
Brian Fitzgerald is a well-known intellectual property and technology lawyer. He has published articles on intellectual property law in Australia, the United States, Europe, Nepal, India, Canada and Japan and his latest (co-authored) books are *Cyberlaw: Cases and Materials on the Internet, Digital Intellectual Property and E Commerce* (2002); *Jurisdiction and the Internet* (2004); *Intellectual Property in Principle* (2004). Over the past five years he has delivered seminars on intellectual property law in Australia, Canada, New Zealand, the United States, Nepal, India, Japan, Malaysia, Singapore, Norway and the Netherlands. In October 1999 he delivered the Seventh Annual Tenzer Lecture, "Software as Discourse: The Power of Intellectual Property in Digital Architecture", at Cardozo Law School in New York. Through the first half of 2001, he was a Visiting Professor at Santa Clara University Law School in Silicon Valley in the United States. In January 2003 he delivered lectures in India and Nepal and in February 2003 was invited as part of a distinguished panel of three to debate the theoretical underpinning of intellectual property law at University of Western Ontario in London, Canada. In 2005 he presented talks in Germany, India and China and was a Visiting Professor in the Oxford University Internet Institute's Summer Doctoral Programme in Beijing in July. He is also a Chief Investigator and Programme Leader for Law in the newly awarded ARC Centre of Excellence on Creative Industries and Innovation. He is also Project Leader for the DEST-funded Open Access to Knowledge (OAK) Law Project, looking at legal protocols for open access to the Australian research sector. His current projects include work on intellectual property issues across the areas of copyright and the creative industries in China, open content licensing and the creative commons, free and open source software, research use of patents, science commons, e-research, licensing of digital entertainment and anti-circumvention law. He is a Project Leader for Creative Commons in Australia. From 1998-2002 he was Head of the School of Law and Justice at Southern Cross University in New South Wales, Australia, and in January 2002 was appointed Head of the School of Law at QUT in Brisbane, Australia.

Sean O'Connor
Sean O'Connor is an Assistant Professor at the University of Washington School of Law in Seattle, where he is also the Associate Director for both the Center for Advanced Studies and Research on Intellectual Property (CASRIP) and the graduate IP Law and Policy Program. He teaches courses in intellectual property, biotechnology, business and securities law. His research focuses on the legal issues involved in commercialising science and technology, as well as the social and cultural context of scientific and technological innovation. Before entering academia, he was in private practice with major international law firms specialising in technology transactions, licensing, corporate and

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securities law and representation of emerging and established biotechnology and information technology companies. He holds a J.D. from Stanford Law School and an M.A. in philosophy, concentrating in the history and philosophy of science, from Arizona State University. He is admitted to practice in New York and Massachusetts.

John H. Raubitschek
Since 1990, John Raubitschek has been Patent Counsel for the US Department of Commerce. In this position, he gives advice on all intellectual property matters, obtains and licenses patents and evaluates claims of patent, copyright and trademark infringement involving the Department. He also negotiates intellectual property rights provisions in international science and technology agreements. He is a recognised expert on the Bayh- Dole Act and has lectured and published on that law. He previously served as an Associate Solicitor and Patent Examiner in the US Patent & Trademark Office and as patent counsel for a number of other agencies, which he represented before various US courts and administrative tribunals. He received a bachelor of art's degree from Princeton University and a law degree from Georgetown University.

Elisabeth Thouret-Lemaitre
Elisabeth Thouret-Lemaitre is Vice President and Head of Patent Operations of the Sanofi-Aventis pharmaceutical group. She was Patent Director of Sanofi-Synthelabo (1999-2004) and Synthelabo (1975-99); Patent *Ingénieur* of Cabinet Armengaud Jeune (1968-75). She is member of the Intellectual Property Policy Committee of EFPIA (European Federation of Pharmaceutical Industry Associations) and French Representative of MEDEF at UNICE (Patents Group). She is Past President of ASPI (French Association of Industry Patent Attorneys); Past President of EPI (European Patent Institute); and Past President of LES-France (1998-2001).

Alain Gallochat
Prior to his appointment as adviser at the Ministry of Research, Alain Gallochat spent 13 years at the Institut Pasteur, Paris, as General Counsel. He was previously Industrial Property Manager in a French pharmaceutical company and a patent agent in a private practice. His other responsibilities include Associate Professor at the University of Paris I Sorbonne; European patent attorney before the European Patent Office (Munich); European Trademark Attorney before the Office for Harmonization in the Internal Market (Alicante); Past President of the Union of European Practitioners in Intellectual Property; lecturer at the Centre Paul-Roubier (Lyon) and at the French Patent Office (INPI) in Paris; NATO expert for Intellectual Property matters; and European Commission expert for Intellectual Property matters. He co-authored *La brevetabilité des innovations biotechnologiques appliquées à l'Homme* with Marie-Catherine Chemtob. His other writing credits include: author or co-author of reports for national authorities (in France: Minister of National Education, Research & Technology and Minister of Industry; in Canada: Federal Government), and author of articles on industrial property issues, especially in the biotechnology field (*Le Monde*, *Les Echos*, *La Recherche*, *Réalités industrielles*, *Patent World*, *European Brief*, *Dossiers Brevets*, *Revue du Droit de la Propriété Industrielle*). Mr. Gallochat graduated in industrial property from the Centre d'Études Internationales de la propriété industrielle (CEIPI) and in chemistry from the École nationale superieure de chimie, both in Strasbourg. He is a Chevalier de la Légion d'Honneur.

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Registered Participants

ABOITES, JAIME	UNIVERSIDAD AUTONOMA METROPOLITANA, CAMPUS XOCHIMILCO, MEXICO
ALBARRAN GOMEZ, ELENA	OFICINA ESPAÑOLA DE PATENTES Y MARCAS, SPAIN
ALONSO ANDALUZ, JOAQUIN	FUNDACION PARA EL CONOCIMIENTO MADR+D. SPAIN
ALONSO SANCHEZ, FRANCISCO	CSIC, SPAIN
ANGOLOTI BENAVIDES, JOAQUIN	OFICINA ESPAÑOLA DE PATENTES Y MARCAS, SPAIN
ARMIJO, ENRIQUE	ELZABURU, SPAIN
ASHER, JANA	AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE (AAAS), UNITED STATES
AYLAGAS CANCIO, HORTENSIA	OFICINA ESPAÑOLA DE PATENTES Y MARCAS, SPAIN
BALLESTER, MONTSERRAT	LABORATORIOS ESTEVE, SPAIN
BALLESTEROS RUIZ, LOLA	AMIZDIA, SPAIN
BARRANCO, OSCAR	MIND KAPITAL, SPAIN
BARTON, JOHN	STANDFORD LAW SCHOOL, UNITED STATES
BERCOVITZ, ALBERTO	UNED Y ESTUDIO JURÍDICO ALBERTO BERCOVITZ, SPAIN
BERNEMAN, DANIELLE	INSTITUT PASTEUR, FRANCE
BERTRAN VALLS, SILVIA	GENETRIX SL, SPAIN
BOGAERT, BO	UNIVERSITY OF GHENT, BELGIUM
BRAVO, EDUARDO	GENETRIX SL, SPAIN
BRIMELOW, ALISON	THE PATENT OFFICE, UNITED KINGDOM
BRUS, HELENA	MERCK, UNITED STATES
CABRERA, JUAN ANTONIO	CIEMAT, SPAIN
CAMPO-RUIZ, VANESSA	FIBHGM, HOSPITAL GREGORIO MARAÑON, SPAIN
CAPART, GILLES	PROTON EUROPE, BELGIUM
CARRACEDO, LEONOR	MINISTERIO DE EDUCACIÓN Y CIENCIA. DIRECCIÓN GENERAL DE UNIVERSIDADES, SPAIN
CASAS, LIDIA	CENTRE DE PATENTS DE LA UNIVERSITAT DE BARCELONA, SPAIN
CEBADERA MIRANDA, ELENA	PROPI SL, SPAIN
CERRILLOS GONZALEZ, Mª LUISA	ANDALUSIAN INNOVATION AND DEVELOPMENT AGENCY, SPAIN
CESTER SCHLAAK, HELGA	NEUROPHARMA, SA, SPAIN
CHRISTIE, ANDREW	INTELLECTUAL PROPERTY RESEARCH INSTITUTE OF AUSTRALIA (IPRIA), AUSTRALIA
COMBEAU, JACQUES	AIR LIQUIDE, FRANCE
COOK, TREVOR	BIRD&BIRD, UNITED KINGDOM
CORRAL, PAZ	OFICINA ESPAÑOLA DE PATENTES Y MARCAS, SPAIN
COSTA, KATYSSULLA	CDTI, SPAIN
CRUZ CALVO, ESTEFANIA	UDAPI&ASOCIADOS PATENTES Y MARCAS, SPAIN
CUBEIRO, BEATRIZ	UNIVERSIDAD POLITECNICA DE MADRID, SPAIN
DAMBOIS, DENIS	EUROPEAN COMMISSION, DG RESEARCH, BELGIUM
DE GRADO SANZ, MYRIAM	MICROBIONTA, SPAIN
DE LA PEÑA CAÑETE, YOLANDA	UNIVERSIDAD CARLOS III DE MADRID. INDUSTRIAL LIAISON OFFICE, SPAIN
DE NÓ, JOSÉ	CSIC/INST. AUTOMATICA INDUSTRIAL (IAI), SPAIN
DEL CASTILLO, VOLGA	CSIC, SPAIN
DENT, CHRIS	INTELLECTUAL PROPERTY RESEARCH INSTITUTE OF AUSTRALIA (IPRIA), AUSTRALIA
DIAS, IRENEU	INESC PORTO, PORTUGAL
DIAZ MENDEZ, BEATRIZ	TECHNICAL UNIVERSITY OF MADRID, SPAIN
DIEZ HERNANDEZ, ELIECER	FUNDACION CENTRO NACIONAL INVESTIGACIONES CARDIOVASCULARES CARLOS III SPAIN
DORRONSORO, CARLOS	CSIC, SPAIN
DRIECE, ROLAND	MINISTRY OF ECONOMIC AFFAIRS, NETHERLANDS
DUQUE, JUAN PABLO	CSIC, SPAIN
ESTEBAN GIL, INMACULADA	OFICINA ESPAÑOLA DE PATENTES Y MARCAS, SPAIN
FERNANDEZ ORDAS, CRISTINA	OFICINA ESPAÑOLA DE PATENTES Y MARCAS, SPAIN
FERNANDEZ-BORRELLA, ANTONIO	CSIC, SPAIN
FITZGERALD, BRIAN	QUEENSLAND UNIVERSITY OF TECHNOLOGY, AUSTRALIA
FLORES, MIGUEL ANGEL	REPSOLYPF, SPAIN
FRAGUAS, LOURDES	FARMAINDUSTRIA, SPAIN

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GABALDON, EVA	CENTRO NACIONAL DE BIOTECNOLOGIA, CSIC, SPAIN
GALAN JUAREZ, MERCEDES	UNIVERSIDAD REY JUAN CARLOS, SPAIN
GALLOCHAT, ALAIN	MINISTÈRE DE LA RECHERCHE DIRECTION DE LA TECHNOLOGIE, FRANCE
GARCIA, LUDI	KETCHUM/SEIS, SPAIN
GARCIA, LUIS	OFICINA ESPAÑOLA DE PATENTES Y MARCAS, SPAIN
GARCIA, INMACULADA	CEPSA (COMPAÑÍA ESPAÑOLA DE PETROLEOS), SPAIN
GARCIA, NORMA	UNIVERSIDAD POLITECNICA DE MADRID, SPAIN
GARCIA-FABRY, MERCEDES	INSTITUT PASTEUR, FRANCE
GERHARDSEN, TOVE IREN S	INTELLECTUAL PROPERTY WATCH, SWITZERLAND
GOICOLEA, ANA	UNIVERSIDAD POLITECNICA DE MADRID, SPAIN
GONZALEZ, VICENTE	ABG PATENTES, SPAIN
GONZALEZ, BELEN	AUTONOMA UNIVERSITY OF MADRID TECHNOLOGY TRANSFER OFFICE, SPAIN
GONZALEZ LOPEZ, INMACULADA	CUATRECASAS ABOGADOS, SPAIN
GONZALEZ-MORENO, RUBEN	UNIVERSIDAD CARLOS III DE MADRID, SPAIN
GUASCH, LUIS	CSIC TECNOLOGY TRANSFER OFFICE, SPAIN
GUELLEC, DOMINIQUE	OECD, FRANCE
HERNANDEZ FERNANDEZ, DIANA	OFICINA ESPAÑOLA DE PATENTES Y MARCAS, SPAIN
HERNANDO MARTIN, CARMEN	OFICINA ESPAÑOLA DE PATENTES Y MARCAS, SPAIN
HERNANDO SAIZ, YOLANDA	OFICINA DE TRANSFERENCIA DE TECNOLOGIA CSIC, SPAIN
HORVÁTH, ALEXANDRA	NATIONAL OFFICE FOR RESEARCH AND TECHNOLOGY, HUNGARY
ILLESCAS, MANUEL	ELZABURU S.A., SPAIN
IONUS, GERALDINE	SGA2, FRANCE
IRIBARREN, BEATRIZ	UNIVERSIDAD CARLOS III DE MADRID, SPAIN
JOHNSON, RICHARD	BIAC TECHNOLOGY COMMITTEE AND ARNOLD & PORTER, UNITED STATES
JOSE, MARCO	CSIC, INSTITUTO DE QUIMICA ORGANICA GENERAL, SPAIN
JUSELIUS, PETER	OY TRIO CONSULTING GROUP AB, FINLAND
KAISER, LORENZ	FRAUNHOFER GESELLSCHAFT, GERMANY
KAMIYAMA, SHIGEKI	OECD, FRANCE
KLETT, PETER	IBM RESEARCH GMBH ZURICH RESEARCH LABORATORY, SWITZERLAND
LACALLE, NATALIA	LILLY, S.A., SPAIN
LAMBERT, JANET	INVITROGEN CORPORATION, UNITED STATES
LATORRE ZACARES, JESUS	AIMPLAS INSTITUTO TECNOLOGICO DEL PLASTICO, SPAIN
LICHVAROVA, MARIA	MINISTRY OF EDUCATION OF THE SLOVAK REPUBLIC, SLOVAKIA
LLABRES, JUAN	CSIC/OTT, SPAIN
LOBATO, MANUEL	BIRD&BIRD, SPAIN
LOPEZ, MARTA	FUNDACIÓN GENERAL DE LA UNIVERSIDAD AUTONOMA DE MADRID, SPAIN
LOPEZ MARTINEZ, JOSE ANTONIO	LOPEZ GIMENEZ TORRES, ALICANTE TRADEMARK PROFFESSIONALS, S.L., SPAIN
MACLEOD, GENOFFIR	INVITROGEN CORPORATION, UNITED KINGDOM
MANSO, JAVIER	OFICINA ESPAÑOLA DE PATENTES Y MARCAS, SPAIN
MARTIN BENITO, ELENA	NEUROPHARMA, SA, SPAIN
MARTIN MORONTA, ANGELICA	OFICINA ESPAÑOLA DE PATENTES Y MARCAS, SPAIN
MARTINEZ, JUAN	CSIC, SPAIN
MARTINEZ, CATALINA	OECD, FRANCE
MARTINEZ DE MIGUEL, BEGOÑA	OFICINA ESPAÑOLA DE PATENTES Y MARCAS, SPAIN
MATEU, AMPARO	CTT- UNIVERSIDAD POLITECNICA DE VALENCIA, SPAIN
MEDRANO, JULIA	INSTITUTO DE SALUD CARLOS III, SPAIN
MÉNIÈRE, YANN	CENTRE D'ECONOMIE INDUSTRIELLE (CERNA) ECOLE DES MINES DE PARIS, FRANCE
MERELLO, FERNANDO	UNIVERSIDAD DE CADIZ, SPAIN
MERINO, RICARDO	UPV/EHU (UNIVERSITY OF THE BASQUE COUNTRY), SPAIN
MERRILL, STEPHEN	SCIENCE, TECHNOLOGY AND ECONOMIC POLICY THE NATIONAL ACADEMIES, UNITED STATES
MIGUELEZ, CARMEN	INSTITUTO DE SALUD CARLOS III, SPAIN
MIYAMOTO, TOMOKO	WORLD INTELLLECTUAL PROPERTY ORGANIZATION, SWITZERLAND
MOGIN, TERESA	OFICINA ESPAÑOLA DE PATENTES Y MARCAS, SPAIN

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MOLNAROVA, MILOSLAVA	MINISTRY OF EDUCATION OF THE SLOVAK REPUBLIC, SLOVAKIA
MONTEJO, MARIA JOSEFA	FUNDACION COTEC, SPAIN
MORENO GOMEZ, FRANCISCO JOSE	OFICINA ESPAÑOLA DE PATENTES Y MARCAS, SPAIN
MORERA CUESTA, RAFAEL	FUNDACION ESPAÑOLA PARA LA CIENCIA Y LA TECNOLOGIA, SPAIN
MOSNA, MARTA	MINISTRY OF EDUCATION OF THE SLOVAK REPUBLIC, SLOVAKIA
MOTYK, KRZYSZTOF	MINISTRY OF EDUCATION AND SCIENCE, POLAND
NAGAOKA, SADAO	INSTITUTE OF INNOVATION RESEARCH HITOTSUBASHI UNIVERSITY, JAPAN
NAKAMURA, KENTA	JAPAN SOCIETY FOR THE PROMOTION OF SCIENCE, JAPAN
NAVARRO REVIEJO, ESTELA	CSIC, SPAIN
NORIEGA, FRANCISCO BERNARDO	ABG PATENTES, SPAIN
O'CONNOR, SEAN	CENTER FOR ADVANCED STUDY AND RESEARCH ON INTELLECTUAL PROPERTY (CASRIP), UNITED STATES
OIEN, MORTEN	NORWEGIAN UNIVERSITY OF SCIENCE AND TECHNOLOGY (NTNU), NORWAY
PALOMERAS, NEUS	UNIVERSIDAD CARLOS III DE MADRID, SPAIN
PATO COUR, ISABEL	CLARKE, MODET &Cº, SPAIN
PENAS, GERARDO	OFICINA ESPAÑOLA DE PATENTES Y MARCAS, SPAIN
PEREZ, JAIME	CSIC, SPAIN
PEREZ-ILZARBE, JAVIER	OFICINA ESPAÑOLA DE PATENTES Y MARCAS, SPAIN
PIERA GOMEZ, FERNANDO	ASOCIACION DE TECNICOS DE INFORMATICA (ATI), SPAIN
PREGNOLATO, MASSIMO	UNIVERSITY OF PAVIA, ITALY
QUILCHANO, CHELO	CSIC, SPAIN
RADIN, JANE MARGARET	STANDFORD LAW SCHOOL, UNITED STATES
RAMIREZ PINEDA, ELVIRA	AGENCIA DE INNOVACION DE ANDALUCIA, SPAIN
RAUBITSCHEK, JOHN H.	U.S. DEPARTMENT OF COMMERCE, UNITED STATES
REPRESA, DOMINGO	CSIC, SPAIN
RIPIO, MAYTE	UNIVERSIDAD COMPLUTENSE DE MADRID, SPAIN
ROMERO TORRES, JUAN ANTONIO	ELZABURU S.A., SPAIN
ROSENTHAL, JERRY	OPEN INVENTION NETWORK, UNITED STATES
RUIZGEMA	FUNDACION GENERAL UNIVERSIDAD AUTONOMA DE MADRID, SPAIN
RUIZ HERVAS, BLANCA	KETCHUM/SEIS, SPAIN
RUTZ, BERTHOLD	EUROPEAN PATENT OFFICE, GERMANY
SAEZ, FRANCISCO JAVIER	ELZABURU S.A, SPAIN
SALAS, MARGARITA	CENTRO DE BIOLOGÍA MOLECULAR SEVERO OCHOA CSIC/UAM, SPAIN
SANCHEZ-VALLVE, XAVIER	UNIVERSIDAD AUTONOMA DE BARCELONA, SPAIN
SANZA GUTIERREZ, MARIA ISABEL	SERONO INTERNATIONAL S.A., SWITZERLAND
SHEEHAN, JERRY	OECD, FRANCE
SLOAN, BRIAN	EUROPEAN COMMISSION, DG RESEARCH, BELGIUM
STOUT, ROBIN	THE PATENT OFFICE , UNITED KINGDOMUNITYED KINGDOM
STRAUS, JOSEPH	MAX-PLANCK-INSTITUTE FOR INTELLECTUAL PROPERTY, COMPETITION AND TAX LAW, GERMANY
TAKESHIGE, TATSUO	TECNOLOGY RESEARCH DIVISION, JAPAN PATENT OFFICE, JAPAN
TANAKA, NOBUO	OECD, FRANCE
TEICHER, MINA	MINISTRY OF SCIENCE AND TECHNOLOGY, ISRAEL
THOMAS, NEIL	GENETRIX SL, SPAIN
THOURET-LEMAITRE, ELISABETH	SANOFI-AVENTIS, FRANCE
THUMM, NIKOLAUS	SWISS FEDERAL INSTITUTE OF INTELLECTUAL PROPERTY, SWITZERLAND
TOLEDO, CARMEN	OFICINA ESPAÑOLA DE PATENTES Y MARCAS, SPAIN
VAN POTTELSBERGHE, BRUNO	EUROPEAN PATENT OFFICE, GERMANY
VAN ZEEBROECK, NICOLAS	EMILE BERNHEIM CENTER ULB - SOLVAY BUSINESS SCHOOL, BELGIUM
VELASCO, CARLOS E.	OFICINA ESPAÑOLA DE PATENTES Y MARCAS, SPAIN
VILA RIUDAVETS, BLANCA	OFICINA ESPAÑOLA DE PATENTES Y MARCAS, SPAIN
WALSH, JOHN	UNIVERSITY OF ILLINOIS AT CHICAGO - DEPARTMENT OF SOCIOLOGY, UNITED STATES
WATANABE, TORU	RESEARCH DEPARTMENT INSTITUTE OF INTELLECTUAL PROPERTY, JAPAN
YILMAZ, NURTEN	UNIVERSITY OF GHENT, BELGIUM
YPYÄ, TUIJA	MINISTRY OF TRADE AND INDUSTRY, FINLAND
ZULEGER, THOMAS	FEDERAL MINISTRY OF ECONOMICS AND TECHNOLOGY, GERMANY

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Conference Rapporteurs

- Yann Ménière, Research Fellow, CERNA, Ecole de Mines de Paris
- Nicolas van Zeebroeck, Research Fellow, Emile Bernheim Center, ULB-Solvay Business School

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- Jerry Sheehan, Science and Technology Policy Division, Directorate for Science, Technology and Industry[8]
- Dominique Guellec, Economic Analysis and Statistics Division, Directorate for Science, Technology and Industry

[7] Now Research Fellow at the Unidad de Políticas Comparadas of the Spanish Nacional Research Council (UPC-CSIC).
[8] Now Assistant Director for Policy Development at the National Library of Medicine of the US National Institutes of Health.

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Organising and Supporting Institutions

The Spanish Patent and Trade Mark Office (OEPM) is an autonomous body that forms part of the Ministry of Industry, Tourism and Trade and which promotes and supports technological and economic development. It provides legal protection to all types of industrial property by awarding patents and utility models (inventions); industrial designs; trade marks and trade names (distinctive signs) and rights protecting topographies of semiconductor products. It also disseminates information on the various ways in which industrial property can be protected. The OEPM also represents Spain in international forums and organisations that are responsible for protecting industrial and intellectual property. The OEPM has, therefore, a dual function: to award industrial property rights following due examination of applications and to provide technological information services based on information about the various types of industrial property rights awarded by the OEPM and other offices overseas. The main objectives of the OEPM are as follows: to protect and promote creation and technological innovation in Spain as well as corporate business identity by awarding industrial property rights, to provide information that helps to guide research activity by maintaining archives and databases that enable quick and easy access to up-to-date information on the latest global technical developments in all sectors and to promote the circulation and exchanging of goods and services by disseminating information on registered distinctive signs.

The Spanish National Research Council (CSIC), attached to the Ministry of Education and Science, is the country's main body for basic research. It represents by itself 20% of the scientific output of the country, or 0.55% of the world's scientific publications. It is perhaps astonishing that CSIC is also the first applicant from Spain to the Patent Cooperation Treaty. With its 62 applications in 2003 it ranks indeed above not only all the country's universities, but all the industrial companies too. CSIC researchers are attracting more and more financial resources through contracts with industry, as the CSIC has become the reference organisation for the transfer of technology in Spain. Approximately 600 contracts are concluded annually with Spanish industry for a total amount of over 24 million. As a multidisciplinary research organisation, the Spanish National Research Council covers virtually every field of knowledge. CSIC has 125 institutes installed all over Spain, almost half of them are located in Madrid, where the central headquarters are also situated. Besides libraries and laboratories, CSIC owns museums, oceanographic vessels, natural parks and reserves, experimental farms, astronomic observatories and it administers one of the Spanish Antarctic bases and the polar ship B/O Hespérides. More than 12.000 people work in the CSIC, from tenured scientists, to technicians, administrative staff and research fellows. Circa two thousand doctoral students are carrying out their thesis in CSIC´s different institutes.

The Organisation for Economic Co-operation and Development (OECD) is a unique forum where the governments of 30 market democracies work together to address the economic, social, environmental and governance challenges of the globalising world economy, as well as to exploit its opportunities. The Organisation provides a setting where governments can compare policy experiences, seek answers to common problems, identify good practice and work to co-ordinate domestic and international policies. Exchanges between OECD governments flow from information and analysis provided by a Secretariat in Paris. The Secretariat collects data, monitors trends, and analyses and forecasts economic developments. It also researches social changes or evolving patterns in trade, environment, agriculture, technology, taxation and more. Work on intellectual property rights and innovation within the OECD Directorate for Science, Technology and Industry aims to provide evidence-based analysis of the links between IPR, innovation and economic performance, and to inform development of IPR regimes that improve innovation and economic performance. Work is currently being done to address issues related to innovation and knowledge diffusion, in particular the role of licensing and technology markets in stimulating knowledge diffusion and innovation, and

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mechanisms for promoting research access to patented inventions. Ensuring that patents continue to serve their dual role of providing incentives to innovate and contributing to the diffusion of knowledge is high in the policy agenda of OECD countries. Science and Technology Policy Ministers of OECD countries expressed concerns about the impact of patents on the conduct of scientific research at a meeting in Paris in January 2004 and invited the OECD to examine national policies regarding exemptions for research use of patented inventions. This conference is part of the effort made since then to address their request. More information on this and other OECD activities related to IPR can be found online at: www.oecd.org/sti/ipr.

The European Patent Office (EPO) is the executive body of the European Patent Organisation, an intergovernmental institution established by the European Patent Convention and to which all the EPC contracting states belong. The EPO's governing body is the Organisation's Administrative Council, made up of delegates from the 30 contracting states. The EPO has its headquarters in Munich, a branch at The Hague and sub-offices in Berlin and Vienna. With over 6 000 staff, it is the second biggest European organisation after the European Commission. The EPO was set up with the aim of strengthening co-operation between the countries of Europe in the protection of inventions. This was achieved by adopting the EPC, which makes it possible to obtain patent protection in several or all of the contracting states by filing a single patent application in one of the three official languages of the EPO (English, French and German). The EPC also establishes standard rules governing the treatment of patents granted under this procedure. More than two decades have clearly demonstrated the advantages of this approach: Since its creation in 1977, the EPO has received more than 1.8 million European patent applications and granted nearly 650 000 European patents. Moreover, the Office has established itself as the leading authority for international procedures under the Patent Cooperation Treaty, a treaty that makes it possible to file for patent protection in more than 100 countries on the basis of a single patent application. In 2004 the Administrative Council adopted regulations establishing the European Patent Academy. Its aim is to foster the advancement of education and training in the field of European and international patent related intellectual property law and practice for the benefit of the European Patent System.

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