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IPR in Nanotechnology - lessons from experiences worldwide

Proceedings

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Executive Summary

The aim of the nanotechnology IPR workshop was to identify specific IPR issues for nanotechnology and to discuss possible consequences for patent offices, policy makers, patent consultants and the research community. Many aspects have been identified in ongoing academic and political discussions, such as the costs of patenting and the accessibility of patents for SMEs or Developing Countries, the need of a transparent and clearly defined scope of patent protection, the implications of "nanopatent land grab" and "patent thickets" (R. Bawa), "nanotechnology patent battles" (Lux Research), "second nature" and "monopoly patent" (ETC Group) etc.

The discussions were steered to the development of possible actions specific for nanotechnology, e.g. the definition and classification of nanotechnology for patenting and patent examining purposes, the development of a nanotechnology patent monitoring system, the steps towards a harmonisation of the patent application processing between the EU, the USA and Japan, the development of standards for the protection of IPR and models for consortium and licensing agreements, the need for a new regime for nanotechnology patent, lessons for collaborative research projects and other research collaborations etc. (non-exhaustive list).

Main conclusions of the discussions can be summarised as follows:

A ‘patent monitoring system in nanotechnology’ can serve three purposes:

- Prior art searches for patent applicants and examiners
- Technology analyses for anticipating current and future developments
- Information tool for policy makers for identifying hot fields and main players

Patent offices have developed different strategies for nanotechnology, e.g. by creating nanotechnology working groups and training sessions, by introducing a nanotechnology classification (EPO: Y01N tag, USPTO: 977 class, JPO: ZNM class), and by creating a Patent Statistics Information System with nanotechnology search facility (EPO with OECD: PATSTAT).

The ongoing activities for classifying nanotechnology patents lead into the right direction and should be continued and expanded. Patent applicants should train patent examiners in their fields of nanotechnology research. There is no major need for a common, unique definition for patent examining and application purposes if nanotechnology is broken down into subfields and only these subfields would be compared. This can overcome differences in definition and would help to better identify important fields. A common, unique terminology, although beneficial for patent applicants, examiners, analysts and users, is unrealistic for a new and dynamic technology like nanotechnology and cannot be imposed on patent applicants.

Is there a need for a new patent regime in nanotechnology? A high pendency rate can be in the interest of the patent applicants because it keeps competitors out of the field and, in the EU, it postpones the costs for translation. As long as this motivation does not change, there is little chance to reduce the pendency rate for nanotechnology patents.

When it comes to patents, nanotechnology does not differ much from other technologies. Most alleged problems described in the literature (‘patent thickets’, ‘patent land grab’, 'overlapping patents', ‘patent battles’, ‘monopoly patents’ etc.) apply to other emerging technologies as well. The experts agree that there is no need for a new patent regime in nanotechnology, and that patent offices should continue to strive to ensure high quality patents.

Consequences for research collaborations: The awareness of IPR issues is insufficient, especially at universities and public research institutes, but sometimes also at SMEs. Patent and licence strategies differ between sectors. For instance, while there is a tendency to cross licences in electronics, the pharmaceutical industry tends much more to exclusive licenses. This is in particular a problem for nanotechnology licence agreements, which are – because of nanotech’s interdisciplinary nature - on the crossroad between these sectors.

In collaborative projects, IPR issues (partners’ needs and project’s needs) have to be addressed at earliest possible stage, e.g. by involving an independent IPR expert in the set up of the project. Research projects should offer training to patent examiners on their topic. A good composition of the consortium along the value chain (basic research – applied research – production – utilisation) can ensure an adequate IPR strategy and enables technology transfer. Guidelines for licence agreements and model licences in nanotechnology fields with high interdisciplinarity are needed as well as analyses of best practices in terms of exclusive vs. non-exclusive licences, non disclosure strategies (trade secrets), patent pools.

The global dimension: Harmonisation activities between patent offices are ongoing, but limited due to different approaches, rules and traditions. Less industrialised countries encounter similar problems in IPR, thus networking between them (‘South-South’) is a first step to find solutions. ‘North-South’ cooperation is needed as well, especially on how to apply patents at the ‘Northern’ patent offices.

Introduction

The aim of the nanotechnology IPR workshop was to identify specific IPR issues for nanotechnology and to discuss possible consequences for patent offices, policy makers, patent consultants and the research community. Many aspects have been identified in ongoing academic and political discussions, such as the costs of patenting and the accessibility of patents for SMEs or Developing Countries, the need of a transparent and clearly defined scope of patent protection, the implications of "nanopatent land grab" and "patent thickets" (R. Bawa), "nanotechnology patent battles" (Lux Research), "second nature" and "monopoly patent" (ETC Group) etc.

In order to approach the IPR issues in nanotechnology and to learn more about the state of the art at patent offices, research centres and in the patent consultant and patent analysis community, presentations were held on following topics:

- Using Patents as an Information Source for Nanotechnology Policy & Business, *by Martin Meyer, SPRU Brighton, UK*
- Nanotechnology-Related Issues at the United States Patent and Trademark Office, *by Charles Eloshway, USPTO*
- Nanotechnology Patents at the European Patent Office*, by Christian Kallinger, nanotechnology working group, EPO*
- Nanotechnology and Intellectual Property in Brazil - The Perspective of an Innovative Developing Country, *by Claudia Ines Chamas, Oswaldo Cruz Foundation, Rio de Janeiro, Brazil*
- IP in nanotechnology - Philips' perspective, *by Maaike van Velzen, European Technology Platform for Nanomedicine and Philips Intellectual Property & Standards, The Netherlands*
- Nanotechnology, Patents and the US Patent Office, *by Raj Bawa, Bawa Biotechnology Consulting and Rensselaer Polytechnic Institute, Troy, New York, US*
- Patents&Industry-Science relations - case study: IMEC – nanopatents, *by Kristel van den Broeck and Vincent Ryckaert, IMEC, Belgium*

After these presentations, each participant had the possibility to express his or her views in a *tour de table*, independently from the topics which have been identified for the three discussion lines for the final discussions of the workshop. These final discussions were steered to the development of possible actions specific for nanotechnology, e.g. the definition and classification of nanotechnology for patenting and patent examining purposes, the development of a nanotechnology patent monitoring system, the steps towards a harmonisation of the patent application processing between the EU, the USA and Japan, the development of standards for the protection of IPR and models for consortium and licensing agreements, the need for a new regime for nanotechnology patent, lessons for collaborative research projects and other research collaborations etc. (non-exhaustive list).

In the first section of the proceedings, the seven presentations of the workshop are summarised, in chronological order. Afterwards, results of the *tour de table* are

presented, grouped by main issues that have been addressed. The main discussions along the three discussion lines are reported in the next section, followed by some more general conclusions.

Annex I to these proceedings summarises the political responses to the European Strategy and the Action Plan on nanotechnology on aspects related to IPR in nanotechnology, from nanotechnology stakeholders in Europe (750 responses to an open consultation, carried out in 2004), from the European Social and Economic Council (EESC) and the European Parliament (EP). These responses serve as background information on the political debate in Europe related to IPR and Nanotechnology.

Annex II provides the list of participants.

1 Presentations:

In order to approach the IPR issues in nanotechnology and to learn more about the state of the art at patent offices, research centres and in the patent consultant and patent analysis community, following presentations were given:

Martin Meyer of the Science and Policy Research Unit (SPRU) at the University of Brighton, UK gave an overview over the use of patents as an information source for nanotechnology policy and business. The analysis of patents in the field of nanotechnology is an important tool for nanotechnology stakeholders (industry, researchers, policy makers). The existing methodology for analysis is complex and a number of indicators can be applied (counts of patents and applications - normalised by population, GDP, R&D expenditures, through benchmarking, counts of patent citations, size of patent families, coverage of patent classes, dynamics of patent portfolio etc.). Bibliographic mapping based on co-occurrence of main patents is an appropriate method for visualisation of the structure of a field. The analysis can proof little or no convergence of some fields (e.g. nanobio and nanooptics), and identification of holders of essential patent families. Any analysis is very dependent on the applied definition during the searches.

Charles Eloshway, Patent Attorney in the Office of International Relations at the United States Patent and Trademark Office (USPTO), presented nanotechnology-related issues at the USPTO. The USPTO classification is consistent with the definition of the National Nanotechnology Initiative (NNI), which is scale and unique phenomena dependent. ("Nanotechnology is the understanding and control of matter at dimensions of roughly 1 to 100 nanometers (a nanometer is one-billionth of a meter), where unique phenomena enable novel applications. At this level, the physical, chemical, and biological properties of materials differ in fundamental and valuable ways from the properties of individual atoms and molecules or bulk matter."). The number of patents which actually claim a nanotechnology invention is still limited, but there are many more patents which include nanotech-related terms. The informal nanotechnology classification Class 977 Digest I (established Oct. 2004) has now been expanded from a

single “digest” to a cross-reference art collection of 263 new subclasses. The tool is publicly available on the USPTO web page. The main technology areas represented in the class in terms of patents and patent application publications are from electronics, followed by chemical and materials engineering and by biotechnology and pharmaceuticals. The United States leads the world in multinational patent activity (applications for the same invention published in three or more jurisdictions), followed by Japan and Germany. In terms of foreign filings at the USPTO, most come from Japan, followed by Germany and France. In order to keep pace with this emerging technology, the USPTO has taken a number of proactive steps, including sponsorship of annual nanotechnology customer partnership meetings as well as nanotechnology training and seminars for examiners. Examiners that have developed expertise in nanotechnology as it is applied in their particular discipline serve as the nanotechnology contact points in order to assist other examiners.

Christian Kallinger, patent examiner at the European Patent Office (EPO) and member of EPO's nanotechnology working group, presented the EPO's approach towards nanotechnology patents. The number of patents families related to nanotechnology increased enormously in year 2000 and is still increasing. The B82B nanotechnology definition according to ECLA/IPC is very "narrow" and only a limited number of patents fits in this definition. According to the definition used by the research and development community, nanotechnology related patents are scattered throughout the existing EC/IPC classification schemes. A tagging system (Y01N) has therefore been introduced as an additional tool for identifying nanotechnology patents. This tagging is further divided to six sub-classes according to technology and/or applications.The Y01N tagging collects documents from over 140 ECLA classes that have been identified by EPO and external experts as containing nanotech related applications. In addition ad-hoc tagging by experienced examiners adds documents to the collection. There are about 108.000 documents (including about 30.000 patent families and 19.000 Non-patent literature documents) up to date tagged by Y01N. Nevertheless, the number of nanotechnology patents is still marginal compared to other technologies (less than 1% of all patents applied for at EPO are nanotechnology related). The tagging facilitates interdisciplinary prior art search as well as trend monitoring in nanotechnology. The search for these tagged patents can be done through the publicly available patent search service Esp@cenet. Harmonisation between IP offices (JPO, USPTO, EPO) is ongoing. This trilateral cooperation is focussed on adopting a common definition for tagging (ZNM, Class 977, Y01N) and harmonization of classification in nanotechnology. Good practice is also exchanged by comparison of examination practices.

Claudia Ines Chamas of the Oswaldo Cruz Foundation of the Brazilian Ministry of Health, Rio de Janeiro, presented results on nanotechnology and IP in Brazil - the perspective of an innovative Developing Country. Searching for nanotechnology patents according to the nanotechnology class IPC B82B, there are only 21 hits in the Brazilian Patent Database. This result clearly indicates the need for reclassification effort of this IPC class in order to get a better overview about the nanotechnology activities in Brazil. Most applicants are from Brazil, followed by the US and some few applicants from European countries. Main obstacles to adequately searching nanotechnology patents

are identified on side of the patent office (i.e. quality of the patent database, reliable search system, identification of nanotechnology patents, insufficient cooperation with other patent offices) and on side of applicants (poor information about the protection of invention and poor access to patent information in nanotechnology). It is important to develop IP policies in nanotechnology connected to the local system of innovation, to improve patent search capacities and tagging systems for nanotechnology and to train patent examiners in the field of nanotechnology. It is needed to develop guidelines to analyse the patent applications in nanotechnology consistent with the TRIPs (Trade Related aspects of Intellectual Property) Agreement of the WTO (World Trade Organization), such as standards for patentability, to avoid excessive protection that could create disincentives to research and innovation activities. Fostering dialogue between patent offices of innovative developing countries and developed countries is an important action to take.

Maaike van Velzen of the European Technology Platform for Nanomedicine and patent attorney at Philips Intellectual Property & Standards, The Netherlands, presented Philips' perspective on IP in nanotechnology. The multidisciplinary character of new emerging technologies such as nanomedicine brings industry in the field of high patent density. The scope of a new invention has to be carefully evaluated during the process of patenting. Early filing approaches should be connected with the potential use of the know-how. The clarity of claims and the multidisciplinary of the team which is drafting the documents are essential. Novel approaches of using know-how could be applied through public private partnership co-operations. There are two different approaches of inter-company co-operation. In the pharmaceutical industry, exclusive licences dominate while the electronics industry is well known for tending to cross-licensing. Applications of nanomedicine are often covered by “old” IP in the life science area. A mosaic of future generation patents will soon be reality with many pending applications, because of the high speed technology development, high patent awareness, a risk of overlapping scopes and complicated distribution of rights, and a high risk for quality patents. Semi-exclusive licensing policies could be a solution for the future. The current patent monitoring system for nanotechnology and its developments is useful. There is no need for new patent regime, but there is a need for strict application and interpretation of existing laws. New IP models may be developed for business strategy, when needed.

Raj Bawa of Bawa Biotechnology Consulting and Rensselaer Polytechnic Institute, Troy, New York, US spoke about nanotechnology, patents and the US Patent Office. There is enormous excitement and expectation regarding nanotechnology’s potential impact. However, securing valid and defensible patent protection will be critical. Although early forecasts for nanotechnology commercialisation are encouraging, there are bottlenecks as well. One of the major hurdles is an emerging thicket of patent claims and patents with too broad claims. Granted patents are in many cases overlapping and could prevent further exploitation. The call for high quality patents could improve the situation significantly. Patent pendency has prolonged in the last years and the ratio patents applied/patents granted has increased enormously. A nano hype is reflected by the number of nanotechnology related patents applied for recently. The expression of a political will for nonexclusive patents can protect future progress in research and innovation.

Kristel van den Broeck and **Vincent Ryckaert**, patent attorneys at IMEC, Belgium, presented a case study on nanopatents, including some aspects of patents and industry-science relations at IMEC. The IP policy of a large research institute such as IMEC is to avoid IP blocking against research and business partners, to secure IPR for partners (industrial affiliation program with licensing or co-ownership of IP) and to enable publications for researchers. This could be achieved by a selective patenting strategy and by a careful case-by-case designation of a proper IP model. The business IP model applied at IMEC is characterised by an open, multi-party approach with non-exclusive licensing as a base-line. The applied model is supposed to minimise unnecessary IP dilution in view of transferability. To this respect, it is important to place the IPR on the research and development life cycle (who pays? - what is the value?). Using a cost-based approach and risk sharing by covering research and development risks but focus on continuity of actions. Economic growth will be even more IP driven in the future.

2 Results from the "Tour de table" (statements by all participants)

The representatives of the European Commission expressed the need for ideas for improving the IPR situation in nanotechnology. The experts are invited to tell the Commission which actions they consider as being most appropriate in order to solve the problems discussed during the workshop. (The European Commission (DG Enterprise) has recently published a call for tender for a an Awareness and Enforcement project, which integrates existing awareness and enforcement projects related to IPR in order to provide a common level of advanced services to SME. Another helpdesk is established in China in order to provide information for EU companies setting business at China. The European Commission (DG Research) also published recently a Communication on technology transfer from university to industry which covers IPR issues as well.)

For data analysis, the choice of an appropriate methodology as well as a high quality of data is important. Policy makers and other recipients of the statistics need to be advised on how to read and interpret the data. Therefore it is crucial to have comparable data with not too many particularities due to different methodologies or sources. In addition, technology analyses for policy recommendation should not concentrate on patent data but also taking into account other indicators for the development of nanotechnology. These indicators can also be used in order to assess the quality of the indicators retrieved from the patent data. In addition, a patent monitoring system should include an analysis of patent strategies.

The harmonisation of definitions for identifying nanotechnology patents can lead to comparable data and can also lead to a better assessment of the technology evolution, also compared to other technologies ('benchmarking'). A definition which specifies the nano-scale such as "100 nm and below" can lead to irrelevant analysis or to oversimplification because this excludes nano-scale effects that are above 100nm, which is not unusual in nanobiotechnology. Patent classifications should base on

realistic definitions and should not be biased towards a nanotechnology subdiscipline such as material sciences (for which the scale of 100nm appears to be crucial). The size dependent part of the definition should be withdrawn. However, it is also clear that the patent offices can not 'invent' their own definition but rely on what they are told by their government and the scientific community. A possibility to overcome the problems of defining nanotechnology as such is breaking down the definition to nanotechnology subfields, which are anyway more appropriate for technology and patent policy analyses, and which make different definitions more comparable.

The OECD has set up a nanotechnology working party which will address IPR as well as definition and terminology issues. So far, there is not much experience with nanotechnology, but examples such as biotechnology show that errors can happen at the early development of a new technology (such as too broad or wrongly issued patents). The OECD in cooperation with the EPO is developing a system for statistical patent analysis (PATSTAT) for nanotechnology, which will be publicly available in the internet. This service will provide data for technology analyses. Common terminology of existing nanotechnologies would help the key word search, and facilitate communication with patent attorneys and potential investors. This could become an important step towards the patent monitoring system in nanotechnology.

The quality of patents granted is of main importance because correcting steps are lengthy and costly. No changes in legislation are currently needed. However, the strict application of patent laws in the patent examination and patent granting process has to be ensured in order to avoid too broad, not novel or overlapping patents. For the identification of the potential problems, it is important to take the real data into account. So far, there have been no reported cases that lend support to the observations made some at this workshop such as too broad patents or tollbooth patents. An empirical approach is needed to better ascertain the real significance of these issues. In addition, despite the high number of tagged patents, the number of nanotechnology patents is still very low (below 1%) compared to the number of patents in other technologies at the EPO.

Long patent pendency rates could create problems for start-ups or SMEs, which need patents for acquiring financial support. Investors are looking for security, of which granted patents are the strongest. The pendency rate could by decreased by the applicants by "pro-active" behaviour during the patent examination process or by a request for rapid examination, which does not implicate higher costs. However, it has also been observed that many applicants do not have the interest to decrease the patent pendency rate. This is due to the fact that a pending patent is a strong signal towards competitors who can get discouraged to undertaking research and applying patents in the same field. It was also argued that this behavior may explain the observation by some concerning an allegedly high number of low quality patents with low expectations for success that are submitted to the patent offices, which can de facto claim a field without providing the appropriate innovation.

An alternative to patents is trade secrets. They imply a non-disclosure strategy and could be a strong protection against imitation and industrial espionage. However, the

utilisation of trade secrets is not yet harmonised in the European Union. In Belgium for instance, a researcher who knows about the trade secret cannot be prevented to change his job and go to the competitor taking the knowledge with him.

At research institutes, universities and within project consortia, the awareness of IP issues is low and must be increased. For instance, WIPO is running a project on improving the awareness in the IP system in Finland and promotes a rather holistic IP perspective. The preparation of guidelines for different IP strategies (licensing and model license contract, value of the patent, internal and external exploitation, background and foreground knowledge) would help facilitating the technology transfer and improve the exploitation of results. The exploitation of results should be discussed before the start of any collaborative project. The analysis should be focused on the identification of potential IPR issues inside the consortia (between partners) as well as related to the use of knowledge after the end of a project. The patent offices support this by an in-house service for prior art search.

Best practice should be shared between patent offices. In addition, information exchange with patents offices in the developing countries is essential. The definition of examination criteria should be re-evaluated in developing countries if needed. Standards for patentability of inventions (especially of up-stream inventions) should be developed, including the limits. In order to avoid further divide of South and North, harmonisation of IPR is essential. This is not only important in order to support technological and economic development in less industrialised countries, but also in anticipation of the increasing technological and economic significance of some of them in the future.

There were concerns expressed by some that nanotechnology could continue the tendency of privatising nature, by patenting smaller and smaller parts of it. Opposition to granted patents from public interest groups (such as ETC Group) can easily take 10 years or more between submission of the opposition and opening the case at the relevant court. In addition, nanotechnology research is heavily publicly financed but privately held. For example, as a consequence of the Bayh-Dole Act in the USA from 1980, 19 out of 20 nanotechnology patents owned by universities between 2003 and 2005 were licensed exclusively. This share shows that exclusive licences seem to be the normal case, which could prevent further progress of the technology. However, it was also mentioned that the licensing strategy can be well regulated by the market.

Many of the topics discussed were identified as not nanotechnology specific, but rather general for all emerging technologies.

3. Results from the discussions

The discussions have been structured along three lines of discussion, i.e. the monitoring system for nanotechnology patents (3.1), the demand for a new patent regime in nanotechnology (3.2) and lessons to be learnt for research collaborations (3.3). Each

discussion line has been introduced by a list of questions which helped to approach the main aspects of the discussion.

3.1 A monitoring system for nanotechnology patents

Following questions were discussed

- Is the 'patent monitoring system in nanotechnology' of the patent offices sufficient? How can it be improved? Who could contribute? Or do we need a different nanotech patent monitoring system? Who should do it?
- Is there a need for a common definition, terminology and classification of nanotechnology for searching and patent examining purposes?
- Do the criteria 'novelty' and 'inventive step' differ in nanotechnology compared to other technologies?
- Do patent examiners have to be trained specifically for this multidisciplinary technology? What do they need to know?

A patent monitoring system for nanotechnology can serve several purposes. It could provide an advanced search facility for patents granted in the field of nanotechnology, but ideally it should also facilitate more pro-active analyses on state of the art and future developments for technology analyses and policy recommendations. For these purposes, the monitoring system has to offer well elaborated quantitative search facilities and should be accompanied by regular data analysis.

The EPO approach with the Y01N tag and the USPTO's class 977 help to identify the nanotechnology patents but they have to be further elaborated in order to allow quantitative analyses. The Y01N tag and the 977 class haven't changed the criteria of patent examination, but were introduced for easier identification of nanotechnology patents and to facilitate more reliable search in the pool of patents. The patent offices have a natural interest in providing transparency about their results. Combined with their needs to foresee future developments in order to employ adequately qualified and a sufficient number of patent examiners, and to have a system at their disposal that allows advanced prior art search for patent examining purposes, this is a strong argument for the patent offices to provide tools for monitoring purposes.

While the current steps towards a nanotechnology patent monitoring system at the different patent offices are promising, further harmonisation of examination and identification of nanotechnology patents world wide is needed. The OECD has developed a system for quantitative patent analyses (PATSTAT), which is already running, but which has not yet identified nanotechnology patents. EPO and OECD cooperate on the introduction of the Y01N tag into the PATSTAT statistics. Once this is achieved, the PATSTAT could become the major tool for quantitative patent analyses in nanotechnology, which cover all world regions and which provide comparable data and methodologies. Whether this system allows forecasting exercises that exceed pure ex-post overviews has to be proven.

Thus, a patent monitoring system in nanotechnology is already on its way. It remains questionable whether the pure patent data should be taken into account or whether additional indicators such as market and company data should be included. At this stage of the development, it appears more advisable to focus on patents, in order to allow patent specialists to work with it and to develop it further. However, data on licences would be an added value to the analysis of the patents. Usually, the patent offices do not have such data, but it has been reported that the database of the French Patent Office (INPI) provides data on licences (via the host Questel-Orbit). This has to be explored and if possible taken into consideration for the nanotechnology patent monitoring system.

In order to assess the quality of such a monitoring system, the classification and tagging strategies for nanotechnology patents should be analysed and if needed revised. The EPO and the USPTO have offered seminars and outreach events and have sent out questionnaires in order to get input and feedback to their classification exercises. This assessment could also be done by experts outside the patent offices who provide both expertises in patent analysis and from the nanotechnology field. A report on such a patent survey, written by Martin Meyer (SPRU Brighton), will be published end of this year. The report reveals that the search strategies differ considerably between the different hosts of the databases. In addition, it shows that the terminology in nanotechnology, in particular in nanotechnology literature, is very dynamic and cannot be determined in a unique, standardised terminology.

The question of an appropriate definition of nanotechnology raises some more controversy. On the one hand, some experts consider the definition by the US' National Nanotechnology Initiative and applied by the USPTO as being inappropriate. For instance, the limitation to the size (below 100 nm) is somehow artificially biased towards nanomaterials and does not fit to reality in disciplines such as nanobiotechnology. On the other hand, the problems connected with this definition decrease if the field is broken down to nanotechnology subfields, which would avoid many of the controversies related the overall definition of nanotechnology. In addition, a common, unique terminology for nanotechnology as such does not seem to solve the problems connected with the particularities of specific nanotechnology subfields.

In order to increase the quality of the patent examining process, the training of patent examiners at EPO and USPTO has to be continued, also in order to compensate the lost of knowledge connected with high exit rates of patent examiners at the USPTO. Annual meetings with patent applicants and multidisciplinary training in patent academies (or in house education) with lectures on technological and legal aspects are good practices. Patent offices welcome any initiative for further education of their examiners, e.g. by patent attorneys and researchers. The above mentioned survey on the classification exercises in nanotechnology could also be used as reference for further improvement of the patenting process.

3.2 Towards a new patent regime in nanotechnology?

- Does the protection of IP in nanotechnology have to be changed? Is there a need for a new patent regime?
- If yes, how shall it look like and how can it be established?
- How to treat fundamental patents in nanotechnology?
- How to treat university patents which lack a proper exploitation strategy?
- Will business strategies change, away from patenting to non-disclosure, and what would this mean for the nanotechnology patent system?
- Will patent pools, cross-licensing agreements or non-exclusive licences solve the problems?

Different patent regimes occur in the US and in Europe, thus it has to be carefully examined which parts of them are under discussion. For instance, the lack of a grace period in Europe - compared to the US – may lead to a loss of rights in Europe and also prevents early disclosure of an innovation. The lack of a grace period implies at least 18 months of confidentiality of a patent application, representing the time from filing the application to its publication. This is a major concern of some patent applicants in this technology because it prevents the earlier dissemination of new developments e.g. by publishing the results at a conference before filing the patent applications or transferring the technology.

Trade secrets can be an alternative to patents, but they are limited because universities, public research institutes and SMEs usually do not have the motivation for keeping their research secret. This is due to the fact that they need partners for exploiting the research commercially or for acquiring venture capital. However, signing trade secrecy agreements before applying for a patent could be a solution for bridging the time between invention and exploitation. This strategy may lead to problems in the US, in view of its first-to-invent system and certain jurisprudence that prevents an applicant from maintaining a trade secret and later applying for a patent, while in Europe, patented know-how can be substituted by the non-disclosure contract.

A high pendency rate is prolonging the time between application and granting. However, this rate of currently about 48 months for nanotechnology patents at the EPO is not necessarily due to slow treatment by the patent examiners. It is sometimes in the interest of the applicants to slow down the process in order to postpone the payment for the translations (in the EU) and to keep the status of the patent application pending. A patent application with with a pending status can discourage competitors from entering the field, even if a patent may not ultimately be granted on the application. A change of incentives towards rapid examination would be needed.

Fundamental (structural) patents are difficult to be identified and thus any special treatment cannot be implemented. In addition, if the claims are justified, the inventor should benefit from pioneering the field. Compulsory licences could be a solution, but they are rarely used (for instance, Germany is unable to apply compulsory licences while the Netherlands are liberal to them) and should be approached with a high degree of caution due to their impact on innovation and disclosure of new technologies.

However, problems connected with a lack of exploitation of fundamental patents could be solved by cross-licensing or non-exclusive licensing.

Universities are the main applicants of fundamental patents due to their basic research activities. A special approach for patenting can be observed. Patents addressing the beginning of the technology are often deliberately pending because usage is not clear yet. This is also because universities usually lack funding for patenting. Once granted, these fundamental university patents should, according to some, be exploited only through non-exclusive licences. On the other hand, patent applications by universities at the end of the product life cycle should be timely granted. This is essential for spin-offs and SMEs and a prevailing strategy could be the issuing of exclusive licences. Universities should be provided with clear guidelines for their patenting and licensing strategies.

Despite all these arguments in favour of changing the regime in terms of conventions, incentives, guidelines, laws, etc., when it comes to patents, Nanotechnology does not differ much from other technologies. Most problems described above and in the literature (‘patent thickets’, ‘patent land grab’, 'overlapping patents', ‘patent battles’, ‘monopoly patents’ etc.) apply to other technologies as well. The experts agree that there is no need for a new patent regime in nanotechnology, as long as the patent offices make sure that only high quality patents are granted.

3.3 Consequences for research collaborations

- Which lessons can be learnt for IPR agreements of European projects and other research collaborations?
- Is there a need for a special treatment of nanotechnology research collaborations, compared to other technologies?
- How to develop new standards for the protection of IPR and models for consortium and licensing agreements?
- Which business strategies will prevail? How can conflicts between partners (e.g. university vs. industry) be solved?
- Which consequences will this have for SMEs and start ups?
- Which role can the funding agencies (e.g. EC) play?

The awareness of IPR issues is insufficient, especially at universities and public research institutes, but sometimes also at SMEs. In addition, patenting and licensing strategies differ between sectors. For instance, while there is a tendency to cross licences in electronics, the pharmaceutical industry tends much more to exclusive licenses. This is in particular a problem for nanotechnology licence agreements, which are – because of nanotech’s interdisciplinary nature - on the crossroad between these sectors.

At earliest possible stage of a project, i.e. the proposal phase, negotiation phase or the project's start, possible IPR issues (partners’ needs and project’s needs) should be

identified and a prior art search should be carried out. There are possibilities to use services offered by the patent offices or by independent IPR experts. (In return, research projects should offer training to patent examiners on their topic.) IPR agreements should be balanced and realistic and should provide individual solutions on a case-by-case basis. However, more general discussions of new IP models should be opened, which can avoid lengthy negotiation.

The negotiation on IPR is very difficult with many partners, so smaller projects with fewer partners have an advantage. Experience shows also that a good composition of the consortium along the value chain (basic research – applied research – production – commercialisation) can ensure an adequate IPR strategy and enables technology transfer.

Guidelines for licence agreements and model licences in nanotechnology fields with high interdisciplinarity are needed as well as analyses of best practices in terms of exclusive vs. non-exclusive licences, non disclosure strategies (trade secrets), patent pools etc. For improving the patent system, the OECD has developed guidelines for biotechnology patents, issued report on access to patented knowledge, on IPR and the internet, on licensing, and on innovation strategy for OECD countries.

4 Conclusions

The great interest in this international workshop, also outside the group of participants, has proven the relevance of the IPR in nanotechnology topic. IPR will be a success factor for industry and research centres for further competitiveness in this highly dynamic and important field and will therefore shape the further development of nanotechnology. However, many IPR issues, which have been identified as crucial for the development of nanotechnology, are valid for many if not all other technologies as well. It was a challenge to concentrate in issues that are specific to nanotechnology and can therefore be tackled by nanotechnology stakeholders. This explains why more general aspects of IPR such as the cost of patenting or the demand for a Community patent (as it is the case in the European Union) were deliberately excluded from the discussions.

The focus on the three discussion lines (nanotechnology patent monitoring system, nanotechnology patent regime, lessons for research collaborations) turned out to cover the topics discussed in the IPR and nanotechnology community adequately. Some recommendations could be derived from the discussions, which can serve as a valuable input to follow up activities by (research) policy makers and by the patent offices.

The experts agreed that the ongoing activities for classifying nanotechnology patents lead into the right direction and should be continued and expanded. Patent applicants should train patent examiners in their fields of nanotechnology research. There is no major need for a common, unique definition for patent examining and application purposes if nanotechnology is broken down into subfields and only these subfields

would be compared. This can overcome differences in definition and would help to better identify important fields. A common, unique terminology, although beneficial for patent applicants, examiners, analysts and users, is unrealistic for a new and dynamic technology like nanotechnology and cannot be imposed on patent applicants.

In general, it can be said that, when it comes to patents, nanotechnology does not differ much from other technologies. Most problems described in the literature (‘patent thickets’, ‘patent land grab’, 'overlapping patents', ‘patent battles’, ‘monopoly patents’ etc.) apply to other technologies as well. The experts agree that there is no need for a new patent regime in nanotechnology, as long as the patent offices make sure that only high quality patents are granted.

In collaborative projects, IPR issues (partners’ needs and project’s needs) have to be addressed at earliest possible stage, e.g. by involving an independent IPR expert in the set up of the project. Research projects should offer training to patent examiners on their topic. A good composition of the consortium along the value chain (basic research – applied research – production – utilisation) can ensure an adequate IPR strategy and enables technology transfer. Guidelines for licence agreements and model licences in nanotechnology fields with high interdisciplinarity are needed as well as analyses of best practices in terms of exclusive vs. non-exclusive licences, non disclosure strategies (trade secrets), patent pools.

Harmonisation activities between patent offices are ongoing, but limited due to different approaches, rules and traditions. Less industrialised countries encounter similar problems in IPR, thus networking between them (‘South-South’) is a first step to find solutions. ‘North-South’ cooperation is needed as well, especially on how to apply patents at the ‘Northern’ patent offices.

Annex I: Political requests to the European Commission on IPR in nanotechnology

Results from open consultation on the European strategy for nanotechnology:

This consultation has been carried out in order to collect feedback and suggestions for concrete actions for the European strategy for nanotechnology, resulting in an Action Plan on nanotechnology (http://cordis.europa.eu/nanotechnology/actionplan.htm). About 750 nanotechnology stakeholders mainly from Europe have answered. The report (see http://www.nanoforum.org/dateien/temp/nanosurvey6.pdf?20122004094532) presents all answers, including some feedback on patents and IPR in nanotechnology.

a) Patenting/IPR issues

- Realise a strong, affordable and harmonised IPR regime throughout Europe. This can be done by introducing the **Community Patent** and/or **strengthening the European Patent System**. The **costs** of applying for and maintaining a patent must be made cheaper in Europe compared to the US and Japan.
- Have an **EU level body concerned with patents** - ideally researchers could contact them, provide the material, they could handle all the patenting issues, and could be partly or fully self-funded by taking a small percentage of income from the resultant patents.
- Change the patent **laws to be in line with those of the US**. I.e. you can publish and still protect IP retrospectively. Current UK patent laws make IP exploitation extremely difficult in start ups/SMEs compared with the US.
- Some kind of academia-industry '**IP and know-how transfer fair or web-site**' could be helpful, if connections made at that place are followed up with some kind of **EU exploitation support scheme**.

b) European projects / EU Framework Programme

- **Improve IPR rules** in EU projects
- Involve specialised (even small) companies in R&D public/private consortia to look for **fast exploitation of the results**, with special granted license agreement (e.g. few years at discounted fees; supporting labs for quality-reliability-health verification; reduced submission costs for shared patents...)
- Easier negotiation of IP, one of the biggest problems is often the **negotiation of consortium agreements**. There also often problems with multinational companies which have a strong presence in Europe but are based in USA. These are sometimes classed at non EU and therefore are not eligible for funding and so drop out of European research projects.
- "Patent applications for academic institutions are practically impossible, because the **costs of patenting** can't be covered from the project budget when the project is finished."

- "IPR is key issue; even more difficult with **different industry sectors** (e.g. pharma and ICT) within a project. The projects are demanding (more demanding than national programs)."

c) Risks and regulation
Health and safety issues, toxicology, risk management/assessment, and establishing regulation were highlighted as crucial issues for which more R&D is needed. A wide span of views were given include one respondent who asked for "A complete moratorium on lab-research until compulsory safety protocols are introduced; and a strict **"no patents" policy on new molecules**." Among those who are positively minded towards nanotechnology, the **patenting issue was addressed by asking for "one EU patent".**

Opinion of the Economic and Social Council (EESC) on the European strategy and the Action Plan on nanotechnology:

*The EESC has welcomed the **European strategy for nanotechnology** in its session on 15 November 2004.*

8.7 Researchers must be certain that their **intellectual property is protected**, particularly in such a sensitive field. The EESC believes that solving the patenting issue in a clear and satisfactory way is a top priority if the success of applied research in the field of nanotechnology is to be secured. No time must be wasted in establishing a **European-level Nano-IPR helpdesk**, to meet the needs of researchers, companies and research centres.
8.8 The Commission, in conjunction with the Member States, must step up its efforts and promote in-depth studies in universities and research centres, to ensure that the patenting process appears feasible, with **straightforward and inexpensive procedures**, particularly in such an innovative sector.
[…]
8.9 Alongside and in connection with the European forums, there should be a number of worldwide forums, open to UN countries, and able to deal with issues relating to patents
[etc.]

*The EESC has welcomed the **Action Plan on nanotechnology** in its session on 28 March 2006:*

1.3.5 The Committee believes that European industry should expand and intensify N&N research and application efforts, increasing investment to levels at least equal to those of its more advanced competitors. This could be achieved by means of the following actions: […] creation of a **common framework** for technical standardisation and **intellectual and industrial property**.
2.3 In order to achieve this, there is, in the Committee's opinion, a need to:
• **adjust** normative and **patent systems**,
[…]

3.2.7 The Commission should facilitate industrial exploitation by introducing the following by 2007, under the FP7 N&N work programme:

- a **Nano-IPR Helpdesk**, as proposed by the EESC in its previous opinion on N&N;
- a **European clearing house for** exchange of best practices and **monitoring of patents** and new applications on the world market;

[…]

3.5.3 The Committee is convinced that this approach, which advocates **strong business involvement**, is vital to N&N research and development and application, provided that arrangements are made for support actions at European, national/regional and, most of all, the joint level, aimed at:

- sounding out, in a clear and predefined way, the **opportunities and limits of industrial and intellectual property** to guarantee a **proper balance between cooperation and competition**; production confidentiality and the dissemination of N&N-related progress, publication and free movement of new knowledge within the European and international scientific community, and **protection of intellectual property rights**;

Statement of the European Parliament (EP) on the Action Plan on nanotechnology:

The EP has endorsed the Action Plan on nanotechnology in its session on 27 September 2006. The resolution includes following topics related to IPR and patents in nanotechnology:

The European Parliament

14. […] considers that the protection of intellectual property rights is essential for innovation, both in terms of attracting initial investment and for ensuring future revenue; calls on the Commission to develop **standards for the protection of intellectual property rights** and **models for licensing agreements**;

15 Regrets the fact that patenting of nanoscience and nanotechnology inventions in Europe is developing slowly; calls on the EU to **create a nanoscience and nanotechnology patent monitoring system governed by the European Patent Office**;

16. Encourages **general reforms in the field of the European patent system** in order to **cut the costs of patenting** and to **improve the accessibility of patents for SMEs;** stresses the **need for greater transparency** and **clear limits to the scope of patent protection;**

Annex II: List of participants of the IPR in nanotechnology workshop

Name	Organisation
Bawa, Raj	Bawa Biotechnology Consulting and Rensselaer Polytechnic Institute, Troy, New York, USA
Blackman, Michael	World Patent Information (WPI), UK
Calles Sanchez, Alfonso	European Commission – Internal Market DG, Brussels, Belgium
Caocci, Mauro	CIMATEC, La Spezia, Italy
Chamas, Claudia Ines	Oswaldo Cruz Foundation (Brazilian Ministry of Health), Rio de Janeiro, Brazil
Cimniak, Thomas	BASF, Ludwigshafen, Germany
Dambois, Denis	European Commission – Research DG, Brussels, Belgium
Eloshway, Charles	US Patent and Trademark Office (USPTO), USA
Frycek, Rudolf	European Commission – Research DG, Brussels, Belgium
Gaster, Jens	European Commission – Internal Market DG, Brussels, Belgium
Guellec Dominique	OECD, Paris, France
Harrison, Robert	24IP Law Group, Munich, Germany
Holtmannspötter, Dirk	Association of German Engineers (VDI-TZ), Düsseldorf, Germany
Hullmann, Angela	European Commission – Research DG, Brussels, Belgium
Kallinger, Christian	European Patent Office (EPO), Munich, Germany
Meyer, Martin	SPRU Brighton, UK
Passino, Sean A.	Foley & Lardner LLP, Washington, DC, USA
Perschke, Wawrzyniec	European Commission – Enterprise DG, Brussels, Belgium
Pitkethly, Mike	CENAMPS, Newcastle upon Tyne, UK
Rip, Arie	Univ Twente, Enschede, The Netherlands
Ryckaert, Vincent	IMEC, Leuven, Belgium
Scheu, Manfred	European Patent Office (EPO), The Hague, The Netherlands
Singh Jaiya, Guriqbal	World Intellectual Patent Organization (WIPO), SMEs Division, Geneva, Switzerland
Tomellini, Renzo	European Commission – Research DG, Brussels, Belgium
van den Broeck, Kristel	IMEC, Leuven, Belgium
van Velzen, Maaike	Philips Intellectual Property & Standards, Eindhoven, The Netherlands
Wetter, Kathy Jo	ETC Group, Carrboro, North Carolina, USA