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Intellectual Property and Science: A Complex Partnership

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Growing importance of intellectual property rights in the global knowledge based economy

During the last ten years, intellectual property rights, *i.e*. patents, trademarks, copyrights or, for instance, design rights, have gained an economic importance, which is unprecedented in their long history. If one takes patents as potentially most important and statistically relatively easily ascertainable category of intellectual property rights, the number of patents granted and patent applications filed, for instance in the USA has doubled in the period from 1988 to 1998 to 160.000 patents granted, and 260.000 applications filed, respectively. For the European Patent Office these data are even more impressive: The number of patent applications doubled in only six years, from some 80.000 in 1995 to more than 160.000 in 2001. Maybe most impressive data come from the People's Republic of China, where in 2003 more than 300.000 patent applications were filed.

Very impressive are also data concerning royalty payments for patent licenses in the USA: They increased from 3 billion US $ in 1980, to 15 billion US $ in 1990, and already in 1997 left behind the magic mark of 100 billion US $. The growing importance of intellectual property rights is also revealed by the fact that whereas in 1982 commodities accounted for some 62% of the market value of the US manufacturing industry, their share by 1998 fell under 30%. Figures available for high tech industry in Japan indicate that commodities account for less than 20% of the market value of respective industries. In other words, the so-called intangibles, *i.e.* inventions, trademarks, literary, artistic and scientific works, know-how, etc., which are to a large extent covered by intellectual property rights, account for 70-80% of the market value of stock exchange quoted manufacturing industry.

The reasons for this development can be seen, on the one hand in the rapid progress of science and technology, especially communication and

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information technology and biotechnology, which led to the establishment of new knowledge based industries and the penetration of new areas of technology, such as life sciences by intellectual property rights, and on the other hand, and possibly even more decisive, in the impact, which the establishment of the World Trade Organization (WTO) in 1994, with the new General Agreement on Tariffs and Trade (GATT 1994) and the International Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) had on global economy. Whereas GATT 1994 resulted in gradual opening of international markets, TRIPS introduced, especially in the area of patents, for the first time in the history, mandatory international standards for the protection of intellectual property rights. In particular, under TRIPS patents must be available in all WTO members for inventions in all fields of technology. Developments following the establishment of WTO are characterized not only by the globalisation of markets, but also by globalisation of research and development.

Academic science as generator of intellectual property rights and innovation - US universities as an example

The growing importance of intellectual property rights, especially patents, for innovation and economic development in general, is also reflected by policies which the US law maker has adopted since 1980 when the Bayh-Dole and Stevenson-Wydler Act entered into force. The Bayh-Dole Act explicitly allowed intellectual property rights to be retained by the recipients of public funds, be it universities or other research institution, and to grant for such rights exclusive licenses. This was a quasi-revolutionary departure of the former US approach, which did not allow for exclusive licensing of the results of publicly funded research, but which ended up in thousands of non-exploited patents. The Stevenson-Wydler Act introduced offices of research and technology applications with all publicly funded institutions, which have an annual research budget of more than 20 million US $. In 1986, the Federal Technology Transfer Act followed. Under this Act it is required that publicly funded research results are exploited through so-called Cooperative Research and Development Agreements (CRDAs). This new US legislation is based on the belief, first, that imagination and creativity are national resources of utmost importance, then, that the patent system facilitates and permits the delivery of that resource to the public, and, finally, that placing the management of publicly funded research results is in the public interest. The US lawmaker has realized that the then existing Federal patent policy was to the disadvantage of the USA in a time when innovation was becoming the preferred currency in international trade. Thus, activating the innovation potential of the publicly funded research and integrating it into national economic policy as an important factor for increasing the US competitiveness in the global economy is to be viewed as one if not *the* driving force behind the new US approach.

Notwithstanding the differences which exist in assessing the economic impact of the new US legislation and also notwithstanding the criticism frequently expressed on the impact, which this legislation has on publication behaviour of scientists, *i.e.* the increased tendency to secrecy and less exchange of information, which cannot be analysed and discussed in detail here, the statistics concerning the patenting and licensing activities of US universities speak a clear language.

In 1974 US universities owned 177, and in 1984 408 patents, respectively. In 1994 that figure was 1,486 and in 2001 3,721 patents issued to US universities. In 2001 US universities filed 11,265 patent applications and granted 4,058 new licenses and options, of which 62% to small businesses. In the same year 2001, the US universities had some 1.07 billion US $ adjusted gross license income, out of 9,707 licenses and options. This resulted in creation of more than 300,000 new jobs, some 494 new companies and an overall economic activity of more than 30 billion US $. The total number of companies based on university license reached in 2001 3,870. It goes without saying that the license income of US universities, measured against their research budgets is not substantial, but the overall macro-economic impact of university licenses, especially also in strengthening the global competitiveness of the USA, cannot and may not be underestimated. In some areas of technology, such as for instance genetic engineering and in particular patenting of DNA sequences US universities, such as UC California System, Johns Hopkins, Harvard and Massachusetts Institute of Technology (MIT), but also US Government's Agencies, such as NIH, USDA or DOE, have overtaken or are on par even with the leading companies in the field, such as Incyte Pharmaceuticals or Human Genome Sciences (HGS), in numbers of patents issued. A great number of important drugs, such as Hepatitis B vaccine (University of California and University of Washington), synthetic Penicillin (MIT) metal oxide process for Taxol production (Florida State University), Prostate specific Antigen (PSA) test (HRI/Roswell Park Cancer Institute), or the recombinant DNA technology

(Stanford University and University of California, San Francisco), originate from academic environment.

For the successful activities of US universities in exploiting research results, however, not only the Federal legislation reported has been instrumental, but also the generally liberal approach toward patentability of new research achievements, such as DNA sequences, tissues, micro-organisms, plants and animals but also computer programs and business methods (according to the US Supreme Court "everything man-made under the sun" is patentable), and the fact that the US patent law provides for a grace period of one year, which enables researchers to successfully apply for a patent also in cases in which they have already published the research result at issue, *i.e.* the invention to be patented. Moreover, the cheap US patent granting procedure, interested and available venture capital and the large US domestic market were also instrumental. In case of pre-published inventions, patent protection can be successfully thought in the US and some 30 other countries, but not in Europe, where no general grace period exists and where publication of a research result, as a rule, automatically leads to loss of proprietary rights in it.

Although also in Europe non-industrial research institutions, such as the German Max Planck Society for the Advancement of Science with its Garching Innovation GmbH, or the British Technology Group (BTG) and the University Directors of Industrial Liaison of the United Kingdom, and more recently also universities in Germany and other countries have engaged in patenting activities and exploitation of research results, Europe is lagging far behind the United States. Judged on citations in US human genetic patents, the share of European Scientists in generating new knowledge is greater than the share of Europe in appropriating the knowledge it generates. 62.2% of citations in those patents originate from USA, 6.4% from United Kingdom, 4.8% from Japan, 2.9% from France and 2.5% from Germany. However, 71.2% of those patents are owned by the USA, 12.3% by Japan, 2.8% by United Kingdom, 2.5% by Germany and 1.8% by France.

Public awareness of the role of intellectual property rights for innovation and economic development

Whereas the United States of America has adopted a so-called 21st Century Strategic Plan to create an organization worthy of the unique role intellectual property plays in the American and global economies, and which takes a global perspective by envisioning the patent and trademark system of that American innovation would need to remain competitive around the world, and whereas Japan has established a new Strategic Council on Intellectual Property, directly attached to the Prime Minister's Office, whose aim is to develop basic intellectual property policy directions, including creation strategies, such as creation of intellectual property in universities, public research institutions, etc., or strategic creation, acquisition and management of intellectual property in companies, in Europe a wide-spread distrust towards patents in general and patents in modern technologies more specifically, seemingly prevails. This is demonstrated, for instance, by the fact that the Directive 98/44 of July 1998 on the Legal Protection of Biotechnological Inventions, is still awaiting its implementation into national laws of more than half of the 'old' EU-Member States, despite the deadline of July 30, 2000, and also by the resistance which the proposed Directive on the Patentability of Computer-Implemented Inventions was faced with in the European Parliament in September 2003 and is still facing in discussions across EU Member States. In case, the 118 amendments proposed by the European Parliament for the Directive on the Patentability of Computer-implemented Inventions, were adopted by the Commission and the Council, no patents would be available in Europe for, for instance inventions of Automatic Breaking Systems (ABS), of Electronic Stability Control (ESC), or Electronic Traction Control (ETC), *i.e.* the core innovations in the car industry. Moreover, patents in this area of technology would become practically unenforceable.

In addition, the functioning and the present design of the intellectual property rights system have been put into question under a number of aspects by the Report 'Integrating Intellectual Property Rights and Development Policy' submitted by the Commission on Intellectual Property Rights of the Government of the United Kingdom (2002), by the Report of the Royal Society 'Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science' (2003), and, in part, also by the Report 'The Ethics of Patenting DNA' of the Nuffield Council on Bioethics (2002). Apart from some balanced proposals for revising the patent law, for instance by clarifying the rule of research exemption, for introducing a grace period and for the establishment of the long overdue Community Patent, these reports predominantly criticize the expansion of patentable subject matter, the imbalances of the international regime as regards developing countries, the weak examination standards, too broad claims and in general too high costs of the system. Neither report, however, contains any specific proposal for integrating the academe into the innovation process, as is the case in the United States of America and Japan.

Can Europe afford its approach toward intellectual property rights?

The present debate in Europe on the importance and economic impact of intellectual property rights on innovation and science, be it in the European Parliament, or a number of national parliaments, be it in many, although not all, academic fora, which may, at best, be characterized as being sceptical, seemingly disregards the role, which intellectual property rights started to play on investment in research and development since the adoption of the new GATT-TRIPS regime. The combination of high intellectual property standards, guaranteed by TRIPS, and the liberalized commodity and intellectual property world markets, guaranteed by GATT, especially as far as technology markets are at hand, further combined with low labour and regulatory costs, reliable judiciary, predictable and stable political environment, as well as well functioning education systems, has become irresistible for multinational companies to relocate not only production sites to such parts of the world, but also to shift research and development activities to such countries. China, Taiwan, India, Malaysia, Singapore, but in part also Brazil, are prominent examples. Not only have these countries improved their export capabilities, but by all means also local R & D skills. There can be not doubt that the Tiger states of South-East Asia have successfully coped with globalisation and have massively narrowed the welfare gap. Most impressive statistics exist for China: The R & D personnel have grown from 781,000 in 1986 to 1,035,000 million in 2002. China has increased its investment in research by percentage of Gross Domestic Product from 0.60% in 1995 to 1.23% in 2002 and thus has already overtaken countries like Italy (investing 1.1%). In 2003 the investment in research of China amounted to some 69 billion US $. Self-explanatory is also the fact that by 2003 foreign firms have established more than 200 research and development laboratories in China in the computer and telecommunications sector alone. Notwithstanding the question of ownership of intellectual property rights involved, establishing of research and development laboratories in China, by necessity, results in knowledge and technology transfer to Chinese employees of those laboratories. Even the best employment contracts will not prevent them to keep and use that knowledge even after leaving the respective company. The new patent system, which China has established in the 90s has been viewed as the corner stone of science and technology development, which has enabled China to participate in the world's intellectual property markets.

Thus, no doubt should exist in the fact that opening of technology markets combined with high standards of intellectual property rights protection, low labour costs and solid education, as well as stable political regimes have already redirected the flow of investment in research and development away from Europe. However, not only into India and East Asia, but also into the United States. German Investments in the US in 2002 alone amounted to 150 billion €.

In this new global economic environment Europe cannot claim a status of an island of happiness but has to fully comprehend to be a part of the competitive world. In order to avoid a weakening of its competitiveness in global economy, Europe can neither afford to lag behind its competitors in investing activities in research and development, nor to put into question the benefits of an effective protection of results of its creativity, on which its wealth at present is still based upon. Political declarations, such as that of the Lisbon summit, targeting 3% of Gross National Product as investment in research and development by the year 2010 may not remain empty promises, far away of having a chance to be achieved, should Europe not be seriously harmed. Should this happen, the economy will suffer and the science will experience a draw back, since one cannot have healthy science in a sick economy (Sir Charles Carter - 1983).

It should, however, be added that the academic community is co-responsible for Europe's competitiveness and therefore has to take up this challenge and responsibility. It has to understand that knowledge and application of knowledge constitute main assets of Europe in global competition and that it is the academe that generates an essential part of that knowledge. Moreover, it has to understand that innovative application of new knowledge requires huge investments and that such investments require adequate protection, *i.e.* presuppose that the new research findings are covered by intellectual property rights. This all despite the fact that intellectual property rights in general and patents in particular may not simply be viewed as an innovation panacea and can well have also a negative impact on scientific developments, especially if the patent protection is not adequately adjusted to the needs of non-industrial research, whose undisputed primary goal is enrichment of knowledge and its early dissemination. However, always also taking into account the legitimate interests of those who are financing research, *i.e.* the tax payers.

European academe, therefore, should adopt a critical but realistic approach towards intellectual property and should, at least for the time being, follow, although not necessarily copy the US model, *i.e.* use intellectual property rights for effectively protecting its research results. As long as US universities and other publicly funded research institutions follow or have to follow the Bayh-Dole and Stevenson-Wydler design, resulting in appropriation of their research results, a policy now also adopted by Japan, undocking from such a trend can only lead to disadvantageous imbalances to the detriment of Europe. Those who criticize the US-approach and warn Europe to follow, simply disregard this aspect, no matter whether other aspects of criticisms are justified or not.

Improvements needed

In order to enable itself to properly cope with the challenge, European academic community should insist in getting legal conditions, which will secure generation, dissemination and appropriation of knowledge. For instance, it should insist in a flexible approach as regards patentable subject matter, such as computer-implemented inventions, or results of stem cell technology, etc. Instead of discussing and attempting to introduce new exceptions to patentability into statutory rules, European lawmaker should trust into the wisdom of the courts. It is undisputed that the USA has, by and large, made a good experience with this method. Of course, Europe is in need of at least a central patent court of last instance, which would secure an EU-wide harmonized interpretation of, *e.g.* patentability requirements and scope of protection. Europe is also in need of a simple and cost efficient Community Patent system, overdue already for decades. There is no doubt that the academic community would greatly benefit from such a system. More specifically, the academe should also insist in the introduction of a general grace period along the lines elaborated in the Directorate General XIII of the EU-Commission, which, for unknown reasons seemingly ended in a drawer. This is difficult to understand and accept, since the envisaged system would clearly take into account the interests of all parties involved in a very balanced way. It would, for sure be in every respect a progress as compared with the present legal situation, and would, if prudently used, facilitate early publication and exchange of information without depriving scientists and their institutions of the chance to appropriate the exploitation of the disseminated knowledge. Another point, which needs further clarification, is the scope of the experimental use exception. Although most national patent laws in Europe, unlike the law of the United States of America, dispose of a statutory experimental use exemption, its scope is not yet but should be clarified. Last, but not least, the European lawmaker should also be invited to introduce a European statutory framework, which would enable universities and other publicly funded non-industrial research institutions to effectively exploit and protect their research results. Bearing in mind that the Gross National Product of the new European Union is by all standards comparable with that of the United States of America and even more so with that of Japan, investment in research and development in the EU should not be lagging behind that of its competitors. Likewise European universities and other non-industrial research institutions should play a similar role in the innovation process as their counterparts overseas. It is high noon for Europe to realize that creativity, generation and innovative application of new knowledge are its most important assets in global competition, and the research community their primary source. In order to perform properly this source is in need of adequate financial support, as well as of the necessary respect of the society for its achievements. Lip services cannot substitute investment and never ending questioning of the social benefits of new scientific achievements is no incentive for pioneering research and its exploitation. Europe is in need of a new culture, which would rank science and research highest and view intellectual property rights as their complement, necessary for thoughtful appropriation and sustainable innovative exploitation of new knowledge.