BIO DEUTSCHLAND

Position paper of BIO Deutschland

concerning

the introduction of a grace period in Europe

1. Summary of the main findings of the position paper

The sector association of the biotechnology industry, the Biotechnologie-Industrie-Organisation Deutschland (BIO Deutschland), calls for the introduction of a grace period with the following key elements:

- Duration: 12 months
- Scope: Any prior disclosure of an invention does not destroy novelty provided that it was directly or indirectly made by the applicant or his legal predecessor
- Territorial field of application: the European Union and the member states of the European Patent Convention

Germany's position as a hub of innovation is currently marked by ambivalence. On the one hand, its level of scientific and technological performance is very high, thanks to having an excellent research landscape and the highest proportion of innovative enterprises in the European Union.[1] On the other hand, it is falling short of its potential in terms of leveraging technology to create new products. Germany has not become less competitive in the race for innovation, yet other countries are proving to be far more dynamic.

Creating favourable framework conditions that foster innovation is therefore crucial to Germany's future success in the international competition to attract business investment. First and foremost, it is about quickly translating advancements in research and technology – especially in key areas such as biotechnology – into market advantages for the companies behind the innovations. This would require a competitive model of patent law, particularly at the EU level, that appropriately strengthens patent protection while countering the rising amount of intellectual piracy that is occurring in the form of counterfeiting and patent infringement.

An often neglected, but vital component of an innovation-friendly patent law is securing the results from basic research for real-world applications. Here there is a great deal of room for improvement concerning cases where inventors make novelty-destroying disclosures prior to the filing date.

A survey conducted by BIO Deutschland among its members revealed that 65% of these support the introduction of a grace period. In addition, patent research commissioned by BIO Deutschland shows that almost 7% of European and international patent applications filed by universities, research institutes and similar establishments that were published in 1999 and 2000 were subsequently abandoned or refused due to inventors making novelty-destroying disclosures in the 12 months preceding the filing date of the priority application and prior to the applicant being informed of the date of filing accorded to his application. This research does not include inventions for which applications were not filed at all due to the lack of a grace period. The number of these non-documented/non-researchable inventions for which applications were not filed due to the absence of patent protection in Europe is certainly high – probably at a similarly high rate as the proportion of patent applicants taking advantage of the grace period in the US (about 20%).

The introduction of a grace period in Europe, similar to that which has existed for a long time in other economically successful countries (e.g. in the US or Japan), can provide swift and cost-neutral relief. This holds significant potential for Germany in particular, as its strong basic research capacity generates numerous new ideas. In order to convert these scientific ideas into applications for the end-user, it is necessary to adequately protect research results.

Furthermore, recent legal developments in the area of clinical trials require data to be disclosed at an early stage, thus making it impossible to subsequently secure patents for the invention. This is another important reason for small and medium-sized enterprises (SMEs) and the pharmaceutical industry as a whole to help promote the introduction of a grace period in Europe (see further details in section 3.3).

[1] Eurostat press release, "Seventh Community Innovation Survey", 11 January 2013, http://epp.eurostat.ec.europa.eu/cache/ITY_PUBLIC/9-11012013-AP/EN/9-11012013-AP-EN.PDF.

The importance of cooperation between SMEs and large industrial companies is constantly growing in terms of overall economic significance. A study published by Accenture at the end of 2011 found that 60% of all innovations have their origins outside of large concerns. This proportion increases to 82% in the case of new biological therapeutics.[2]

Furthermore, the negotiations for a free-trade agreement between the US and Europe are giving added political momentum with regard to the strengthening of the international protection of intellectual property rights,[3] as the German Chemical Industry Association (VCI) also noted in a statement in 2013.[4] At the same time, the issue of international patent law harmonisation should not be left out of the debate on the introduction of a grace period in Europe (the US and Japan have such a system).[5]

For the reasons set out above, BIO Deutschland has developed a proposal that would incorporate the grace period in Europe into the existing legal system.

[2] Accenture, "The Future of Pharmaceutical Innovation – Tackling the R&D Productivity Gap", December 2011, p. 3.

[3] This has also been observed by the International Association for the Protection of Intellectual Property (AIPPI). Ehlers/Hahner/Henke/Königer, Report of the German National Group for AIPPI's Executive Committee meeting from 5-11 September 2013 in Helsinki, GRUR Int. 8-9/2013, p. 759 et seq.

[4] German Chemical Industry Association (VCI), "Questions and Answers from the Chemical Industry Regarding TTIP", 2 August 2013, p. 9.

[5] This issue was pursued by the signatories to the Agreement on Trade-Related Aspects of Intellectual Property Rights (known as TRIPS) as well as the World Intellectual Property Organisation (WIPO).

2. Introduction

Germany's position as a hub innovation is currently marked by ambivalence. On the one hand, its level of scientific and technological performance is very high. With 11% of all international patent applications that entered the national phase[6] and a 8.1% share of world trade,[7] the results of the German innovation system are impressive. German is the leader in mechanical engineering, has first-class vehicle manufacturing and environmental technology, and sets the pace in a number of other areas (e.g. renewable energies and laser, nano and medical technology). These achievements are the result of having an excellent research landscape and the highest proportion of innovative enterprises in the European Union.[8]

On the other hand, it is falling short of its potential in terms of leveraging technology to create new products. Germany has not become less competitive in the race for innovation, yet other countries are proving to be far more dynamic. As a place for research and innovation, Germany is no longer competing just with the US, Japan and Korean, but also with the new EU member states and the BRIC countries (Brazil, Russia, India and China).[9] This becomes particularly clear when one examines the patent applications of companies that invest a high proportion of their total revenues in research and development (R&D). While Germany ranks second worldwide in traditional high-tech industries such as automaking, mechanical engineering and chemicals (R&D intensity > 2.5%), it lags far behind in state-of-the-art technologies (R&D intensity > 7%), which also includes biotechnology. Here countries such as Korea, Japan, the US and China take up the top spots.[10]

Creating framework conditions that foster innovation is of vital importance to the innovative strength of companies. It is primarily about quickly translating advancements in research and technology – especially in key areas such as biotechnology – into market advantages for the companies behind the innovations. This would require a competitive model of patent law, particularly at the EU level, that appropriately strengthens patent protection while countering the rising problem of misuse that is occurring in the form of patent theft and closed markets.

A component of an innovation-friendly patent law that has not previously received much focus is the bridge between basic research and real-world applications. This holds significant potential for Germany in particular, as its strong basic research capacity generates a considerable number of new ideas. However, these ideas will only be developed further if comprehensive protection of intellectual property rights is ensured to such an extent that it corresponds to the economic investment of innovative enterprises that develop these ideas to marketability. There is no way around the introduction of a harmonised grace period in patent law at the European level if cooperation is to take place between research institutes and companies.

A study published already in 2001 by the Federal Ministry of Education and Research (BMBF) came to the following conclusion about the introduction of a grace period: "*Empirical studies in Germany and the US have shown that both countries face the same fundamentally competing objectives with regard to the commercial exploitation of research results: Goals of scientific research such as broad debate and the fast publication of research results come up against the requirement of patent to law to keep inventions confidential prior to the patent application. The universities in these countries deal with these competing objectives in different ways. In the US the grace period helps resolve these competing objectives. It is used on average in 22% of applications from the higher education sector. This means that the grace period plays a role in a significant proportion of applications. It was also learned through individual interviews that even patents that generate very large revenues were filed using the grace period provisions."*[11]

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[6] World Intellectual Property Organization (WIPO) (2013), "2013 PCT Yearly Review. The International Patent System", p. 11.
[7] The Association of German Chambers of Commerce and Industry (2012), "German Exports. AHK World Economic Report", p. 5.
[8] Eurostat press release, "Seventh Community Innovation Survey", 11 January 2013, [http://epp.eurostat.ec.europa.eu/cache/ITY_PUBLIC/9-11012013-AP/EN/9-11012013-AP-EN.PDF].
[9] Commission of Experts for Research and Innovation (EFI) (ed.), "Report on Research, Innovation and Technological Performance in Germany 2013", p. 183.
[10] Ibid., p. 135.
[11] Federal Ministry of Education and Research (BMBF) (ed.), "The Introduction of a Grace Period in Patent Law – A US-Germany Comparison Based on Higher Education", 2001, p. 7.

Other countries besides the US that have also introduced a grace period in their legal system include Japan, Korea, China, Canada, Brazil, India, Russia and Australia. This puts European states at a disadvantage because the scientifically and economically strong nations named above provide far more favourable framework conditions in terms of innovation friendliness.

The BMBF's main recommendation for Europe is set out in the following statement:

"The study's findings show that the introduction of a grace period in German and European patent law would unleash previously untapped potential. This is an argument in favour of an introduction of a grace period. As for the specifics of the issue, the study found that a grace period of one year is viewed as being sufficient. When fleshing out the legal framework, the interests of both science and scientists should be taken into account while ensuring the greatest possible legal certainty." [12]

New discussions in 2010 and 2012 between members of BIO Deutschland's Working Group on Licences and Technical Contracts and representatives from the Federal Ministry of Justice (BMJ), which is responsible for this issue, led to a decision to underpin, at least on a qualitative basis, these general comments with economically relevant examples from the higher education sector, research institutes, technology transfer offices and SMEs. This currently appears to be very sensible from a policy standpoint, because in 2013 the US patent law system took an important step towards harmonisation with the provisions of the European Patent Office (EPO) through the replacement of the previous first-to-invent doctrine with the first-to-file principle.[13] The introduction of a provisional application is not considered a solution to the problem described above. Already on 2 June 2000, the following clause was adopted in the framework of the Patent Law Treaty (PLT) in Geneva:

"… provisional applications do not offer a satisfactory remedy because they do not address inadvertent disclosures at all and even in other cases they pose a risk that the original disclosure will prove inadequate as a basis for any subsequent application."

The following proposal to introduce a harmonised grace period has been brought forward in the Standing Committee on the Law of Patents (SCP) at the World Intellectual Property Organisation (WIPO), but has not been implemented to date:

1. *Introduction of a grace period for any disclosure of the invention (by the inventor, by a third party or by a National Patent Office – NPO) within 12 months before the filing date of the request or 12 months before the priority date;*
2. *The inventor may always invoke this grace period;*
3. *The inventor has to prove that the disclosure took place less than 12 months before the filing date (or where priority is claimed, the priority date of the application).*[14]

In addition to further publications on this topic, the International Federation of Intellectual Property Attorneys (FICPI) recently released a comprehensive white paper that voices its support for the introduction of a 12-month grace period, whereby a disclosure of an invention derived directly or indirectly from the inventor during that period shall not be considered as comprised in the state of the art.[15] The white paper is the outcome of several years of consultations. FICPI has adopted since 1983 several resolutions that call for the introduction of a grace period in order to improve the European patent system.

[12] Federal Ministry of Education and Research (BMBF) (ed.), "The Introduction of a Grace Period in Patent Law – A US-Germany Comparison Based on Higher Education", 2001, p. 9.

[13] USA Patent Reform, Bill Text Version H.R. 1249 of the 112th Congress, http://www.gpo.gov/fdsys/pkg/BILLS-112hr1249ih/pdf/BILLS-112hr1249ih.pdf.

[14] European Commission, "An assessment of the implications for basic genetic engineering research of failure to publish, or late publication of, papers on subjects which could be patentable as required under Article 16(b) of Directive 98/44/EC on the legal protection of biotechnological inventions", 2002, p. 19, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52002DC0002&from=EN.

[15] FICPI, "FICPI White Paper on Grace Period", 24 January 2013, http://ficpi.org/wp-content/uploads/2013/09/FICPI-WP-2013-01Grace-Period.pdf.

Moreover, the German National Group of the International Association for the Protection of Intellectual Property (AIPPI) stated in its report for the meeting of AIPPI's Executive Committee from 5-11 September 2013 in Helsinki, Finland, that the introduction of a 6-month grace period is considered desirable for both scientists and industry (SMEs and large businesses), and that all disclosures by the inventor during this period shall not be considered as novelty destroying.[16]

This position paper of BIO Deutschland aims to demonstrate that the introduction of a harmonised grace period in Europe is absolutely essential in order to keep pace in the global race for innovation and boost Europe's standing as a research and industry location.

3. Introduction of a grace period is urgently needed

The grace period is traditionally seen as a means of balancing the requirements of scientific publication with the substantive protection of inventions and thus as a way of improving the transfer of technology from research institutes to industry (see further details in section 3.4.1). This is certainly a factor, but one should not forget that the era in which the pharmaceutical industry develops blockbuster drugs on its own is coming to an end. Pharmaceutical companies are also increasingly dependent on partnerships with universities and research institutes as well as biotechnology firms. A global marketplace for the best ideas has emerged.

The importance of cooperation between SMEs and large industrial companies is constantly growing in terms of overall economic significance. A study published by Accenture at the end of 2011 found that 60% of all innovations have their origins outside of large concerns. This proportion increases to 82% in the case of new biological therapeutics.[17] It shows that in the future Big Pharma will not only have to manage the competing objectives of publication and patenting, but should also have an interest in seeing that the possibilities for protecting biotech innovations are developed as comprehensively as possible. As cooperation on research becomes more and more complex, a grace period would make it easier to protect new inventions (see further details in section 3.1 et seq.). Harmonisation would create uniform rules for the protection of inventions that originate from cooperation in a global market.

In addition, there is now a trend to disclose research results, clinical trial data, etc. (see further details in section 3.3) at an early stage. A grace period would also make it possible for inventors to secure a patent in such cases. This serves the interests of SMEs and higher education establishments as well as those of larger-sized biotech and pharma firms.

These considerations clearly show that in an increasingly globalised world with an ever-growing interdependence between research institutes, SMEs and larger-sized biotech and pharma firms, there is a legitimate need for a grace period.

3.1. Non-filing of patent applications in the area of biotechnology

It is difficult to obtain data regarding the impact of not having a grace period due to the limited amount of information available. To make the call for the introduction of a grace period credible, BIO Deutschland conducted a survey among its members as well as patent exploitation agencies at universities. They were asked about their experiences with novelty-destroying disclosures made prior to the filing date (see section 3.1.1).

In addition, BIO Deutschland commissioned research to find out how many patent applications are not approved due to inventors making pre-filing disclosures while a patent was granted for the same invention in the US (see section 3.1.2).

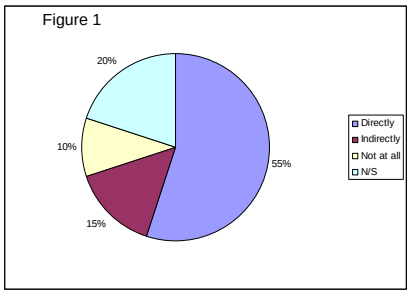
[16] Ehlers/Hahner/Henke/Königer, Report of the German National Group for AIPPI's Executive Committee meeting from 5-11 September 2013 in Helsinki, GRUR Int. 8-9/2013, p. 759 et seq.

[17] Accenture, "The Future of Pharmaceutical Innovation – Tackling the R&D Productivity Gap", p. 3.

3.1.1. *BIO Deutschland's member survey*

Survey respondents were asked about the importance of a grace period for their area of work and about their opinion on the introduction of a grace period. (Note: The "N/S" abbreviation used in the figures denotes respondents did not know or did not specify the answer.)

Figure 1



55% of respondents believed they would be directly affected by the introduction of a grace period (Figure 1).

65% of respondents said they were in favour of the introduction of a grace period (Figure 2).

Figure 2

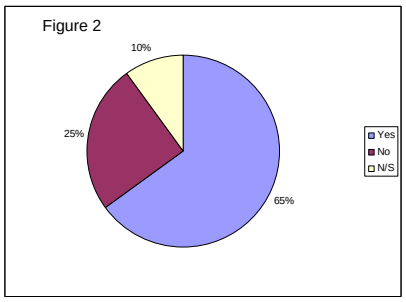
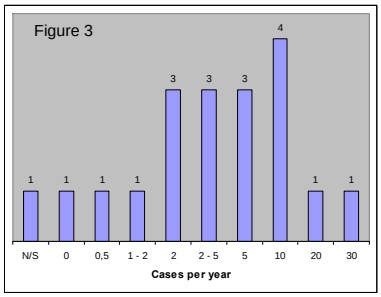


Figure 3



Most of the respondents have to draft a patent application at short notice in two to ten cases per year, in order to avoid a pre-filing disclosure (Figure 3). In addition to the traditional conflicts of interests that arise between companies and research institutes, problems can also occur due to graduate theses and doctoral dissertations: the research results from such academic works are potentially protectable. At the time that dissertations are published, it is likely that the results are not as detailed as would be required to file a patent application. More experiments would probably have to be conducted to receive strong patent protection. If further research shows the necessity of protecting the subject matter of the dissertation, it could be that only a limited portion of the results can be included in a patent application due to the doctoral dissertation being considered a pre-filing disclosure, thus providing at least some protection, albeit minimal. A grace period would also be very useful in such a case.

In up to 30 cases per year applicants forego the application altogether due to novelty-destroying disclosures (Figure 4). One company reported that of the six patents it filed in 2012, three were unsuccessful because of its own pre-filing disclosures (a rate of 50%). In 2013 the company was denied patent protection in one of three applications on the same grounds (a rate of 30%). A grace period would have at least given the applicant the possibility of securing a patent in the case of an otherwise positive outcome.

Figure 4

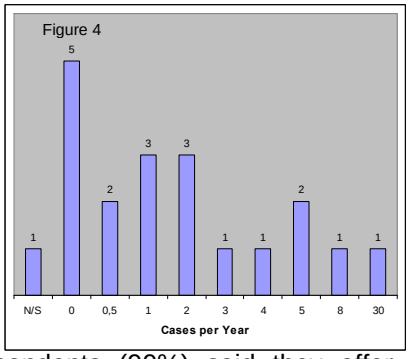
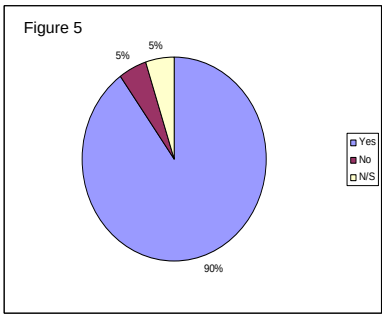


Figure 5



The companies are taking measures in their partnerships and in their own companies to fix this situation. Nearly all respondents (90%) said they offer regular information sessons and training courses on the topic of novelty-destroying disclosures (Figure 5). This helps keep the number of pre-filing disclosures in check, but, as the survey shows, does not completely eliminate them.

In order to further elucidate this issue, we will now present some cases from practice that were reported in the survey.

Case 1 (2012): A university clinic in German filed a patent application that it planned to exclusively outlicence to a biotech company. In discussions the company pointed out the importance of patent protection and that the clinic should not make any pre-filing disclosures because otherwise patent protection could no longer be granted on the grounds of lack of novelty. In particular, it explained that abstracts and lectures were also considered to be novelty-destroying disclosures. In the course of the negotiations, it came to light that the researcher from the university leading the discussions had published an abstract describing the main contents of the patent application before the application was

filed. The researcher stated that, contrary to the information provided, he did not view the abstract as a disclosure. The patent office has yet to issue a communication. The company has decided not to enter into any further contractual commitments because it anticipates that the patent office will refuse the application.

Case 2 (2012): A university clinic in Belgium wanted to conduct a clinical trial in partnership with a biotech company. However, the clinic had already published information about the subject matter. The patent application was not filed; the study not carried out.

Case 3 (2013): A university clinic in Belgium wanted to conduct a clinical trial in partnership with a biotech company. During their discussions, it emerged that the university had already published animal data and presented an abstract at a conference. It had not been clear to the university that its own disclosures could stand in the way of a subsequent patent application, nor did the university regard abstracts as disclosures. After considering the high costs of clinical trials and the lack of prospect of securing strong patent protection due to the pre-filing disclosures, the parties decided not to cooperate on the study.

3.1.2. Findings of the patent research

BIO Deutschland collected additional data to reinforce the information obtained from the member survey. This research sought to find patent applications that deal with medicinal products containing recombinant proteins, thus ensuring that the focus was on typical biotechnological applications. It was also hoped that cases such as these would help facilitate the evaluation of commercial relevance. Out of the search results, patent families were identified that include a valid US patent but only a European patent application (and thus no grant of patent). This process found just 8,000 patent families. To further enhance the reliability of the results, the patent families were narrowed down to include only those published in 1999 and 2000 that were not filed by a pharmaceutical company, based on the assumption that pharmaceutical companies only continue to pursue inventions which they are certain will lead to a grant of patent. After applying these criteria 400 patents families were left, which were then examined in detail.

The analysis thus focuses on a two-year period of European biotechnological applications for patents that – if they had been granted – could still be valid today. Its scope is also confined to inventions that have their roots in academic institutes from which one can expect a certain amount of commercial importance. One should bear in mind, however, that this research is not able to include inventions for which the patentability prospects were considered from the outset to be extremely remote because of pre-filing disclosures made by the inventors, and thus for which a European patent application was not filed in the first place. Also not included are those inventions for which the application was withdrawn before being published. On the basis of other investigations and studies, it can be assumed that the number of these non-researchable inventions is high – probably at a similarly high rate as the proportion of patent applicants taking advantage of the grace period in the US (22%).[18]

The result of the research shows, with all due caution, that <u>almost 7%</u> of the investigated European and international patent applications filed by universities, research institutes and similar establishments that were published in 1999 and 2000 were subsequently abandoned or refused due to inventors making novelty-destroying disclosures in the 12 months preceding the filing date of the priority application and <u>prior to the applicant being informed</u> of the date of filing accorded to his application.

3.2. Economic relevance

The findings of both BMBF's study in 2001 and Franzone and Scellato's paper in 2010 suggest that only the use of the grace period allows inventions that have exceptionally high quality from a qualitative perspective to be patented. The high-quality patent applications in the US correlate directly with the use of the grace period. This is attributed to the observation that public discussions and feedback help to enhance the quality of the invention and the patent application.[19] This is substantiated by so-called "cash cows" – patents that are extremely successful commercially. The patenting of the process developed by researchers Stanley Cohen and Herbert Boyer that pieces together and replicates DNA from different species was only possible thanks to the grace period and brought the universities in-

[18] Federal Ministry of Education and Research (BMBF) (ed.), "The Introduction of a Grace Period in Patent Law – A US-Germany Comparison Based on Higher Education", 2001, p.7.

[19] Franzoni, C. and Scellato, G., "The grace period in international patent law and its effect on the timing of disclosure", *Research Policy*, vol. 39, 2010, p. 209.

volved 255 million US dollars in licencing income. The use of the grace period also enabled the commercialisation of Florida State University's Taxol patent.[20]

Patent protection is designed to reward the inventor for his research efforts and his financial investment. This reward takes the form of an exclusive right to exploit the idea, but only for a limited period of time. The fact that this time period is in most cases shorter in biotechnology – because of the long research and development cycles – than in other (technical) patent applications, e.g. those from the field of mechanical engineering, makes it more difficult to recoup development costs. The restrictive framework conditions should not be allowed to halt the flow of innovations in biotechnology. A grace period would provide a crucial incentive to inventors and companies to continue their research activities in this area.

The following examples serve to illustrate this point while also highlighting the value creation that was not realised due to the lack of a grace period or that occurred in other countries because in Europe patent protection was either not possible or more limited in scope.

Example 1 – Diagnosis of prostate cancer through an imaging method

The German Cancer Research Center (DFKZ) missed out on the opportunity to patent a prostate cancer diagnostic technology, one considered to be extremely relevant economically, due to pre-filing disclosures made at two international congresses less than a year before submitting the invention in 2011 to its technology transfer office. The initial pre-clinical evaluation of 68Ga-labelled HBED-CC-PSMA ligand complex on laboratory animals did not provide an indication of its potential as a contrast agent in patients.

The invention concerned a process that enabled the sensitive diagnostic technique 68Ga-PET imaging to also be used for prostate cancer – which previously had not been possible for this type of cancer due to the lack of a suitable substance. The innovation consisted in the discovery of a highly specific inhibitor of PSMA, the protein marker for prostate cancer, and its application as a contrast agent in combination with the widely used 68Ga-PET technology. It was this combination that enabled extremely improved imaging capabilities and represented a major innovation in prostate cancer diagnosis.

Interpretation

It would have only been possible to secure patent protection in the US due to the fundamental disclosures prior to filing. The industry partners who had previously expressed interest withdraw from the project because of the high risk. Thus DFKZ did not file a patent application, which prevented a very innovative technology developed by German-based research from being turned into a market-ready product.

As a research centre, DFKZ lacked the industrial expertise and the resources to develop the new contrast agent through to regulatory approval. DFKZ was therefore dependent on an industry partner to make this technology accessible to patients. However, as licencing would have only been possible on the US market, it would not have been financially worthwhile for a company to get involved. This example clearly shows how the lack of an internationally harmonised grace period prevented a highly innovative product developed by basic research from being commercialised.

Commercial relevance

DKFZ's technology transfer office estimated the global revenues of this new contrasting agent at approx. 100 to 200 million euros a year. In order to finance the high costs and expenses of securing regulatory approval (500 million to 1 billion euros), established industry partners were contacted, who expressed a high level of interest in the project – provided that broad patent protection (at least in the US and Europe) could be obtained.

[20] Federal Ministry of Education and Research (BMBF) (ed.), "The Introduction of a Grace Period in Patent Law – A US-Germany Comparison Based on Higher Education", 2001, p.112.

Example 2 – HPV vaccine

This example concerns the loss of important intellectual property rights through a pre-filing disclosure made in an academic journal while the development of a human papilloma virus (HPV) vaccine was being pursued. In this area GlaxoSmithKline (GSK) and Merck are now generating revenues of more than 1 billion US dollars with the HPV vaccines Cervarix and Gardasil (see the revenue figures of the HPV vaccines Cervarix[21] from GSK and Gardasil[22] from Merck).

In 1997 research results were published in academic journal,[23] disclosing how various HPV-like particles were constructed to induce an antibody response. The inventors submitted their idea for patent protection in the US on 20 February 1998,[24] while filing a limited patent application in Europe on 24 March 1998.[25]

Interpretation

Substance protection was obtained in the US because of the grace period. In Europe, on the other hand, it was only possible to secure protection for second medical indication. The protection in Europe was also limited to fusion proteins, while the US patent covers proteins free fusion constructs.

Commercial relevance

Revenues from HPV vaccines Cervarix[26] from GSK and Gardasil von Merck[27] totalled more than 1 billion US dollars in 2011.

Example 3 – Utilisation of oncolytic HSV particles

This last example deals with the loss of important intellectual property rights through a pre-filing disclosure of the use of oncolytic herpes simplex virus (HSV) particles, which resulted in Amgen acquiring Biovex, a biotech firm developing similar technology, in 2011 for up to 1 billion US dollars (see Amgen press release[28]).

In September 1995 research data and an abstract were disclosed at a conference.[29] Patent protection was applied for at the beginning of October 1995.[30]

Interpretation

Third parties used the inventors' disclosure of research data and an abstract at a conference approx. two weeks before the priority data to stop the grant of a patent at a late procedural stage through the submission of observations. Evidently, the inventors' own anticipation by the disclosure of the abstract was the main reason for the application being significantly limited in further proceedings. Now, five years later, proceedings for grant with limited claims are again pending.[31]

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[21] Presentation by Martin Andrews (Senior Vice President) GlaxoSmithKline (2011), "GSK Vaccines in 2011", http://www.gsk.com/content/dam/gsk/globals/documents/pdf/Investors/presentations/2011/2011-03-23-martin-andrews-citi.pdf.

[22] Merck news release, February 2012, http://www.merck.com/investors/financials/02-02-2012-4Q11SERelease.pdf.

[23] Müller M et al., "Chimeric papillomavirus-like particles" *Virology* vol. 234, no. 1, 1997, pp. 93-111.

[24] US 7,182,947 (Hallek, Burger), "Papillomavirus truncated L1 protein and fusion protein constructs", Priority date: 20 February 1998.

[25] EP 1064014 (Burger, Hallek), "Medicament for preventing or treating papilloma virus-specific tumors", Priority date: 24 March 1998.

[26] Presentation by Martin Andrews (Senior Vice President) GlaxoSmithKline (2011): "GSK Vaccines in 2011" http://www.gsk.com/content/dam/gsk/globals/documents/pdf/Investors/presentations/2011/2011-03-23-martin-andrews-citi.pdf.

[27] Merck news release, February 2012, http://www.merck.com/investors/financials/02-02-2012-4Q11SERelease.pdf.

[28] Amgen press release, "Amgen acquires Biovex", http://www.amgen.de/Aktuelles/50/Amgen+%FCbernimmt+Biovex/News.html.

[29] Sibley , G. S. et al. "Evaluation of a gene therapy system using a replication competent, non-neurovirulent HSV-1 viral vector used in combination with radiotherapy," *Int. J. of Radiation Oncology Biology Physics*, vol. 32, supplement 1, 21 September 1995.

[30] EP 862445/ WO 9712623 (Hallahan, Weichselbaum, Kufe, Sibley, Roizman), "Methods and composition for viral enhancement of cell killing", Priority date: 6 October 1995.

[31] EPO0862445 "Combination of herpes simplex virus and chemotherapy for treating cancer", https://register.epo.org/espacenet/regviewer?AP=96934086&CY=EP&LG=de&DB=REG.

Commercial relevance:

The patent application was licenced to MediGene.[32] Amgen acquired Biovex, which was developing similar technology, for up to 1 billion US dollars, according to a press release.[33] The lost opportunity with the patent application for oncolytic (HSV) particles can therefore be estimated at a similar economic value.

3.3. Impact of new legal developments in Europe on intellectual property rights in biotechnology

One can increasingly observe that new legislative initiatives are putting an emphasis on the transparency of clinical data. While this is a welcome proposal when seen from the perspective of patients, it carries significant risks for the patent protection of substances yet to be developed. One of these new rules is being discussed in a proposal for a regulation of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, which is currently under negotiation.

Article 78(3) of the proposed regulation concerns data confidentiality in the EU database that would be set up for clinical trials. The database would include information on all clinical trials conducted in Europe, and information on all applications for authorisation of clinical trials. Companies would be required to submit documents containing confidential data that are essential for their survival. This information needs to be protected comprehensively. In many cases, the information is not yet protected by intellectual property rights as one first has to wait for the outcome of the clinical trial and the resulting findings, owing to the fact that patentable data are not available at the outset or it is not yet possible to obtain comprehensive protection, e.g. for a new indication. Article 78(3) of the proposed regulation does not provide for the confidential treatment of information that could possibly be protected by intellectual property rights. However, it is crucial that sponsors receive patent protection to cover the high investment costs.

Changes that require documents from the clinical trials to be disclosed at an early stage have also been incorporated into the proposed regulation during the parliamentary process.

Moreover, the European Medicines Agency (EMA) has revised its policy on the publication of clinical data. In addition to its "Policy on access to documents (related to medicinal products for human and veterinary use)",[34] the EMA has also released a draft policy on "Publication and access to clinical-trial data."[35] It is currently in consultation phase, but is expected to come into force by the end of the year. The EMA's new policy seeks to establish rules that govern how data from clinical trials and the application process for clinical trials are published and accessed.

The EMA has, furthermore, already released clinical trial data to requesting companies pursuant to EU Regulation (EC) No 1049/2001regarding public access to European Parliament, Council and Commission documents.[36] The companies affected took legal action to block disclosure.[37] The cases are currently pending before the European Court of Justice (ECJ). The General Court has already made an interim ruling instructing the EMA not to release the data (until a decision in the main proceedings).

These efforts to adopt far-reaching transparency rules for clinical trials will lead in practice to the circumvention of data exclusivity provisions, and could also have significant adverse impacts on patent protection. Moreover, the data for clinical trial applications could be used for marketing authorisation procedures in third countries.

However, this trend is not only seen at the European level. The Paul Ehrlich Institute (PEI) also publishes clinical trial applications on the internet once approval of phase 2 has been granted. Publication of paediatric studies occurs already from phase 1.[38]

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[32] News release: "MediGene acquires patents on anti-cancer drugs under development", http://www.bionity.com/en/news/29407/medigene-acquires-patents-on-anti-cancer-drugs-under-development.html.

[33] Amgen press release, "Amgen acquires Biovex", http://www.amgen.de/Aktuelles/50/Amgen+%FCbernimmt+Biovex/News.html.

[34] http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/11/WC500099473.pdf

[35] http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/06/WC500144730.pdf

[36] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001R1049:EN:HTML

[37] Case AbbVie and Others v EMA (T-29/13) of 17 January 2013, Case AbbVie and Others v EMA (T-44/13) of 29 January 2013 and Case InterMune UK and Others v EMA (T-73/13) of 11 February 2013.

[38] See PEI's guidelines at http://www.pei.de/DE/infos/pu/genehmigung-klinische-pruefung/eudract/register-klinische-pruefungen-node.html.

3.4. Further arguments for the introduction of a grace period in Europe

3.4.1. Improvement of partnerships with research institutes

The publication of articles in academic journals is extremely important in the fields of natural science and technology, particularly for young researchers. So as not to jeopardise publishing success, researchers traditionally pursue a strategy that calls for fast publication. It is not uncommon for research groups working on different continents to investigate the same problem and for the race to publish new discoveries or solutions first to be decided by days or weeks. The dissemination of research results through publication (in journals or orally at conferences) prior to filing a patent application can significantly inhibit or prevent the findings from being sensibly exploited commercially. In following the formal path and thus submitting the patent application beforehand, the researchers take the risk of delaying publication and allowing other research groups to publish ahead of them. Currently, European researchers, who put off publication because of patents they plan to apply for, publish three to eight months later that their US colleagues for whom the requirement to defer publication is not as stringently prescribed because of the grace period there.[39] The German expertgroup for Research and Innovation (EFI) describes this problem in its report from 2009:[40]

It is necessary to *"… weigh up between long-term research cooperation or licence receipts in the short term, and between licensing or setting up a spin-off company. A particularly difficult situation arises as a result of the processing times for reports of inventions. In this case, the publication of the research results as quickly as possible can conflict with the intention of filing a patent."*[41]

3.4.2. International harmonisation of patent law

As many countries, including economic powers such as Canada, Japan and the US, already have grace period provisions in their patent systems, researchers can file a patent application there even if this no longer possible in Europe and the EPO contracting states because of prior disclosure. This difference results in innovative companies in Europe not pursuing the further development of their ideas as sensible commercial exploitation appears to be impossible.

The extent to which an internationally harmonised grace period is also important for US universities becomes evident in statements by an employee of Stanford University. She reported that biotechnology inventions disclosed prior to patent application are rarely patented using the grace period. This is because industry partners are only interested in worldwide (at least the US and Europe) licencing rights, particularly in the area of biotechnology. As a result, innovative inventions of universities fail to be developed and exploited commercially.[42]

3.4.3. German Employee Inventions Act (ArbnErfG, Section 42)

In accordance with Section 42 of the German Employee Inventions Act (ArbnErfG), inventors can disclose their inventions as a part of their research and teaching activities if they give their employer (the university) due notice, normally two months in advance. The university must assess and complete the patent application during this period of time so as not to lose out on obtaining patent protection. An adequate assessment of exploitability and economic viability of a patent application is hardly possible in this amount of time. There is therefore the risk that universities, which typically face budget and time constraints, will decide against filing for a patent, thus foregoing patent protection for valuable inventions.

[39] Franzoni, C. and Scellato, G., "The grace period in international patent law and its effect on the timing of disclosure", *Research Policy*, vol. 39, 2010, p. 209.
[40] Commission of Experts for Research and Innovation (EFI) (ed.), "Report on Research, Innovation and Technological Performance in Germany 2009", p. 42.
[41] Ibid.
[42] Federal Ministry of Education and Research (BMBF) (ed.), "The Introduction of a Grace Period in Patent Law – A US-Germany Comparison Based on Higher Education", 2001, p.110.

3.4.4. Damage claims

Researchers could be in breach of their statutory and contractual duties if they disclose research results, whether deliberately or inadvertently, prior to filing a patent application. This could be considered grounds for damage claims. A grace period provision, on the other hand, would take into account both the researchers' need for fast publication of findings and the general interest in innovation exploitation.

3.4.5. Assessment of commercial exploitability

It is frequently the case that the possibilities for commercially exploiting an invention only become apparent through discussions with experts in the relevant field.[43] The introduction of a grace period would therefore help facilitate the exchange of scientific information.

3.4.6. Technology transfer promotion

The opportunity to be able to discuss the invention with licensees at an early stage would simplify the work of technology transfer offices.[44]

3.4.7. Provisional application

The option to file a provisional application does not offer a viable alternative to a grace period rule as it is not applicable to inadvertent disclosures and, because of the very restrictive case law of the EPO boards of appeal, poses a risk that the original disclosure will not prove suitable as a basis for any subsequent patent application, thus failing to provide any remedy to the problem of inadvertent pre-filing disclosure.

4. Proposal for the introduction of a grace period in Europe

To achieve the introduction of a grace period in Europe, BIO Deutschland proposes that an additional paragraph be included in Article 55 of the European Patent Convention (EPC). Article 55 EPC concerns non-prejudicial disclosures and thus is also the appropriate place to regulate non-prejudicial disclosures made prior to filing. The following provision should be incorporated as paragraph 3 (-new-) of Article 55 EPC:

> Article 55
>
> *[…]*
>
> *(3) For the application of Article 54, a disclosure of the invention shall not be taken into consideration if it occurred no earlier than twelve months preceding the date of filing of the European patent application and if it was directly or indirectly made by the applicant or by his legal predecessor.*

Consequently, Article 55 EPC should also be supplemented so that the date of priority validly claimed for a priority application shall also count as the date of filing under application of the new Article 54(3) EPC:

> Article 89
>
> *The right of priority shall have the effect that the date of priority shall count as the date of filing of the European patent application for the purposes of Article 54, paragraphs 2 and 3,* ***Article 55, paragraph 3****, and Article 60, paragraph 2.*

Berlin, 4 November, 2013

[43] Similar to finding in Commission of Experts for Research and Innovation (EFI) (ed.), "Report on Research, Innovation and Technological Performance in Germany 2009", p. 42.

[44] Ibid.

BIO DEUTSCHLAND

As the sector association of the biotechnology industry, **BIO Deutschland** has set itself the objective of supporting and promoting the development of an innovative economic sector based on modern biosciences in Germany. The Berlin-based association currently has over 300 members. **Dr Peter Heinrich** is Chairman of the Board of BIO Deutschland.

BIO Deutschland's supporting members and partners are **Biotest AG**, **Boehringer Ingelheim Pharma GmbH & Co. KG, Celgene GmbH, Clariant Produkte (Deutschland) GmbH, CMS Hasche Sigle, Deutsche Bank AG, EBD Group, Ernst & Young AG, Isenbruck │ Bösl │ Hörschler LLP, KPMG AG, Merck KGaA, Miltenyi Biotec GmbH, Pricewaterhouse-Coopers AG, Roche Diagnostics GmbH** and **Sanofi-Aventis Deutschland GmbH.**

Further information about the activities of BIO Deutschland can be obtained upon request at the office of the association or at www.biodeutschland.org.

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