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Report Q202

in the name of the German Group
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The impact of public health issues on exclusive patent rights

Questions

I) Analysis of current law and case law

1) Is a research or experimental use exception recognised under your patent law? If so, under which conditions? What is the scope of the research exception? Specifically, is research or experimental use permitted for commercial purposes?

The German Patent Act was amended in 1981 and with the amendment of Sec. 11(2) what has become known as "experimental privilege" came into force. This provision stipulates that the effect of a patent shall not extend to those acts performed for experimental purposes that are part of the subject matter of a patented invention.

However, the case law initially remained restrictive and only experiments on the subject matter of the patented invention were authorized. A liberalization of the case law did not take place until 1995 when extension of experimental privilege was established by the decision of the Federal Supreme Court *"Klinische Versuche I"* [Clinical Trial I] and then by *"Klinische Versuche II"* in 1997 [Clinical Trial I II].

a) Privileged Experiments

The intent of the rulings as rendered by the Federal Supreme Court is that any systematic action directed at obtaining data on the subject matter of an invention is privileged. The ultimate purpose of the studies and experimental acts is not decisive thereby. Thus tests aimed at commercial exploitation of the results may also be carried out. Hence, basic academic research is no more privileged today than commercial, application-oriented industrial research. Privileged experiments can include experiments for a commercial use, e.g. experiments required for a pharmaceutical marketing authorization, or experiments carried out with an economic interest, e.g. obtaining another patent.

Furthermore, such experiments are considered to be harmless which contribute to the advancement aspired under patent law of research and development. The decision *"Klinische Versuche I"* initially privileged experiments aimed at finding new, unknown uses (what is called *use experiments*), whereas according to the decision *"Klinische Versuche II"*, experiments were also permitted directed at finding data on characteristics and effects of the patented active substance within the limits of the indications already known (what is called indication experiments). The following tests are thus admissible today:

- to find indications and contra-indications within and beyond known fields of application,
- to analyze the pharmaceutical form and dosage of an active substance to discover a cure for or to alleviate certain illnesses,

- to find clinically-relevant differences over other products, in particular the effectiveness and tolerance thereof as well as
- testing by plant protection authorities in field trials of a patented active substance of a plant-treatment agent.

b) Non-Privileged Experiments

Experimental privilege, however, is limited in that experiments will only then be deemed harmless if they use the patented subject matter as the object of the test and not merely as a means of realization.

Furthermore, only such tests are deemed harmless that are directed at the technical findings of the patented invention and not only at satisfying a commercial, i.e. entrepreneurial, interest. Thus, it may not be the exclusive aim just to clarify economic factors, such as market demand, price acceptability or distribution possibilities. Obtaining technical/scientific findings may not moreover only be a secondary purpose of the trial on the patented invention.

One criterion has been set up to restrict abuse by experimental privilege, i.e. the so-called quantity argument: The experiments may only be carried out to an extent justifying the experimental purpose.

2) *Is a Bolar-type exception recognised under your patent law? If so, under which conditions? What is the scope of the Bolar exception? Specifically, is it limited to drugs or does it also apply to other products, including biological products, research tools, etc.? If your patent law does not provide for a Bolar exception, will using an invention without the patentee's consent for the purpose of obtaining approval of a generic product be covered by the research exception?*

In addition to experimental privilege as stipulated in Sec. 11(2) German Patent Act, a Bolar-type experimental privilege was incorporated into the German Patent Act by Sec. 11(2b), and has been in force since 6 September 2005. The introduction of Sec. 11(2b) German Patent Act was carried out as part of the implementation of Directive 2004/27/EC. The German Bolar-type experimental privilege excludes from the effect of a patent the studies and trials necessary in order to obtain a marketing authorization for a medicinal product in any member state of the European community or any member state of the European Economic Area, as well as any acts necessary for their performance.

Case law concerning the scope of the Bolar-type experimental privilege has not as of yet been published in Germany. Thus, the exact limits of the Bolar-type experimental privilege have not yet been defined. The wording of the law, however, does not provide any indication of a restriction of the Bolar-type experimental privilege to pharmaceutical substances. To the contrary, the wording and history of the Bolar-type experimental privilege in Germany very much suggest that a very broad experimental privilege is intended that will exempt from the effect of a patent all studies and experiments required to obtain an authorization under the German Law on Drugs. These can include, according to the wording of Sec. 11(2b) German Patent Act, also experiments with patented, biological substances or "research tools". This will at least be the case if these are exclusively used for experiments required for the authorization of pharmaceuticals. Many questions in this regard, however, still remain unanswered. On the other hand, it appears to be clear that the German Bolar-type experimental privilege is not restricted to experiments as part of the authorization process of generic pharmaceuticals, but also includes experiments with innovative pharmaceuticals. An overlap with the classical experimental privilege of Sec. 11(2) German Patent Act could therefore result that is however additionally restricted by the legal requirement that the experimental acts must relate to the subject matter of the patented invention.

3) *Are parallel imports of patented medicines, medical devices or similar permitted? If so, under which conditions? Do the same principles apply if the products originate from markets where they were made available under a compulsory license?*

Parallel imports from countries outside the European Economic Area (EEA) can be prohibited on the grounds of a patent or a Supplementary Protection Certificate.

If, however, a patented product is marketed in the EEA by its proprietor or with its consent, e.g. by its licensee, patentee's rights to the product will also be exhausted in Germany, i.e. the product can be further distributed with limitations within the EEA. The same shall apply to pharmaceuticals. These can therefore, in principle, be re-imported and imported in parallel from any EEA country to Germany.

According to the case law of the European Court of Justice, the parallel import of medicines and medical devices is possible if the product was placed on the market by patentee or with patentee's consent (by way of a license) (cf. decision *"Centrafarm vs. Sterling Drug"* by the European Court of Justice, ECR [1974], at 1147). This even applies if the price of the medicine in the country of export, due to governmental provisions, is regulated and considerably lower than in the country of import or if patentee does not hold a patent in the country of export since he did not apply for one as corresponding protection was not possible at the time of application (cf. decision *"Merck vs. Stephar"* by the European Court of Justice, ECR [1981], at 2063).

As far as imports of medicines from the ten new Member States are concerned, i.e. Czech Republic, Slovakia, Hungary, Poland, Slovenia, Estonia, Lithuania and Latvia as well as Bulgaria and Romania, what is called "specific mechanism", according to the Accession Treaties, must apply. Under the "specific mechanism" provision, the IP-right proprietor can prevent the parallel import of a pharmaceutical product that was first put on the market in one of the aforesaid states if the IP right for the relevant pharmaceutical product was applied for in one of the prior EU states at a time when corresponding protection could not yet be obtained for said product in each of the ten new Member States.

As to pharmaceuticals that were marketed on the basis of a compulsory license (hence without approval of IP-right proprietor), the principle of exhaustion of rights does not apply. These pharmaceuticals may therefore not be imported in parallel, provided there is corresponding patent protection (decision *"Pharmon vs. Hoechst"* by the European Court of Justice, ECR [1985], at 2281). Nor does exhaustion arise if patentee is legally obliged to market the product in the country of export (decision *"Merck vs. Primecrown"* by the European Court of Justice, ECR [1996], at 6285).

The situation is somewhat different with regard to trademark rights if the products are re-packaged. A series of criteria and requirements have been instituted to protect the trademark owner.

4) *Is an individual prescriptions exception recognised under your patent law? If so, under which conditions?*

Yes. Sec. 11(3) German Patent Act provides that the effects of a patent shall not extend to the direct, individual preparation of a pharmaceutical in pharmacies as a result of a doctor's prescription or to the acts of preparing said pharmaceutical.

There is very little case law on this provision as well. This will, when in doubt, be interpreted narrowly as an exemption to the effects of a patent that are otherwise recognized under the law. It has already been decided that this exemption does not authorize the stockpiling of pharmaceuticals in a pharmacy. What is always required is a doctor's prescription for one single patient, on the basis of which the pharmaceutical is prepared in the pharmacy.

5) *Please answer this question only if in your country methods of medical treatment are patentable subject matter: Does your patent law provide for a medical treatment defence or similar exception to the patentee's exclusive rights?*

Methods of medical treatment are not patentable in Germany.

6) *Are compulsory licenses available under your patent law? If so, under which conditions and on which grounds (e.g. to remedy anticompetitive conduct, for cases of emergency, other public interest grounds, etc.)? Are you aware of any compulsory licenses granted in your country for the domestic manufacture and supply of pharmaceutical products? If so, please provide details, including the name of the licensor, the licensee and the product covered.*

Compulsory licenses under a patent in the field of preventive health care can in Germany, in principle, be based on four different grounds.

According to Sec. 24(1) German Patent Act, a compulsory license can be granted under a patent if this is required in the public interest and if the patentee refuses to grant a license under the adequate conditions customary in trade. Public preventive health care is recognized as a public interest within the meaning of Sec. 24 German Patent Act. In practice, compulsory licenses, as stipulated in Sec. 24 German Patent Act, have so far been of very minor significance since the German Federal Supreme Court in its decision *"Polyferon"* of 1995 refused the grant of a license on a pharmaceutical substance and placed the entire burden of proof for the public interest in the compulsory license on Plaintiff as the party seeking a license. Plaintiff would have needed to prove that the license would not merely make room for a more or less equivalent medicament in a certain class, but would fill a real supply gap, for since if only the novel preparation could avoid the problematical side effects of the treatment. Neither the fact that a patent had already been granted for a new use of a patented substance nor the authorization of a new pharmaceutical on the basis of the patented substance were considered as sufficient proof of public interest. Ever since this decision was rendered, no further proceedings pertaining to the grant of a compulsory license have become known.

According to Sec. 24(2) German Patent Act, a compulsory license could also be granted in case of a dependent invention if the dependent invention were to constitute, compared with an earlier patent, an important technical progress of considerable economic significance. This provision was introduced in 2005 with the Law on the Implementation of the Directive on the Legal Protection of Biotechnological Inventions. Sec. 24(2) German Patent Act, however, concerns all types of inventions and will probably become more important than Sec. 24(1) German Patent Act.

The grant of a compulsory license can only be effected after a patent has been granted and must be requested at the Federal Supreme Court which has to decide on compulsory licenses. It is not possible to request the grant of a compulsory license for a pending patent application.

In Germany, the grant of compulsory licenses under patents for pharmaceuticals is also possible for the export to countries having insufficient health care, i.e. on the basis of Regulation (EC) No 816/2006 of 17 May 2006. This provision at the European level corresponds to the provisions of new Art. 31bis TRIPS (for details see below question 7). However, no compulsory licenses have as of yet been granted on this basis in Germany, according to the public register at the WTO.

The right to the grant of a license under a patent on the basis of German or European anti-trust laws has a far greater practical importance in Germany than the explicitly regulated compulsory licenses. A compulsory license under anti-trust laws is not regulated by the requirements of Sec. 24 German Patent Act and can, according to the decision *"Standard-Spundfass"* issued by the German Federal Supreme Court (K ZR 40/02), also be brought

forward as a defense against a patent infringement act. One requirement that must be met when claiming the right under anti-trust laws to the grant of a license is that the refusal to grant a license by patentee is, according to German and European anti-trust laws, contrary to fair competition, and hence constitutes an unjustified discrimination or abuse of market power, and that patentee must have refused a sufficiently specific and acceptable offer for the conclusion of a license agreement. The application of the provisions under anti-trust laws, however, requires that said patentee must be a company having, within the meaning of anti-trust laws, a dominating and powerful position on the market. The requirements for a compulsory license under anti-trust laws can be met particularly in cases where the compliance with a general industry standard requires the use of a patent.

It has not yet been finally clarified whether an interested party must first submit a specific written offer before starting to use the patent or whether he can also submit this offer at a later date should he be sued by patentee on the grounds of patent infringement. The objection that a compulsory license must be granted was recently recognized as a defense against the accusation of patent infringement in proceedings at the Regional Court Düsseldorf which dealt with patents required for the use of GSM standards. In other published decisions, the right to the grant of a compulsory license was largely rejected or no decision was rendered.

7) *Has new Article 31bis TRIPS been ratified in your country? Are you aware of any other legislative amendment in your country with a view to implementing the WTO decision of August 30, 2003? Are you aware of any compulsory licenses granted in your country for the importation or exportation of pharmaceutical products? If so, please provide details, including the name of the licensor, the licensee and the product, if they are publicly available.*

New Art. 31bis TRIPS has not been ratified by Germany. Despite this, its provisions have already become established law in Germany. The starting point in this regard is the ratification, for the European Community, of Art. 31bis TRIPS on 30 November 2007 by the President of the Council of the European Union, also having binding effect for Germany. Ratified at this point was the Protocol Amending the TRIPS Agreement, adopted by the General Council of the WTO in Geneva on 6 December 2005, by which, according to Art. 31 of the TRIPS Agreement, a new Art. 31a (Art. 31bis) was to be added. With decision of 19 November 2007, the Council of the European Union decided to adopt, in the name of the European Community, the Protocol Amending the TRIPS Agreement signed by the General Council of the WTO in Geneva on 6 December 2005. With its entry into force, the Protocol according to Art. 300(7) of the EC Treaty will also be binding for Germany.

The decision of the General Council of the WTO of 30 August 2003 on the implementation of No 6 of the Doha Declaration ("decision") was implemented, upon proposal by the European Commission, with Regulation (EC) No 816/2006 on compulsory licensing for patents relating to the manufacture of pharmaceutical products for export to countries with public health problems ("Regulation") which was adopted by the European Parliament and the Council of the European Union on 17 May 2006. The Regulation entered into force on 29 June 2006. According to Art. 249 EC Treaty, a regulation is obligatory in all its parts and is directly valid in each Member State. The Regulation, consequently, has to be applied as directly applicable law and must be observed in Germany.

The background for the issuance of a Regulation under Community law was, according to Recital (4) of the Regulation, the uniform implementation of the decision on the establishment of the same requirements in all Member States of the European Community for the grant of compulsory licenses regarding the manufacture and sale of certain pharmaceutical products intended for export and for the prevention of unfair competition for economic operators on the domestic market. The uniform implementation moreover contributes to the prevention of re-imports of pharmaceutical products, produced according to the decision of the General Council of the WTO of 30 August 2003, into the territory of the European Community.

Recital (8) of the Regulation stipulates that the grant of compulsory licenses according to this Regulation shall be attached to clear requirements for the licensee. The recital specifically states the activities covered by the license, the identifiability of the pharmaceutical products manufactured under the license and the countries to which these products are exported.

According to Art. 1 of the Regulation, the Regulation establishes a procedure for the grant of compulsory licenses for patents and Supplementary Protection Certificates relating to the manufacture and sale of pharmaceutical products, when such products are intended for export to eligible importing countries in need of such products in order to address public health problems. "Pharmaceutical product" means any product of the pharmaceutical sector, including medicinal products. The following are eligible countries according to the Regulation:

a) any least-developed country appearing as such in the United Nations' list;

b) any member of the WTO that has made a notification to the Council for TRIPs of its intention to use the system as an importer, including whether it will use the system in whole or in a limited way;

c) Any country that is not a member of the WTO and is listed in the OECD Development Assistance Committee's list of low-income countries and has made a notification to the Commission of its intention to use the system as an importer, including whether it will use the system in whole or in a limited way.

According to Art. 6 of the Regulation, any person may, in principle, submit an application for a compulsory license to a competent authority in the Member State where the respective patent has effect. The applicant shall provide inter alia evidence to satisfy the competent authority that he has made efforts to obtain authorization from the rights-holder and that such efforts have not been successful within a period of thirty days before submitting the application. This requirement according to Art. 9(2) of the Regulation shall only be dispensable in situations of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use under Art. 31 lit.(b) of TRIPS Agreement. According to Art. 11 of the Regulation, the competent authority shall refuse an application if any of the conditions for grant is not met. One condition for the grant is *inter alia* the indication of the amount of products the applicant intends to manufacture of the pharmaceutical product under the license. The reason herefor is that a compulsory license is, for the protection of the rights-holder, strictly limited to the quantities required in the import country cited in the application. The products that are manufactured under the license shall be clearly identified through specific labeling or marking to distinguish them from the products manufactured by the rights-holder. The license granted according to Art. 10(1) of the Regulation shall be non-assignable and non-exclusive. The duration of the license shall moreover be indicated. According to Art. 10(9) of the Regulation, the licensee shall pay an adequate remuneration to the rights-holder. The re-import into the territory of the European Union of the products manufactured and distributed on the basis of the compulsory license shall be prohibited. If licensee fails to comply with the license conditions, the competent authority can withdraw the license.

As far as is known, no compulsory license for the import or export of pharmaceutical products has been granted in Germany as of yet. This is true both with regard to compulsory license proceedings pursuant to the Regulation (EC) No 816/2006 and to German proceedings according to Sec. 24 German Patent Act (see in this regard also question 6).

8) Is the government allowed to make use of a patented invention without previous license and if so, on what basis (e.g. crown use) and under which conditions?

In Sec. 13 PatG (*German Patent Act*), German patent law defines the concept of an official order to exploit an invention, which may be issued by the federal government or an appropriate supreme federal authority (or by a subordinate agency acting on behalf of the latter). The

order may be issued if the invention shall be used in the interest of public welfare or in the interest of the security of the Federal Republic. Pursuant to Sec. 13 PatG, a patented invention may also be exploited against the patentee's will, if so required by a superior public interest. The patent itself remains valid.

The order to exploit an invention in the interest of public welfare is specified in Sec. 13 (1) sentence 1 PatG. Only the federal government is authorised to issue such orders. The order is issued by virtue of an administrative act which has to indicate the types or acts of exploitation and the duration of the order. The term "public welfare" has to be construed broadly and, as a rule, includes all cases where state welfare seems necessary. A typical case would be a state of emergency caused for instance by an epidemic. Given the interfering nature of the order to exploit an invention, the order may only be issued if it appears necessary. There is no such necessity if the objective can also be achieved otherwise. Also, an inquiry for a license has to be made with the patentee before the order is issued, except in cases of urgency.

According to Sec. 13 (1) sentence 2 PatG, the order to exploit an invention may also be issued by an appropriate supreme federal authority or, on its behalf, by a subordinate agency, if the invention shall be exploited in the interest of the security of the Federal Republic. An interest in the security of the Federal Republic is given in cases of national defence against attacks from the outside or inside, or other, comparable serious dangers to the security of the Federal Republic, including disaster control.

Although an order for the exploitation of an invention under Sec. 13 PatG does not affect the validity of the patent, it restricts the patent within the limits defined by the order. The scope of an order can be equivalent to an exclusive or nonexclusive license. Within these limits, the patentee cannot prohibit the use of the invention. Other than that, the patentee's right of exclusivity as well as the right of use held by the patentee and other authorised parties remain unaffected. The government or appropriate authority can transfer the right of exploitation, as ordered, to third parties, including private individuals, who, however, have to observe the limits of the order when using the invention. Exploitation is permissible only to promote public welfare or the interest in security. Any use for one's own commercial purposes based on the order for exploitation is inadmissible. When issuing the order the agency has to ensure that the impairment of the patentee's rights is kept to a minimum.

Pursuant to Sec. 13 (3) sentence 1 PatG, the patentee is entitled to a claim against the Federal Republic for a reasonable compensation in the event of a lawful order for exploitation. In the case of an order for exploitation in the interest of public welfare (Sec. 13 (1) sentence 1 PatG), the claim arises when the order is issued, whereas it arises only with the actual exploitation if the order was issued in the interest of the security of the Federal Republic (Sec. 13 (1) sentence 2 PatG).

If an order for exploitation fails to comply with the stipulations in Sec. 13 PatG and unlawfully encroaches upon the patent, the holder of the patent rights is entitled to a claim for compensation against the state agency that benefited from the infringement.

9) Is the government allowed to expropriate a patent and, if so, under which conditions?

In Germany, property is protected under the Constitution, Article 14 (1) sentence 1 Grundgesetz (*German Constitution* – GG); the terms and restrictions are defined by the individual statutes (Art. 14 (1) sentence 2 GG). Pursuant to Art. 14 (3) sentence 1 GG, expropriation is permissible only for the public good and may be ordered only by or pursuant to a law which defines the nature and extent of the compensation.

According to common consent, the patent right qualifies as "property" in the sense of the Constitution. Thus, it is covered by the constitutional guarantee and protected under Art. 14 (1) GG. This has been confirmed by the Federal Constitutional Court as supreme instance.

Art. 14 (3) sentence 2 GG permits expropriation, provided it is ordered by or pursuant to a law. As a law requires an appropriate parliamentary resolution, it is ultimately not the government (executive) but only the legislator (legislature) that can expropriate. Given the substantial nature of the encroachment upon a person's legal position, expropriation is permitted only for the public good, Art. 14 (3) sentence 1 GG, and must in fact be necessary to achieve this particular purpose, i.e. it is not permitted if there is a less severe measure to achieve the same purpose.

There is no law in Germany which explicitly deals with the expropriation of patents. The following provisions of the German Patent Act could be considered laws within the meaning of Art. 14 (3) sentence 2 GG:

Sec. 11 PatG (exemptions from the effects of the patent), Sec. 24 PatG (compulsory license), Sec. 50 PatG (order of nondisclosure) and Sec. 13 PatG (order for exploitation).

With respect to Sec. 11 PatG (exemptions from the effects of the patent) the Federal Constitutional Court held in the decision of 10 May 2000 ("Clinical Trials") in view of the experimental use exception of Sec. 11 No. 2 PatG that this provision does not qualify as an expropriation but as an admissible definition of the scope and limitations of property within the meaning of Art. 14 (1) sentence 2 GG.

As for Sec. 24 PatG (compulsory license, cf. question 6 above), it is assumed in the literature that this provision is a limitation of property as protected by the Constitution in the sense of a definition of the scope and limits, and thus does not qualify as expropriation. This is supported by the fact that Sec. 24 (1) PatG leaves the protection of the public interest to the license seeker's private initiative and private willingness to take risks and, ultimately, only grants the license seeker a claim under private law to the grant of a compulsory license by the patent court. The compulsory license has the effect of granting the license seeker a position comparable to that of a contractual licensee.

§ 50 PatG (order of nondisclosure) provides for an *ex officio* order by the patent office to the effect that no publication of a patent shall take place if the patent is sought for an invention which is a state secret. The Federal Court of Justice ruled already on 4 May 1972 ("Nuclear Energy") with respect to (former) Sec. 30 a PatG, the predecessor provision of Sec. 50 PatG, that the order of nondisclosure does not represent an expropriation measure.

Only Sec. 13 PatG (order for exploitation) is considered at least similar to expropriation in literature. It is referred to as an official measure of a nature similar to expropriation, which lies within the reasonably exercised discretion of the federal government and/or the appropriate supreme federal authority. Under the law as well, the order issued by the federal government is treated as an expropriation measure, with the difference that it is effected for an adequate compensation.

The preconditions for the grant of an order for exploitation under Sec. 13 PatG have been discussed in question 8 above.

Generally, an expropriation by virtue of the law is possible, provided the constitutional regulations, especially Art. 14 GG, are complied with. In light of the available possibilities described earlier, however, any thoughts about additional expropriation laws in the field of patents most likely are of a theoretical nature only.

10) *If your patent law recognises other means of facilitating access to medicines, medical devices, diagnostics and the like, notably in the context of public health crises (including, among others, information tools such as the Orange Book providing timely consumer information on generic drug approvals), which have not been discussed above, please explain.*

German patent law does not provide for any such procedures or means.

II) Proposals for adoption of uniform rules

For the following questions, it should generally be noted that exemptions from the effects of the patent should always be considered in their entirety instead of individually.

1) Should patent law provide for

– *research and experimental use exception;*
Since more than 15 years German patent law provides for an experimental use exception in Sec. 11 (2) PatG. However, the question of which "acts done for experimental purposes" are covered by the exception, to this date has not been answered by a final court decision. The high practical relevance of this issue is obvious especially in the field of generics, as competitors are able to launch generic drugs after the expiry of the patent term only after a substantial number of preparatory acts. For example, these acts include the importation, the manufacture and transportation of substances or devices used in the trial, and possibly also the delivery of raw materials or components to be used in the production of the substances or devices. Even after the introduction of the Bolar exception (please see below), a need for clarification and thus a level of legal uncertainty persists.

– *Bolar exception;*
The introduction of a Bolar-type exception in Germany had been demanded for a long time, especially by the generics industry, and became necessary after the Directive 2004/27/EC entered into force. All in all, the Bolar exception entails a higher legal certainty with respect to clinical trials with pharmaceuticals in Germany and should thus, in principle, facilitate the performance of such trials in Germany. Accordingly, the long open question of the limits of the classic experimental use exception in trials with generics has lost much of its urgency.

  Generally, the introduction of the Bolar exception has shifted the (legal) leeway somewhat towards the generics manufacturers. The European and German legislators hoped to stimulate competition and promote a faster placing on the market of "new", cost-efficient drugs. It remains to be seen whether the Bolar exception will be able to fulfil these expectations.

  Nevertheless, the (harmonised) introduction of this experimental use exception to promote public health and stimulate competition in the pharmaceutical market seems to offer more benefits than drawbacks. It appears reasonable to not restrict the experimental use exception to generics, as trials with patented, innovative active substances often tend to have new, useful results for the public health and should, therefore, also be promoted or at least not obstructed by the legislation.

– *parallel import of patented medicines;*
Given the existing legal situation (practice of the Federal Court of Justice and Specific Mechanism for EU accession countries), there seems to be no need for a regulation of parallel imports of medicines by patent law.

– *individual prescriptions exception;*
The direct individual preparation of medicines in pharmacies is not covered by the effects of the patent, either. This exemption from the effects of the patent, however, has hardly any relevance in practice, nor does it seem required in the interest of public health or for cost-efficient access to pharmaceuticals. It would probably go more or less unnoticed if this provision was cancelled altogether.

– *medical treatment defence;*
As medical treatments are not patentable under German law, there is no need for such a protective mechanism.

– *compulsory licensing;*
In the field of medicinal products and medical devices, the issue of a compulsory license under Sec. 24 PatG should be clarified before investing into the development of a new product.

At this time, a compulsory license can be requested only for a granted patent but not for a pending patent application. A proceeding for a compulsory license for a new drug stands chances of a success only if clinical data are available which prove the special value of the new drug compared to previously available products. Further, the patentee can delay or prevent the grant of a compulsory license, for instance by developing a rival product to the planned new product before the decision on the grant of the compulsory license, or by deriving divisional applications from a patent application which will be examined only after the grant of the original patent.

Thus, the compulsory license usually comes too late for potential applicants. Although development work and clinical trials are possible without a compulsory license under the experimental use exception, hardly anyone will make the substantial investments into a new drug if he cannot be sure that the new product will be marketed later.

For those interested in a compulsory license, it would thus be reasonable to first clarify the situation before investing in the development of a new product.

Generally, the possibility of "compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems" (title of the Regulation (EC) 816/2006) in the interest of the poor countries as well as the resulting, relatively quick transposition of new Article 31bis TRIPS by the Community legislator, is highly appreciated. The procedure set out in the Regulation, however, does not seem suited to provide fast, unbureaucratic support, especially in times of crises. For instance, time limits would be desirable within which the authorities of the Member States have to decide on an application for a compulsory license. The Regulation provides for such time limits for the actions of customs authorities defined in Article 14: If it is suspected that products manufactured under a compulsory license are being re-imported into the Community contrary to the Regulation, the review by the authority and related detaining of the goods may not exceed ten working days.

As far as can be seen, the German legislator has not yet defined any rules for the implementation of the Regulation, in particular in view of the procedure before the national authorities for the grant of a compulsory license. The legislator should adjust and/or amend the German (patent) laws as quickly as possible so as not to unnecessarily complicate the enforcement of rights under Article 31bis TRIPS.

– *expropriation;*
Especially with the provisions on compulsory licenses (Sec. 24 PatG) and the order of exploitation (Sec. 13 PatG), German patent law already today provides for possibilities to use granted patents against the patentee's will through the state and/or private third parties, which allow for flexible solutions tailored to the specific case within the limits of what is permissible under the Constitution. In light of the fact that expropriations are permitted only for the public good under Article 14 (3) sentence 1 GG anyway and, given the related severe consequences for right holders, may be contemplated only if no other, less severe means are available, hardly any cases are conceivable which would require additional regulations above and beyond the existing ones in German patent law.

– *any other limitations of the exclusive patent rights to facilitate access to medicines, diagnostics, medical devices and the like?*
Beyond the limitations of the exclusive rights that have been realised by the legislator in Germany and in the European Union, no further limitations seem necessary or reasonable.

It has to be considered that effective patent protection is essential to the researching pharmaceutical industry and represents a valuable asset also in the sense of medical progress and public health, which should not be carelessly put at risk.

2) *Do you see other ways than by limitations of patent rights in which patent law might facilitate access to medicines, diagnostics, medical devices and the like?*

Please refer to the explanations in the preceding paragraph.

Further, patent law could facilitate access to medicines and the like also by excluding certain inventions from patentability. This idea is behind the exception from patentability of therapy and diagnostic measures on the human or animal body as set out in European and German patent law (Art. 53 c EPC 2000, Sec. 5 PatG).

3) *Should any of the limitations of patent rights, specifically the research and experimental use exception, Bolar exception, and individual prescriptions exception be harmonised? If so, how? If not, why not?*

For reasons of equal legal opportunities alone, a global harmonisation of patent laws and of the legal requirements for acts of business in competition always seems desirable. However, it appears hardly reasonable and useful to only harmonise the exceptions from the effects of a patent, but not the effects as such or the preconditions for maintaining patent protection.

It is true that the Bolar exception exists in all EU Member States as a result of the Directive 2004/27/EC, providing for "harmonised legislation" in this respect. However, the national transpositions of this Directive differ surprisingly, ranging from a verbatim implementation of Art. 10(6) Directive to a substantial extension of the Bolar exception, for instance in Germany and Italy. Whether this promotes the development of a common market and common legal area can be justifiably doubted. On the other hand, the need for harmonisation surely is considerably greater in other areas.

Summary

In view of the public interest German law provides for certain restrictions of the exclusive patent rights of a patentee. Firstly the *experimental use exemption* enables the aimed further development of research and development, with the *Bolar exemption* also considering experiments focusing a commercial exploitation. Moreover *parallel imports* within the EEA and exemptions in case of individual prescriptions are legal. Theoretically *compulsory licenses* can be granted, if any, which do, however, not yet really play a role. In this regard the provisions of *Article 31bis TRIPS* are already applicable law in Germany. The legislator has, however, not yet set any rules for their enforcement.

These restrictions of exclusive patent rights do not constitute an *expropriation* of patent rights which are property constitutionally guaranteed by the German Basic Constitutional Law. Only the *order of use* entitling to a use of a patented invention against the patentee's will is a drastic encroachment on the rights of a patentee. However, in practice an *order of use* has never been rendered.

A global harmonization of the patent laws and their exemptions from the effect of the patent is desirable according to the opinion of the German National Group.

Résumé

Dans un souci d'intérêt public, le droit allemand prévoit certaines restrictions aux droits de brevet exclusifs d'un breveté. D'une part *l'exception d'une utilisation à titre expérimental* permet

l'évolution souhaitée de la recherche et du développement et *l'exception Bolar* tient également compte des expérimentations faites en vue d'une exploitation commerciale. En outre, sont légales des *importations parallèles* au sein de L'EEE ainsi que les exceptions liées à des prescriptions individuelles. En théorie, peuvent également être concédées des *licences obligatoires* qui ne jouent cependant qu'un rôle mineur jusqu'ici. Dans ce contexte les dispositions de l'article 31bis ADPIC sont des dispositions légales déjà en vigueur en Allemagne. Mais le législateur n'a pas encore mise en place une réglementation d'application de ces dispositions.

Ces restrictions aux droits de brevet exclusifs ne représentant toutefois pas une *privation* des droits de brevet qui, en tant que droits de propriété, sont garantis par la Constitution allemande. Seule *l'arrêté d'utilisation* qui permet l'utilisation d'une invention brevetée contre la volonté du breveté constitue une atteinte profonde aux droits du breveté. En pratique un tel arrêté d'utilisation n'a toutefois encore jamais édicté.

Une harmonisation globale des lois relatifs aux brevets et des exceptions des effets des brevets apparaît souhaitable selon le Groupe Allemand.

Zusammenfassung

Im Sinne eines öffentlichen Interesses sind nach deutschem Recht gewisse Einschränkungen der exklusiven Patentrechte eines Patentinhabers vorgesehen. Zum einen ermöglicht das *Versuchsprivileg* die erstrebte Fortentwicklung von Forschung und Entwicklung, wobei die *Bolar-Ausnahme* zudem Versuche berücksichtigt, die auf eine kommerzielle Verwertung hin abzielen. Darüber hinaus sind *Parallelimporte* innerhalb des EWR und Ausnahmen bei individuellen Verschreibungen legal. Theoretischerweise können ebenfalls *Zwangslizenzen* erteilt werden, die bisher jedoch kaum eine Rolle spielen. In diesem Zusammenhang sind die Regelungen des *Artikels 31bis TRIPS* in Deutschland bereits geltendes Recht. Der Gesetzgeber hat aber noch keine Regelungen zu seinem Vollzug vorgegeben.

Diese Einschränkungen der exklusiven Patentrechte stellen keine *Enteignung* des Patentrechts dar, welches als Eigentum im Grundgesetz verfassungsrechtlich gewährleistet ist. Lediglich die *Benutzungsanordnung*, die das Benutzen einer patentierten Erfindung gegen den Willen des Patentinhabers ermöglicht, ist ein tiefgreifender Eingriff in die Rechte eines Patentinhabers. In der Praxis wurde eine *Benutzungsanordnung* aber noch nie erlassen.

Eine globale Harmonisierung der Patentgesetze und deren Ausnahmen von der Wirkung des Patents ist nach Auffassung der Deutschen Landesgruppe wünschenswert.