

**Council for Trade-Related Aspects
of Intellectual Property Rights**

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REVIEW OF LEGISLATION IN THE FIELDS OF PATENTS, LAYOUT-DESIGNS
(TOPOGRAPHIES) OF INTEGRATED CIRCUITS, PROTECTION OF
UNDISCLOSED INFORMATION AND CONTROL OF
ANTI-COMPETITIVE PRACTICES IN
CONTRACTUAL LICENCES

Germany¹

The present document reproduces the questions put to the delegation of Germany and the responses given in the review of legislation on patents, layout-designs (topographies) of integrated circuits, protection of undisclosed information and control of anti-competitive practices in contractual licences at the Council's meeting of 26-30 May 1997.²

I. REPLY TO THE GENERAL QUESTION ON PRIORITY RIGHTS³

Does your country recognize a right of priority on the basis of an earlier patent application filed in any other WTO Member by a national of a WTO Member?

Yes.

II. REPLIES TO QUESTIONS POSED BY JAPAN

1. In your country, are the following subject matters protectable by patent: (1) plants and animals, and (2) plant and animal varieties?

Under Section 1 subsection 1 of the German Patent Act (Patentgesetz), patents are granted for any inventions which are new, which involve an inventive step, and to industrial application. No restriction is placed on the term "invention" in this sense. Hence, inventions relating to living nature, i.e. for instance plants and animals, may be given patent protection.

Under Section 2 No. 2 of the Patent Act, patents may not be granted for plant varieties and animal varieties. There is a *sui generis* system of protection for plant varieties, according to the Plant

¹ As regards legislation relevant to the areas under review and notified by Germany under Article 63.2 of the Agreement, reference is made to documents IP/N/1/DEU/1/Rev.1, IP/N/1/DEU/P/1-4, IP/N/1/DEU/I/1, IP/N/1/DEU/L/1 and IP/N/1/DEU/U/1.

² The minutes of the meeting have been circulated in document IP/C/M/13.

³ At the meeting of the TRIPS Council of 27 February 1997, Members agreed to respond to this question in the context of the present review (document IP/C/M/12, paragraph 18).

Variety Protection Act (Sortenschutzgesetz). There is no such system for animal varieties. Plant varieties may also be protected in Germany through Community variety protection. Animal varieties may therefore not become the subject of industrial property protection.

2. In your country, is the act of offering for sale included in the exclusive rights of patent?

Under Section 9 of the Patent Act, a patent has the effect that the patentee alone is authorised to use the patented invention. Under Section 9 No. 1. any third party is prohibited from making, offering for sale, putting on the market or using, or importing or stocking a product which is the subject matter of a patent for the purposes which have been specified. Hence, offering for sale is expressly mentioned in the statute as a violation.

3. In your country, what kinds of acts are recognized as exceptions to the exclusive rights conferred by a patent right?

Exceptions to the patentee's exclusive rights are summarised in Section 11 of the Patent Act, which reads as follows:

Section 11 of the Patent Act (Permitted actions)

"The effects of the patent shall not extend to:

1. Acts done privately and for non-commercial purposes;
2. Acts done for experimental purposes relating to the subject matter of the patented invention;
3. The extemporaneous preparation for individual cases in a pharmacy of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared;
4. The use on board vessels of another State party to the Paris Convention for the Protection of Industrial Property, of the patented invention, in the body of the vessel, in the machinery, tackle, gear, and other accessories, when such vessels temporarily or accidentally enter the waters to which the jurisdiction of this act extends. This shall be conditional on this article being used there exclusively for the needs of the vessel;
5. The use of the patented invention in the construction or operation of aircraft or land vehicles of another State party to the Paris Convention for the Protection of Industrial Property or of accessories to such aircraft or land vehicles, when these temporarily or accidentally enter the jurisdiction of this Act;
6. The acts specified in Article 27 of the Convention on International Civil Aviation (Federal Law Gazette 1956 II p. 411) of 7 December 1944, where these acts concern the aircraft of another State benefiting from the provisions of that Article."

4. In your country, in which case is use without the authorization of the right holder permitted, including use by the government or by third parties authorized by the government?

Under Section 24 of the Patent Act, it is possible for a compulsory licence to be issued. This is conditional on the patentee refusing to permit another to use the invention if an appropriate remuneration has been offered. A compulsory licence may only be issued if it is necessary in the public interest. It may be issued restrictively and made dependent on conditions.

Compulsory licences are issued in court proceedings. The Federal Patent Court is responsible for issuing such licences. The Federal Court of Justice may scrutinise the decision of the Federal Patent Court.

Section 13 of the Patent Act provides that a patent is not effective if the Federal Government orders that the invention should be used in the interest of the public good. The patentee may challenge such an order by the Federal Government before the Federal Administrative Court. In such cases, the patentee has a claim against the Federation for appropriate remuneration.

It should also be pointed out that one compulsory licence has been granted by the Federal Patent Court in Germany since 1945. This was however revoked by the Federal Court of Justice on appeal. No use order was made under Section 13 of the Patent Act.

5. In your country, how is the obligation under Articles 34.1 and 34.2 of the TRIPS Agreement regarding the shift of the burden of proof in civil proceedings for patent infringement related to a process patent implemented?

The relevant regulation is to be found in Section 139 subsection 3 of the Patent Act. Under this provision, in cases where a process to manufacture a new product is the subject matter of the patent, it is deemed to be in fact the same product as that manufactured by another, until such time as the opposite has been proved.

III. REPLIES TO QUESTIONS POSED BY THE UNITED STATES

1. Article 1 of the German Patent Law provides that "programs for computers" are not considered to be inventions. Please explain whether, under this provision, inventions within the categories specified below are not eligible to be patented under German law, notwithstanding the fact that the invention is novel, involves an inventive step, and is useful:

- (a) process inventions which, in whole or in part, consist of steps that are performed by a computer and are directed by a computer program,**
- (b) product inventions consisting of elements of a computer-implemented invention, including in particular:**
 - (i) machine-readable computer program code stored on a tangible medium such as a floppy disk, computer hard drive or computer memory; and**
 - (ii) a general purpose computer whose novelty over the prior art arises primarily due to its combination with a specific computer program.**

If any of these types of invention are excluded from eligibility to be patented, please explain how the German patent law complies with the obligations of Article 27 of the TRIPS Agreement, which mandates patent eligibility for all categories of invention without discrimination.

In accordance with Section 1 subsection 2 No. 3 of the German Patent Act (Patentgesetz), "programs for data processing systems", *inter alia*, are not eligible for patenting. In accordance with subsection of Section 1, this means however that protection is denied for "programs for data processing systems" only, if protection is sought for them "as such". This wording of the provision already leads to the conclusion that it is by no means the case that no patent protection is available for computer programs as a whole.

The exclusion of patentability for "computer programs as such" contained in German law corresponds to the exceptions to patentability contained in Article 52 paragraph 2(c) in conjunction with paragraph 3 of the European Patent Convention. As far as the patentability of computer programs is concerned, the patenting practice of the German Patent Office corresponds to that of the European Patent Office. In this context, the German guidelines for examination are in line with harmonised practice.

This practice can be described as follows in patenting computer programs:

A distinction is made as to whether or not a computer program is a technical invention. This is the case, if it is a technical "theory" making use of a computer program. In such cases, if the usual preconditions for patenting are met, computer programs may also be patented. If, however, a computer program is not linked to technology, it is a computer program as such, for which patent protection is in principle not available, and which may be protected under copyright law according to article 10 paragraph 1 of the TRIPS Agreement.

The following comments may be made with regard to the cases mentioned in question 1:

- a) Inventions containing processes or process steps carried out on a computer may be patented as so-called "program-related inventions" subject to the usual preconditions (susceptible of industrial application, novelty, inventive step) if the use of technical means is an integral part of solving the problem.
- b) In principle, patent protection may be granted in relation to machine-readable programs which are stored on a data carrier, subject to the above preconditions, i.e. if the use of technical means is an integral part of solving the problem. If, however, this is not the case, for instance because the memory is not extended by the program being stored, but is merely used as intended, patent protection is not available.

The same applies to a computer which may be used for general purposes with a specific computer program. It is a question of whether the program is of a technical nature, as well as whether the computer is extended by the program, or whether it is only used as intended.

German law is in accordance with Article 27.1 of the TRIPS Agreement, since it offers patent protection for all inventions in technological areas which are new, which involve an inventive step and which are susceptible of industrial application.

2. Article 9 of the German Patent Law grants a patent owner , *inter alia*, the right to prevent third parties from offering for sale, stocking, or putting a patented product on the market. Article 28 of the TRIPS Agreement enumerates the rights that each Member country must confer to a patent owner. Included among these rights are the rights to prevent third parties from *selling* the patented product. Please explain whether the phrase "putting on the market" is interpreted under German law to allow the patent owner to prevent third parties from selling the patented invention. If not, please explain how German law complies with the obligations of Article 28 of the TRIPS Agreement.

Yes.

The sale of a patented item is one of the patent owner's exclusive rights of patent. Sale without his consent is in breach of the patent in accordance with Section 9 subsection 1 No. 1.

3. Article 13 of the German Patent Law permits the Federal Government to declare that a patent "shall have no effect" if it orders the invention subject to the patent to be exploited in the interest of public welfare. Article 13(2) provides an avenue for the patent owner to appeal such a declaration, and Article 13(3) enables the patent owner to pursue a claim for reasonable compensation against the Federal Republic. With regard to this authority, please provide answers to the following questions.

- (a) Please indicate whether the patent subject to an order under Article 13(1) remains in effect as to parties other than the Federal Government, or if the patent is considered nullified or revoked. If the latter, please explain the basis in the TRIPS Agreement under which the German Government would be justified in taking these actions which materially impair the legitimate interests of the patent owner.
- (b) Please indicate how the authority specified in Article 13(1) is considered to be consistent with Articles 30 and 31 of the TRIPS Agreement. In particular, please explain how German law complies with the conditions concerning use without authorization of the patent owner specified in paragraphs (a) to (l) of Article 31 of the TRIPS Agreement.
- (a) An order relating to exploitation in accordance with Section 13 subsection 1 of the Patent Act does not affect the existence of the patent. As the text of the provision states, its effect is merely that "a patent shall have no effect where...". This "where" means that the patent owner has no right of prohibition on the basis of his patent against the agency issuing the order, but also that this applies only so far as the exploitation of the patent is necessary and has been ordered in the interest of public welfare or of the security of the Federal Republic.

Section 13 subsection 1 only permits exploitation by the authority issuing the order or its subordinate agency, but not commercial exploitation of the patent by third parties. The latter may be facilitated only by means of a compulsory licence in accordance with Section 24 of the Patent Act. It is naturally conceivable that the state agency issuing the order is unable to exploit the patent by itself, but that this agency commissions someone to exploit it. The latter is, however, only entitled within the context of the commission which has been conferred on him. If he acts in excess of this commission, he commits a breach of patent. Naturally, any third party commits a breach of patent, if it exploits a patent which is subject to an order in accordance with Section 13 subsection 1 without acting under the instructions of the state agency issuing the order.

As a result, it is therefore possible to say that the patent remains in force and retains its full prohibitive effect with regard to third parties. Only the state, or possibly someone working on its behalf, does not act in violation of the patent owner's right of prohibition if the patent is used to the extent covered by the state's order relating to exploitation.

- (b) It is necessary, first of all, to point out that, on ratifying the TRIPS Agreement, which was preceded by the German Parliament's consent to the Agreement by means of a statute, the provisions of the TRIPS Agreement also became directly applicable in German national law. All courts and authorities are therefore bound by them. Each provision contained in the Patent Act is therefore to be interpreted within the meaning of the provisions of the TRIPS Agreement without it being necessary to be transposed word for word into German law. Reference is made in this respect to the information provided in response to question 4.

Section 13 of the Patent Act is, hence, in accordance with the provisions contained in Articles 30 and 31 of the TRIPS Agreement, i.e. with the provisions also contained in Article 31(a) through (1). In this context, special reference needs to be made to the fact that orders relating to the exploitation in accordance with Section 13 of the Patent Act may not be issued for private purposes, but only in the interest of public welfare and in light of the security of the Federal Republic. This is therefore a question only of non-commercial exploitation under very strict preconditions; in other words, in cases of a national emergency or other extremely urgent circumstances (Article 31(b) of the TRIPS Agreement). Naturally, the order may only be issued after the circumstances of the individual case have been scrutinised. Exploitation is only permissible where it is necessary in the interest of public welfare or of the security of the Federal Republic. The extent and duration of exploitation are therefore also linked to the purpose. Article 31 (d) and (e) are also complied with which clearly results from the answer given to question 3(a). Exploitation is to be terminated as soon as the circumstances leading to its necessity no longer apply. Compensation is to be paid. All decisions taken by state agencies and courts may be challenged before the next higher instance, and, where necessary, before the Federal Constitutional Court. This may be deduced from the general guarantee of legal recourse contained in Article 24 of the Basic Law Constitution (Grundgesetz), but is also expressly set out in Section 13 subsection 2 of the Patent Act for appeals against an order, and in Section 13 subsection 3 of the Patent Act with regard to disputes over amounts of compensation.

4. Article 24(1) of the German Patent Law allows for the granting of compulsory licences to third parties if "the applicant or patentee refuses to permit the exploitation of the invention by another person offering to pay reasonable compensation and to furnish security therefor". The last sentence of this provision specifies that "a compulsory licence may be granted subject to restrictions and made dependent on conditions". Please answer the following questions concerning this provision of German law:

- (a) Article 5(A)(4) of the Paris Convention, as made applicable to WTO Members through Article 2.1 of the TRIPS Agreement, specifies that "no compulsory licence may be applied for on the ground of failure to work or insufficient working prior to the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last...". No limitation appears in the German patent law concerning the earliest date on which a third party is able to apply for or obtain a compulsory licence. Please explain how German law complies with

Article 2.1 of the TRIPS Agreement to the extent it incorporates the obligations of Article 5(A)(4) of the Paris Convention.

- (b) No provisions in the German Patent Law appear to address the numerous specific conditions found in Article 31 of the TRIPS Agreement. Accordingly, please explain how German law complies with each of the requirements of Articles 31(a) to (l) of the TRIPS Agreement.**
- (c) Please identify the specific legal or regulatory provisions that govern the setting of conditions of a compulsory licence under German law.**
- (d) Please explain the procedures that govern the evaluation and grant of an application for a compulsory licence in Germany.**
- (a) German, has ratified both the Paris Convention and the TRIPS Agreement. Both these legal instruments have been approved by the German Parliament. In accordance with German constitutional law, the provisions of both are therefore valid in national law.**

As will be explained in more detail later and in another context, compulsory licences are issued by the Federal Patent Court. The latter determines in detail the form which this licence is to take, as well as the conditions it is subject to. In taking a decision, the Federal Patent Court applies all legislation which is applicable in Germany, hence including the TRIPS Agreement and the Paris Convention. A decision to grant a compulsory licence not in accordance with Article 5(A)(4) of the Paris Convention would hence be in breach of German law, even without there being a need for an express mention of a time-limit in the Patent Act.

- (b) Firstly, please see the preceding answer. In its decision on issuing a compulsory licence, the Federal Patent Court will also need to apply to the provisions contained in Article 31(a) through (l) of the TRIPS Agreement. A decision issued without applying to these provisions would be in violation of the law if the decision were to be in contradiction of these provisions.**

The Federal Government notified in its written statement concerning the WTO Agreement that German law was in accordance with the obligations under the TRIPS Agreement, and that no legal amendments were needed in the area of intellectual property protection. The only point which needed updating was the extension of the duration of patents originating in the former GDR.

Although the provisions contained in Article 31 of the TRIPS Agreement are today applicable law in the Federal Republic of Germany and must be applied by the courts, the Federal Government will undertake clarification in this respect. A draft bill is currently being prepared which is to be put before the legislative bodies in the course of the next few months. This draft bill specifically incorporates into German law the provisions contained in Article 31 of the TRIPS Agreement. Hence, the wording of Section 24 of the Patent Act is to reflect the corresponding provision of the TRIPS Agreement more closely. This measure serves to clarify and improve the comprehensibility of the provision, especially for foreigners who are not familiar with the German legal system, but changes nothing with regard to the legal situation already applicable today.

- (c) If they are not contained in Section 24 of the Patent Act, such conditions are contained in the relevant provisions of international law which have been transposed into national German law, that is Article 31 of the TRIPS Agreement and Article 5(A)(4) of the Paris Convention. There are no further written provisions of this nature.
- (d) Compulsory licences are issued by the Federal Patent Court. The specific provisions relating to an action to issue a compulsory licence are to be found in Sections 81 through 85 of the Patent Act, particularly in Section 85.

The procedure to issue a compulsory licence is initiated by legal action (Section 81 of the Patent Act). The action is then served; the defendant is granted a "legal hearing". The Patent Court then takes a decision on the basis of an oral hearing which, in contrast to other comparable proceedings before the Federal Patent Court, the parties may not forego, in accordance with Section 85 subsection 3 of the Patent Act. The proceedings before the Federal Patent Court are concluded by a judgement. This judgement contains the decision on the part of the Federal Patent Court regarding the issuance of the compulsory licence, together with the provisions which have been made with regard to it, such as instructions, compensation, security et al.

This judgement takes effect once it has entered into legal force. An appeal on points of fact and law may be filed with the Federal Court of Justice against the judgement of the Federal Patent Court regarding the issuance of the compulsory licence, or also against refusal to grant the compulsory licence. The Federal Court of Justice then examines the correctness of the decision taken by the Federal Patent Court from a factual and legal point of view, as is the norm with appeals on points of fact and law.

The general provisions contained in the Patent Act and the Code of Civil Procedure (Zivilprozeßordnung) concerning action proceedings before the civil courts apply in addition to the specific provisions relating to proceedings to issue a compulsory licence.

5. Please indicate how many compulsory licences on a yearly basis have been granted in Germany since 1 January 1993.

One compulsory licence has been issued in the Federal Republic of Germany between 1945 and the present day, by judgement of the Federal Patent Court dated 7 June 1991. This compulsory licence was rescinded by judgement of the Federal Court of Justice dated 5 October 1995 in response to an appeal on points of fact and law filed by the patent owner. The subject matter of the patent which was at the centre of the dispute was a human immune interferon (IFN-gamma) for treating rheumatoid arthritis. The plaintiff in the proceedings had unsuccessfully attempted to obtain a contractual licence to manufacture a medicine containing this active ingredient which was not manufactured by the patent owner himself. The judgement of the Federal Patent Court was based on the assumption that the active ingredient was a superior medicine for treating rheumatoid arthritis, a serious illness which is extremely common.

In the proceedings for the appeal on points of fact and law, the Federal Court of Justice rescinded the compulsory licence because it came to the conclusion that there were other preparations for treating rheumatoid arthritis which could be used equally well for treating the illness. For this reason, the Federal Court of Justice negated the preconditions for issuing a compulsory licence.

6. Article 24(2) of the German Patent Law states that "forfeiture of a patent shall be pronounced if the invention is exclusively or mainly exploited outside Germany". Please explain whether importation can satisfy the standard specified in 24(2) of the German Patent Law, and if not, please explain how this provision complies with Article 27.1 of the TRIPS Agreement, which precludes discrimination in the enjoyment of patent rights with regard to local manufacture or importation of the patented invention.

Section 24 subsection 2 of the Patent Act provides that a patent is forfeit if the invention is exclusively or mainly exploited outside Germany except as otherwise provided by international agreements. An example of such an international agreement opposing the application of the provision is the TRIPS Agreement. Section 24 subsection 2 of the Patent Act is therefore not applicable in relation to other Member Countries of the TRIPS Agreement.

Furthermore, this will also be clarified in the new wording of Section 24 of the Patent Act (cf Section 24 subsection 5 of the Draft).

7. Article 30 of the TRIPS Agreement allows Member countries to provide limited exceptions to the exclusive rights granted by the patent provided these exceptions do not "unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner". Articles 11 and 13 of the German Patent Law provide for exceptions to a patent owner's exclusive rights for "private and non-commercial purposes" (Article 11(1)) and for public welfare and security (Article 13(1)). Please explain how each of these exceptions complies with Article 30.

The exceptions to Section 11 No. 1 and Section 13 subsection 1 of the Patent Act do not unreasonably conflict with normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner. First of all, it should be pointed out that, in accordance with Article 30 of the TRIPS Agreement, the legitimate interests of third parties should also be taken into consideration with regard to the question of whether the legitimate interests of the patent owner have been unreasonably prejudiced.

In accordance with an established line of rulings, the exception contained in Article 11 No. 1 is to be given a very narrow interpretation. First of all, both preconditions must be met, i.e. acts must be done privately and for non-commercial purposes. If one of these preconditions is not met, the exception is not granted. Thus, carrying out acts privately, but for commercial purposes, is not free of patent protection. Acts carried out by public institutions, for non-commercial purposes for instance, by local authorities or by state or Church institutions, do not fall within the exception either.

Thus, the potential for patent-free exploitation under Section 11 No. 1 of the Patent Act is very restricted. No cases have ever been known in which unreasonable prejudice, or indeed any prejudice at all worth mentioning, of the interests of patent owners has been caused within the framework of this provision.

The provision contained in Section 13 subsection 1 of the Patent Act also does not permit unreasonable prejudice to be caused to the rights of patent owners. The provision applies only to cases in which exploitation serves public welfare or the security of the Federal Republic, cases therefore where the supreme interests of society have been or may be prejudiced. An order relating to exploitation is only to be maintained as long as and to the extent required by the prejudice caused to these supreme interests. Reference is made to the answer to question 3.

No orders relating to exploitation in accordance with Section 13 of the Patent Act have been issued in the Federal Republic of Germany since 1945.

8. Please indicate the nature of measures, if any, that are taken by judicial authorities in Germany to protect the confidentiality of undisclosed information furnished by a party to the court during legal proceedings, when the information has been provided either to enforce rights in such information, or for other purposes.

In accordance with Section 172 No. 2 of the Courts Constitution Act the court may hold the entire proceedings or a part of them in camera, if "an important secret is discussed relating to business, a company, an invention or to fiscal matters the public discussion of which would violate priority interests which are worthy of protection". In accordance with Section 174 subsection 3 of the Courts Constitution Act the court may also obligate the persons remaining at the session, in particular the parties and their counsel, to keep secret facts which they learn during the proceedings.

In order to comply as closely as possible both with the interest of secrecy and of clarification, the court may order that an article or a document may not be examined before the court in the presence of the parties, but by a neutral person who has been sworn to secrecy, such as an auditor. The latter is given a precisely defined commission to investigate, on which he is then to report before the court.

9. Please explain the measures, if any, that have been implemented in Germany to protect against unfair competition those parties that have provided confidential test or other data concerning a pharmaceutical or agricultural chemical product to German regulatory authorities pursuant to a request for marketing approval. Please explain how such measures, if any, are consistent with Article 39.3 of the TRIPS Agreement.

Those parties in Germany that have provided confidential test or other data concerning a finished medical product in order to obtain a marketing authorization from the national competent authority are protected, according to Article 39.3 of the TRIPS Agreement, against unfair competition by some of the regulations of the Drug Law of the Federal Republic of Germany (GDL Arzneimittelgesetz).⁴

Nonetheless, the health-protection of patients is to be regarded as a high priority. Pursuant to Section 40 subsection 1 Nos. 6 and 7 GDL preclinical data which is needed for the performance of clinical trials is of crucial interest for the parties involved. Therefore, a larger circle of persons of various authorities have to take part in the above mentioned assessment and evaluation.

In Section 24a of the GDL, documentation - required for a marketing authorization - from a previous applicant is regulated. This documentation might include relevant and undisclosed information. This Section refers to new pharmaceutical substances as well as to their correspondent preparations (see Section 49 subsection 1 GDL).

The applicant may refer to documents of pharmacological testing and clinical trial (see Section 22 subsection 2 and 3 GDL) or to pharmacological/toxicological testing and clinical expert opinion (see Section 24 GDL).

The analytical expert opinion (see Section 24 subsection 1 GDL) as well as the data of the analytical testing (see Section 22 subsection 2 No. 1 GDL) are kept strictly confidential and well protected.

The general right of exploitation of restricted data by the national competent authority is laid down by law in Section 24c GDL. Therefore, documents concerning the physical quality of drug

⁴ See Annex attached to the document.

determining parameters (manufacture, preservation, method of quality control, analytical testing and analytical expert opinion) must be restricted as well.

In addition to that, the provisions of the German Penal Law are applicable to protect data in the licensing application regarding industrial and intellectual property.

IV. REPLIES TO QUESTIONS POSED BY INDIA

1. Could Germany specify the scope and meaning of the term "public policy" in Section 2.1 of the Patent Law 1980?

"Public policy" in Section 2.1 of the Patent Law means that the publication or exploitation of the invention must be in line with all basic rules and regulations which are applicable in Germany, namely those basic rules and regulations created to ensure the security of the state and its people.

2. With reference to Section 2.2 of the Patent Law, are non-biological processes patentable?

Biological and micro-biological processes can be applied for the breeding of plants and animals.

According to Section 2.2 of the Patent Law, microbiological processes are patentable, whereas biological processes are not patentable. If there were non-biological processes for the breeding of plants and animals, they would be also patentable.

3. What are the restrictions or conditions which could accompany the grant of a compulsory licence under Section 24.1? Is non-working of a patent a ground for grant of compulsory licences?

Restrictions or conditions which can accompany the grant of a compulsory licence are case by case determined by the Federal patent Court (Bundespatentgericht) which grants compulsory licences. In taking this decision, the Federal Patent Court applies all legislation which is applicable in Germany, hence including the TRIPS Agreement and the Paris Convention.

As an example, scope and duration of the use will be limited.

Non-working of a patent is not a ground for the grant of compulsory licences.

ANNEX

FOURTH CHAPTER
MARKETING AUTHORIZATION FOR DRUGS

Section 21

Obligation to obtain a marketing authorization

(1) Finished drugs which are drugs as defined in section 2 sub-section 1 or sub-section 2 no. 1, may only be placed on the market within the purview of the present Law, if they have been authorized by the competent higher federal authority. The same shall apply to drugs which are not finished drugs and which are intended for administration to animals, provided they are not intended for distribution to pharmaceutical entrepreneurs holding an authorization for the manufacture of drugs.

(2) A marketing authorization (*Zulassung*) shall not be required for drugs which

1. are intended for administration to human beings and the essential manufacturing stages of which, owing to evidence that they are frequently the subject of medical and dental prescriptions, are carried out in a pharmacy which produces batch sizes of up to one hundred packages ready for dispensing in the space of one day as part of its normal operations and are intended for distribution in the same pharmacy,
2. are intended for use in clinical trials on human beings,
3. are medicated feeding stuffs, manufactured in keeping with their designated purpose from premix drugs for which a marketing authorization has been issued in accordance with section 25,
4. are manufactured for individual animals belonging to a specific stock in pharmacies or in veterinarians' house dispensaries,
5. are intended for use in clinical trials on animals or in residue tests.

(2a) Drugs which contain substances or preparations from substances which have not been released for trade outside of pharmacies and are intended for Administration to food-producing animals may, pursuant to sub-section 2 no. 4, only be manufactured if no drug authorized for marketing exists to treat the specific animal species or suitable for use in this field of application, if the necessary medical care of the animals would otherwise be seriously jeopardized, if a direct or indirect danger to the health of human beings and animals is to be

feared and the drugs are intended for use by the veterinarian or for administration under his or her supervision. However, such drugs may only contain substances or preparations from substances which are to be found in drugs which are authorized for Administration to food-producing animals; the transfer of drugs to another container packaging or labelling of drugs in their unaltered form shall not be considered manufacturing within the meaning of sentence 1. Sentences 1 and 2 shall not apply to homeopathic medicines, which are either registered or exempt from registration, the degree of dilution of which does not lie below the sixth decimal potency.

(3) Application for a marketing authorization shall be made by the pharmaceutical entrepreneur. For a finished drug manufactured in pharmacies or at other retail dealers' using standardized procedures and distributed to the consumer under a standardized name, application for marketing authorization shall be made by the party responsible for the issue of the master formula. If a finished drug is manufactured for several pharmacies or other retail dealers and is to be distributed to the consumer under their name and under a standardized name, then the manufacturer shall apply for marketing authorization.

Section 22

Documents required for marketing authorization

(1) The applicant shall attach the following particulars, written in German, to his application for a marketing authorization:

1. the name or the company and the address of the applicant and the manufacturer,
2. the name of the drug,
3. the constituents of the drug by type and quantity; section 10 sub-section 6 shall apply,
4. the pharmaceutical form,
5. the effects,
6. the fields of application,
7. the contra-indications,
8. the side effects,

9. the interactions with other products,
10. the dosage,
11. a brief summary of the drug's manufacture,
12. the method of administration and, in the case of drugs which should only be administered for a limited period of time, the duration of the administration,
13. the package sizes,
14. the method of preservation, the shelf-life, the storage conditions, the results of stability tests,
15. the methods of quality control (test methods).

(2) Furthermore, the following information shall be submitted:

1. the results of physical, chemical, biological or microbiological examinations and the methods used in their determination (analytical test),
2. the results of the pharmacological and toxicological examinations (pharmacological-toxicological test),
3. the results of the clinical or other medical, dental or veterinarian test (clinical trial).

The results shall be substantiated by documentary evidence in such a way that the type, scope and exact time of the tests are clearly evident.

(3) Instead of results specified in sub-section 2 nos. 2 and 3, other scientific documents may be presented

1. in the case of a drug, the effects and side effects of which are already known and which are evident from the scientific documents,
2. in the case of a drug which, in its composition, is comparable to a drug as specified in no. 1,
3. for the constituents of the drug, in the case of a drug which is a new combination of constituents which are already known; however, other documents containing scientific

findings may also be presented for the combination as such, if the efficacy and safety of the drug according to its composition, dosage, pharmaceutical form and fields of application can be determined by these documents.

Furthermore, the medical experience gained by the specific schools of therapy must also be taken into consideration.

(3a) If the drug contains more than one medically active constituent, evidence shall be provided to prove that every medically active constituent contributes to the positive assessment of the drug.

(3b) In the case of radiopharmaceuticals which are generators, a general description of the system including a detailed description of those components of the system which are able to influence the composition or quality of the secondary radioactive nuclide preparation, as well as the particular qualitative and quantitative characteristics of the eluate or the sublimate.

(4) If an application is made for a marketing authorization in respect of a drug manufactured within the purview of the present Law, proof shall be furnished that the manufacturer is entitled to manufacture the drug. This shall not apply in the case of an application as specified in section 21 sub-section 3 sentence 2.

(5) If an application is made for a marketing authorization in respect of a drug manufactured outside the purview of the present Law:

1. proof shall be furnished that the manufacturer is entitled to manufacture drugs in accordance with the legal regulations laid down by the country of manufacture and, in the event that the drug is imported from a country which is not a member state of the European Communities or a state party to the Agreement on the European Economic Area, that the importer is in possession of an authorization to bring the drug into the purview of the present Law,
2. the authorization to place the drug on the market in the country of manufacture shall also be presented; should such an authorization not exist, the reasons for this shall be stated.

(6) In so far as a marketing authorization has been applied for, granted or refused or an application for such a marketing authorization has been withdrawn in another state or in several other states, this shall also be stated.

(7) The application for a marketing authorization shall be accompanied by the text of the particulars which are meant to appear on the container, the outer package and the package leaflet as well as by the draft of the expert information pursuant to section 11a sub-section 1 sentence 2. The competent higher federal authority may require the submission of one or more samples or mock-ups of the sales presentation of the drug including the package leaflets.

Section 23

Particular documents required for drugs intended for administration to animals

(1) In respect of drugs intended for Administration to food-producing animals, the following particulars shall be given in addition to those specified in section 22:

1. particulars of the withdrawal period shall be given and shall be substantiated by documents on the results of the residue tests and particularly on the fate of the active ingredients and their metabolic products in the animal body and on the influence had on foodstuffs of animal origin, in so far as these results are necessary for the assessment of withdrawal periods taking stipulated maximum levels into account,
2. the description of a routine procedure by means of which the type and quantity of residues from substances which are harmful to health can be detected reliably, especially in such quantities as exceed the stipulated maximum levels, or from which reliable conclusions can be drawn regarding such residues (residue test procedures), as well as documents containing proof thereof,
3. in the case of a drug the active ingredient of which is not listed in Annexes I, II or III of Council Regulation (EEC) No. 2377/90 of 26th June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foods of animal origin (OJ EC No. L 224, p. 1), a duplicate of the documents submitted to the Commission of the European Communities pursuant to Annex V of this resolution.

(2) In the case of premix drugs, the particulars of the mixed feed intended as carrier shall be given with the designation of the type of feeding stuff. Furthermore, it shall be justified and proved by documents that the premix drugs are suited for the intended manufacture of the medicated feeding stuff, and particularly that they allow a homogeneous and stable distribution of the active ingredients in the medicated feeding stuffs taking into consideration the manufacturing methods applied in the production of mixed feed; furthermore, the shelf-life of medicated feeding stuffs shall be indicated, grounds provided and proved by documents. Moreover, a routine test

method suitable for the quantitative and qualitative analysis of the active ingredients in the medicated feeding stuffs, shall be described and documents on test results submitted as proof.

(3) The nature and scope of as well as the date on which the tests were carried out shall be inferable from the documents containing the results of the residue tests and the residue test procedures pursuant to sub-section 1, as well as from the evidence regarding the suitability of the premix drugs for the intended manufacture of the medicated feeding stuff and the test results of the test methods pursuant to sub-section 2. Instead of the documents, the evidence and test results referred to in sentence 1, other scientific findings may be submitted.

(3a) In cases where the storage of the drug, its administration to animals or the disposal of its waste products require special safety precautions or security measures to avoid endangering the environment or impairing the health of human beings, animals or plants, this shall also be stated. Information on how to reduce these dangers shall also be submitted and substantiated.

(4) The competent higher federal authority shall publish the residue test procedures pursuant to sub-section 1 no. 2.

Section 24

Expertises

(1) Expertises in which the test methods, test results and residue test procedures are summarized and assessed, shall be included with the required documents as specified in section 22 sub-section 1 no. 15, sub-sections 2 and 3 and section 23. In particular, the following information shall be included in detail in the expertises presented:

1. the analytical expert opinion shall state whether the drug is of appropriate quality in accordance with recognized pharmaceutical practice, whether the proposed test methods comply with the prevailing standard of scientific knowledge and are suitable for quality assessment,
2. the pharmacological-toxicological expert opinion shall state the drug's toxic effects and pharmacological properties,
3. the clinical expert opinion shall state whether the drug has the required effect in the specified fields of application, whether it is tolerated, whether the prescribed dosage is appropriate and which contra-indications and side effects exist,

4. the expert opinion on the residue test shall state whether, and if so how long after the administration of the drug, residues occur in the foodstuffs obtained from the animals which have undergone treatment, how these residues are to be assessed, whether the prescribed withdrawal period is sufficient and whether the residue test procedure can reliably detect the presence of residues of substances which may be detrimental to health, as well as their type and quantity, and whether it lends itself to routine use.

Moreover, the expert opinion must state whether the type and quantity of residue present after the prescribed withdrawal period has elapsed are below the maximum levels stipulated by EEC Council Regulation No. 2377/90.

(2) In so far as scientific documentation is presented pursuant to section 22 sub-section 3 and section 23 sub-section 3 sentence 2, it must be evident from the expert opinion, that the documents on scientific findings were elaborated under analogous application of the Guidelines for the Testing of Drugs.

(3) The expert opinion shall be accompanied by particulars regarding the name, training and professional practice of the expert as well as his professional relationship with the applicant. The experts shall sign their statements personally, stating the place and the date of issue of the expert opinion.

Section 24a

Use of documentation from a previous applicant

(1) In the case of a drug which is or was subject to prescription pursuant to section 49, the applicant may refer to documents pursuant to section 22 sub-section 2 nos. 2 and 3 and section 23 sub-section 1 including an expertise pursuant to section 24 sub-section 1 sentence 2 nos. 2 to 4 from a preceding applicant (previous applicant) if the previous applicant has granted permission in writing. The previous applicant shall respond to a request for permission within a period of three months. The permission of the previous applicant shall not be necessary in cases where the applicant can prove that more than ten years have elapsed since a marketing authorization was granted for the drug for the first time in one of the Member State of the European Communities.

(2) Deleted

Section 24b

Request for additional documents

If several holders of a marketing authorization have to be requested to submit additional documents, the competent higher federal authority shall notify every holder of a marketing authorization of the documents necessary for the further assessment as well as of the names and addresses of the other holders of a marketing authorization who are involved. The competent higher federal authority shall give those holders of the marketing authorization who are involved the opportunity to decide among themselves as to who shall submit the documents within a period of time to be determined by the authority. If an agreement is not reached, the competent higher federal authority shall decide and immediately notify all persons concerned. Unless the other holders of a marketing authorization choose to forgo the marketing authorization granted for their own pharmaceutical product, they shall be obliged to contribute proportionally to the expenditure incurred in the preparation of the documents calculated according to the number of holders of a marketing authorization involved: they are jointly and severally liable. Sentences 1 to 4 shall apply *mutatis mutandis* for persons using standard marketing authorizations as well as in cases where documents with the same contents are requested from several applicants in ongoing marketing authorization procedures.

Section 24c

General right of exploitation

The competent higher federal authority is empowered to utilize the documents submitted to it, with the exception of those referred to under section 22 sub-section 1 nos. 11, 14 and 15 as well as sub-section 2 no. 1 and the expert opinion pursuant to section 24 sub-section 1 sentence 2 no. 1, in fulfilling its tasks under the present Law, provided that at least 10 years have elapsed since the drug first received a marketing authorization in one of the Member State of the European Communities or a procedure pursuant to section 24b has not yet been terminated.

Section 25

Decision on marketing authorization

(1) The marketing authorization, together with a marketing authorization number, shall be issued in writing by the competent higher federal authority. The marketing authorization shall only be applicable to the drug specified in the marketing authorization notice and, in the case of drugs manufactured according to homeopathic manufacturing procedures, and which are not subject to prescription, it shall also apply to the degree of dilution mentioned in results published

SIXTH CHAPTER PROTECTION OF HUMAN BEINGS DURING CLINICAL TRIALS

Section 40 General preconditions

(1)¹¹ The clinical trial of a drug shall only be performed on human beings if and as long as

1. the risks, which are involved for the person on whom the trial is to be carried out, are medically justifiable, when compared with the anticipated significance of the drug for medical science,

¹¹ Pursuant to Article 1 no. 25 letter a), in conjunction with Article 6 sub-section 2 no. 1 of the Fifth Law Amending the Drug Law of 9th August 1994 (Federal Law Gazette I, p. 2071), section 40 sub-section 1 shall be worded as follows; effective as of 17th August 1995:

"(1) The clinical trial of a drug shall only be performed on human beings if and as long as

1. the risks, which are involved for the person on whom the trial is to be carried out, are medically justifiable, when compared with the anticipated significance of the drug for medical science,
2. the person, on whom the clinical trial is to be carried out, has given his consent, having been informed by a physician of the nature, significance and scope of the clinical trial, and with this consent has at the same time declared that he agrees with the recording of disease-related data which will take place in the course of the clinical trial as well as the transmission of such data to the person commissioning the clinical trial, the competent supervisory authority or the competent higher federal authority,
3. the person, on whom the trial is to be carried out, has not been committed to an institution by virtue of an order issued either by judicial or administrative authorities,
4. it is run under the supervision of a physician, who can prove at least two years' experience in the field of the clinical trial of drugs,
5. a pharmacological-toxicological test has been carried out which is in compliance with the prevailing standard of scientific knowledge,
6. the documents on the pharmacological-toxicological test, on the test plan reflecting the prevailing standard of scientific knowledge and containing the names of those testing and the places where the trials are conducted, as well as the opinions of the ethics committee, have been deposited with the competent higher federal authority,
7. the person directing the clinical trial has been informed by a scientist responsible for the pharmacological-toxicological test about the findings of said test and the risks to be anticipated with the clinical trial,
8. in the event that a person is killed or a person's body or health is injured or impaired in the course of the clinical investigation, an insurance policy which also provides benefits when no one else accepts liability for the damage, exists in accordance with the provisions contained in sub-section 3.

A clinical trial of a drug may be commenced on a human being, subject to the provisions contained in sentence 3 only if a favourable opinion on it has been delivered beforehand by an independent ethics committee established on the basis of Laender law; the prerequisite for a favourable opinion is the observance of the conditions laid down in sentence 1. In so far as no favourable opinion has been delivered by the ethics committee, the clinical trial may be commenced only if the competent higher federal authority has not delivered a decision to the contrary within 60 days of receipt of the documents referred to in sentence 1 no. 6. The ethics committee shall be informed of all serious or unexpected undesirable events which occur during the clinical trial and which could compromise the safety of the participants or the conduct of the trial itself."

2. the person, on whom the clinical trial is to be carried out, has given his consent, having been informed by a physician of the nature, significance and scope of the clinical trial,
3. the person, on whom the trial is to be carried out, has not been committed to an institution by virtue of an order issued either by judicial or administrative authorities,
4. it is run under the supervision of a physician, who can prove at least two years' experience in the field of the clinical trial of drugs,
5. a pharmacological-toxicological test has been carried out which is in compliance with the prevailing standard of scientific knowledge,
6. the documents on the pharmacological-toxicological test have been deposited with the competent higher federal authority,
7. the person directing the clinical trial has been informed by a scientist responsible for the pharmacological-toxicological test about the findings of said test and the risks to be anticipated with the clinical trial,
- 7a. a test plan which is in keeping with the prevailing standard of scientific findings is available and,
8. in the event that a person is killed or a person's body or health is injured or impaired in the course of the clinical investigation, an insurance policy which also provides benefits when no one else accepts liability for the damage, exists in accordance with the provisions contained in sub-section 3.

(2) A declaration of consent as specified in sub-section 1 no. 2 shall only be valid if the person granting it

1. has legal capacity and is in a position to comprehend the nature, significance and scope of the clinical trial and to form a rational intention in the light of these facts,
2. has granted consent in person and in writing.

The declaration of consent may be revoked at any time.

(3) The insurance specified in sub-section 1 no. 8 must be taken out in favour of the person undergoing the clinical trial with an insurance carrier authorized to conduct business within the purview of the present Law. Its size must be commensurate with the risks involved in the clinical trial and must amount to a minimum of one million deutsche marks to cover the risk of death or permanent disability. In so far as benefits are paid by the insurance, all claims to damages shall be extinguished.

(4) In respect of a clinical trial carried out on minors, sub-sections 1 to 3 shall apply with the following proviso:

1. The drugs must be intended to diagnose or prevent diseases in minors.
2. The administration of the drug must be indicated in accordance with medical knowledge for the purpose of diagnosing or preventing diseases in the minor.
3. Clinical investigations performed on adults cannot be expected to produce satisfactory test results according to medical knowledge.
4. The consent shall be granted by the minor's legal representative or guardian. It shall only be valid if this person has been informed by a physician on the nature, significance and scope of the clinical trial. If the minor is in a position to comprehend the nature, significance and scope of the clinical trial and to form a rational intention in the light of these facts, then his written consent shall also be required.

(5) The Federal Ministry is hereby empowered to stipulate by ordinance, with the approval of the Bundesrat, provisions to guarantee the proper conduct of clinical trials and the production of documents which comply with the prevailing standard of scientific knowledge. The ordinance may cover, in particular, further details regarding the tasks and areas of responsibility of the persons having the clinical trial conducted, those conducting or supervising it, as well as requirements regarding the keeping and preservation of records.

(3) The ordinance specified in sub-section 2 no. 1 may be limited to specific dosages, potencies, pharmaceutical forms or fields of application. Similarly, an exception to the prescription requirement may be envisaged for dispensing to midwives and obstetric nurses where this is deemed necessary for the proper exercise of their profession.

(4) The ordinance shall be issued in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, in so far as radiopharmaceuticals and drugs in the manufacture of which ionizing radiation is used are concerned, and in agreement with the Federal Ministry for Food, Agriculture and Forestry, as far as drugs intended for administration to animals are concerned.

Section 49

Automatic prescription requirement

(1) Drugs as defined in section 2 sub-section 1 or sub-section 2 no. 1 containing substances or preparations made from substances the effects of which are not generally known in the field of medical science shall only be dispensed to the consumer upon presentation of a medical, dental or veterinarian prescription. The same shall apply to drugs which are preparations made from substances, the effects of which are generally known, if the effects of these preparations as a whole are not generally known in the field of medical science, unless the effects can be determined according to the composition, dosage, pharmaceutical form or application field of the preparation.

(2) Sub-section 1 shall not apply to drugs which are preparations from substances, the effects of which are known, in so far as these substances may be distributed outside of pharmacies.

(3) The prescription requirement as specified in sub-section 1 shall end on the 1st January or 1st July following the termination of a five-year-period after the ordinance pursuant to sub-section 4 has entered into force.

(4) The Federal Ministry shall be empowered, by ordinance not subject to the approval of the Bundesrat:

1. to specify the substances or preparations referred to in sub-section 1,
2. to make use of the empowerments defined in section 48 sub-section 2 nos. 2 to 4 and sub-section 3 for the substances or preparations determined by ordinance pursuant to no. 1,

3. to cancel the prescription requirement if, after the termination of a period of three years following the coming into force of an ordinance pursuant to no. 1, by virtue of the experience made with the administration of the drug, it is clear that the conditions stipulated in section 48 sub-section 2 no. 1 do not exist.

The ordinance pursuant to sentence 1 shall be issued in agreement with the Federal Ministry for Food, Agriculture and Forestry, in so far as drugs intended for administration to animals are concerned.

(5) A renewed specification of substances or preparations pursuant to sub-section 4 no. 1 shall be permissible after expiry of the period of time mentioned in sub-section 3 if their effects are still not generally known in the field of medical science or if the data available do not enable an assessment of the preconditions for specifying the substances or preparations pursuant to section 48 sub-section 2 no. 1.

(6) The pharmaceutical entrepreneur shall be obliged to present a report to the competent higher federal authority on the experience gained with any drug containing a substance or preparation as specified in sub-section 4 no. 1, two years after the drug received its marketing authorization and, in the case of sub-section 5, two years after the specification of the substance or the preparation in the ordinance pursuant to sub-section 4 no. 1. This report shall give details of the quantities distributed during the period under review; furthermore, new findings on effects, type and frequency of side effects, contraindications, interaction with other products, habituation, dependence or a use of the drug not complying with the intended purpose shall be given. In the case of drugs intended for Administration to food-producing animals, a report shall also be submitted on the experience gained for example on whether and how often residues have been found in foodstuffs produced from treated animals after administration of the drug, where appropriate, to what it is ascribed and how successful the described residue test procedures have proved to be. In the case of premix drugs, reports must also be submitted on the experience gained, saying how successful the described test method has proved to be for the qualitative and quantitative detection of the active ingredients in medical feeding stuffs.
