FEDERAL CONSTITUTIONAL COURT

- 1 BVR 1864/95 -

IN THE NAME OF THE PEOPLE

In the proceedings
on
the constitutional complaint

of B. ... GmbH

- Lawyers Heinrich Deubner and colleagues,
  Mozartstrasse 13, Karlsruhe -

against a) the decision of the Federal Court of Justice (Bundesgerichtshof) of July 11, 1995 - X ZR 99/92 -,

the First Chamber of the First Panel of the Federal Constitutional Court

- Judges Vice-President Papier,
Steiner,
Hoffmann-Riem

decided on May 10, 2000, pursuant to § 93 b in conjunction with § 93 a BVerfGG [*Bundesverfassungsgerichtsgesetz - Federal Constitutional Court Act*] as amended in the notification of August 11, 1993 (BGBl [*Bundesgesetzblatt - Federal Law Gazette*] I, p. 1473), unanimously as follows:

The constitutional complaint is not admitted for decision

Grounds:

The constitutional complaint concerns the question whether it is compatible with Art. 14(1), sentence 1 GG (*Grundgesetz - Basic Law*) to regard clinical trials which involve a pharmaceutical drug under patent protection as acts of use to which the effects of the patent do not extend. 1

I.

1. The complainant is the exclusive licensee for the territory of the Federal Republic of Germany of the European patent which concerns a polypeptide with human interferon (IFN-gamma) characteristics obtained by means of genetic engineering which contains a specific amino acid sequence. The patent application was filed on October 18, 1982. The grant of the patent was published on June 28, 1989. In a declaration dated February 13, 1995, the patentee waived the grant of a corresponding German patent of which the complainant was the exclusive license holder as well. 2

The defendant under point 4. of the original proceedings was supplied with Interferon-gamma from abroad whose amino acid sequence corresponds to the patents which are subject of the complaint and used it to produce the pharmaceutical 3

drug Polyferon, which had been approved by the Bundesgesundheitsamt (Federal Health Office) in its decision of January 24, 1989, for the treatment of classical rheumatoid arthritis. Subsequently, the defendant supplied the product to another defendant which distributed it. The Bundespatentgericht (Federal Patents Court) issued a compulsory licence of the patents which were the subject of the action to the defendant under point 4. This license entitled the defendant under point 4 to make Polyferon, to offer it for the approved medical indication, to put it on the market and to use it or to import and stock it.

Moreover, the defendants of the original proceedings conducted clinical trials involving the substance Interferon-gamma with a view to verifying further indications which were thought possible. 4

The Regional Court (*Landgericht*) allowed the lawsuit against the defendants under points 1. to 6. for refraining from the use of the patents which were the subject of the action, sentenced the defendants under points 1., 2., 4., and 5. to the rendering of accounts and held that the defendants were obliged to pay a reasonable compensation. The Regional Court, however, dismissed the request for bringing a legal action which intended to establish the obligation of paying damages and of rendering accounts with a view to a claim to damages. In the revision proceedings, the parties of the original proceedings concurrently declared that the claims which were the subject of the action insofar as they had been referred to the compulsory licence had been dealt with on the merits. The Higher Regional Court (*Oberlandesgericht*) allowed the remaining relief sought by the complainant and dismissed the defendants' revision. 5

In the revision proceedings instituted by the defendants, the Federal Court of Justice, in its decision of July 11, 1995, dismissed the main points of the action (*BGHZ [Entscheidungen des Bundesgerichtshofs in Zivilsachen, decisions of the Federal Court of Justice in civil proceedings]* 130, 259). It held that the complainant was not entitled to request the defendants to refrain from clinical trials in which further indications of the drug Polyferon were to be ascertained. Moving away from its previous decisions on the basis of the legal situation before the coming into force of Section 11 , subsection 2 of the Patent Law as amended in the notification of December 16, 1980 *(- PatG [Patent Law] BGBl [Federal Law Gazette] 1981 I p. 1*), the Federal Court of Justice expressed, in the decision which is the subject of the constitutional complaint, the opinion that if a patented pharmaceutical substance was used in clinical trials with the aim to ascertain whether, and if so, in what form this substance was suitable for healing or alleviating certain other human diseases, this could be regarded as a lawful act done for experimental purposes in the sense of the regulation mentioned above. 6

2. In its constitutional complaint, the complaining company reprehends an infringement of its fundamental rights under Art. 14(1), sentence 1 GG. 7

According to the complainant, the judgement of the Federal Court of Justice infringes the protection of ownership guaranteed by the Basic Law, as the interpretation 8

of the "Versuchsprivileg" (*experiment privilege*) under Section 11 , subsection 2 PatG advanced by the Federal Court of Justice results in the patentee being deprived of its exclusive right to the subject of the patent.

The Federal Ministry of Justice, the defendants of the original proceedings and the Verband Forschender Arzneimittelhersteller (*Researching Pharmaceutical Drugs Manufacturers' Association*) have had the opportunity to give their opinions concerning this constitutional complaint. 9

The Verband Forschender Arzneimittelhersteller is of the opinion that the interpretation of the experiment privilege advanced by the Federal Court of Justice does not correspond to the reasonable balancing between, on the one hand, the patentee's interest in exclusivity and, on the other hand, the interest of the general public as well as of the research and teaching communities in the verification, perfection and development of the patented invention as envisaged by the legislator. According to this association, the extension of the experiment privilege does not promote scientific research by the manufacturers which imitate the original substance to the benefit of the general public but hinders innovative research by the researching branch of the pharmaceutical industry to the detriment of the general public, as innovators are, to an increasing extent, deprived of the possibility to amortise their high investment by revenue during the term of the patent and, possibly, during the term of subsequent protection by a certificate, and to provide the financial means for the continuation of their research and development activities. 10

II.

The constitutional complaint is not accepted for decision as it does not provide the conditions for acceptance under Art. 93 a (2) BVerfGG. 11

1. This constitutional complaint has no fundamental constitutional significance (§ 93 a [2] letter a BVerfGG). A fundamental constitutional significance exists only if the constitutional complaint raises a constitutional issue which cannot be resolved with reference to the Basic Law alone and which has not yet been settled by constitutional jurisdiction or which requires to be dealt with again due to a change of framework conditions (cf. *BVerfGE-Decisions of the Federal Constitutional Court* - 90, 22, <24>). 12

In the decisions of the Federal Constitutional court it already been settled that the work created by the author and the performance it embodies are property in the sense of Art 14(1), sentence 1 GG, that the author's constitutional ownership guarantee results in his obligation to commercially exploit this "intellectual" property, and that the legislator, in the framework of the regulation requirement under 14(1) sentence 2 GG, has the obligation to define appropriate standards which ensure that its use and appropriate exploitation correspond to the nature and the social significance of this right (cf. BVerfGE 31, 229 <238 et seq.>; 49, 382 <392>). These principles apply accordingly to the patent right (cf. BVerfGE 36, 281 <290-291> concerning the inventor's technical intellectual property right which has not yet gained patent right status). 13

2. It is not necessary either to enforce the fundamental right which is regarded as infringed (Art. 93 a (2), letter b BVerfGG), as there is no sufficient prospect of success as concerns the result of the constitutional complaint. 14

a) The constitutional complaint is certainly admissible. The complaining company can put forward an infringement of its fundamental right under Art. 14(1) sentence 1 GG, since the complainant, as the licensee, is conferred the exclusive right of use, within the scope of the licence, vis-à-vis third parties under Art. 15 (2) PatG (cf. Keukenschrijver, in: Busse, Patentgesetz, 5th ed. 1999, Art 15 PatG, marginal number 60). Thus, this licence is a position which can be regarded as property in the sense of Art. 14 (1) sentence 1 GG. Restrictions of the right of preclusion under patent law directly affect the right of granting a licence so that in the decision which is the object of the constitutional complaint the complainant's property right is directly affected by the interpretation of the patent law regulation of Section 11 , subsection. 2 PatG. 15

b) The constitutional complaint, however, is not well-founded. The decision of the Federal Court of Justice does not infringe Art. 14 (1), sentence 1 GG. 16

aa) Section 11 , subsection 2 PatG, which is the main basis of the decision which is the object of the constitutional complaint, does not itself infringe the property right. This regulation limits the effects of the patent but it constitutes an admissible definition of the contents and the limits of property in the sense of Art. 14 (1) sentence 2 GG. 17

Pursuant to Art. 12 (1) of the Law on the European Community Patent and the change of patent law regulations (*Gemeinschaftspatentgesetz [European Community Patent Law], - GpatG*) - of July 26, 1979 (BGBl I, p. 1269), Art. 11 PatG may only be applied to patents whose application has been filed with the German Patent Office since January 1, 1981. 18

Pursuant to Art. 64 (1) of the Convention on the Grant of European Patents (- EPÜ [*European Patent Convention*] -, BGBl 1976 II p. 649, 826), this applies, accordingly, to European patents as well (cf. Keukenschrijver, in: Busse, Patentgesetz, l. c., Section 11, marginal number 4, Section 9, marginal number 9). This means that the legislator has not interfered with existing patents by limiting the effects of patents, but has regulated the content and the protective effects of future patents. Insofar as patents have been created since January 1, 1981, the owners have, from the outset, only been granted a legal position which is limited in this way (cf. BVerfGE 58, 300 <336>). 19

When defining the content of property, the legislator, however, is also bound for the future by constitutional limitations. The legislator cannot act without any limitation on the discretion when further refining patent law but must conserve the basic content of the ownership guarantee when defining the authorities and obligations which constitute the contents of the law and, at the same time, remain in line with all other constitutional standards (cf. BVerfGE 31, 229 <240>). 20

First of all, Art. 14 (1), sentence 1 GG guarantees the legal institute of private property whose essential characteristics are its private benefit and the right to dispose of the owned object (cf. BVerfGE 24, 367 <389-390>; 26, 215 <222>; 31, 229 <240>). As far as the patent right is concerned, this means: one of the constituent characteristics of the patent right as property in the constitutional sense is the principle of the association of the valuable result of the creative activity to the patentee by way of private law standardisation and the patentee's freedom to dispose of this result at his own discretion. This is what constitutes the core of the patent right which is protected by the Basic Law. 21

This basic association of the valuable side of the patent right to the owner's disposition does not establish, however, a constitutional right to any conceivable way of exploitation. 22

The guarantee of the legal institute ensures a basic repertoire of standards which must exist so that the right may be regarded as "private property". As far as the details are concerned, it is the legislator's task to define appropriate standards when establishing the contents of the patent right pursuant to Art. 14 (1), sentence 2 GG which ensure that its use and adequate exploitation correspond to the nature and the social importance of this right (cf. BVerfGE 31, 229 <240-241>). 23

With the right of exclusivity under Sections 9 and 10 PatG, the legislator has established a regulation which complies with these basic requirements of the property guarantee. Section 11 PatG establishes limits to the patent right, as it precludes the effects of patents for certain areas. When evaluating the legal limits of Section 11 , subsection 2 PatG from a constitutional point of view, the starting point must be that the task of the legislator does not only consist in securing individual interests but also in establishing limits to individual rights and authorisations which are necessary in the interest of the public good; the legislator must achieve an equitable balance between the sphere of the individual and the concerns of the public good (cf. BVerfGE 31, 229 <241-242>). 24

As far as can be ascertained, it is denied neither in jurisdiction nor in legal literature that the experiment privilege under Section 11 , subsection PatG is a constitutional determination of content of the patent right according to these provisions. Research as well as scientific and technical development are only possible through experiments which are based on the latest research results at the respective point in time. From the constitutional point of view, there are therefore no objections against the legislator giving these matters priority over the patentee's interests in this respect. This approach is also shared by the complainant. According to the complainant, the legislator has established an equitable balance between, on the one hand, the inventor's, or, respectively, the patentee's interest in exclusivity and, on the other hand, the interest of the general public as well as of the research and teaching communities in the verification of the patented invention and its perfection and development. 25

bb) Correspondingly, the complainant's complaint is not directed immediately 26

against the legal regulation of Section 11 , subsection 2 PatG but exclusively against the interpretation of the Federal Court of Justice which - in the complainant's opinion - is too far-reaching.

The interpretation of legal provisions subordinate to the Basic Law and their application to the individual case fall within the competence of the courts which are originally competent for the case; they are not normally subject to review by the Federal Constitutional Court (cf. BVerfGE 18, 85 <92>). The threshold of an infringement of constitutional law which would have to be corrected by the Federal Constitutional Court is only reached if the interpretation shows errors which are due to a fundamentally wrong view of the importance of the property guarantee, especially of the extent of the scope of protection, and which are, in their material importance, of considerable weight for the specific legal case (cf. BVerfGE 89,1 <10> and other sources). 27

There is no evidence for the Federal Court of Justice having failed to see the importance and implications of Art 14(1), sentence 1 GG in the decision which is subject of the constitutional complaint. 28

Certainly, the Federal Court of Justice has not explicitly designated the patent right as protected property in the sense of Art. 14(1), sentence 1 GG, but has made it clear that the legal system grants the inventor, as an adequate compensation for having benefited the general public, an exclusive right of use. The Federal Court of Justice has also recognised, as can be seen from the subsequent statements concerning the justification of patent right restrictions with a view to the social obligations connected with property, the constitutional protection of the patent right as property. 29

As concerns the balancing of the conflicting interests, the Federal Court of Justice has also given due consideration to the importance of Art. 14(1), sentence 1 GG. Subsequently, the Federal Court of Justice has examined the result gained by the interpretation of the wording and the history of the creation of Section 11 , subsection. 2 PatG, considering in particular if it is compatible with the patentee's right. In this context, the Federal Court of Justice has explained in an understandable way that unlimited protection of the patent pursuant to the principles of freedom of research and of the social obligations connected with property is not justified in cases in which this hinders technical development. The purpose of the patent right, i. e. to promote technical progress and to stimulate inventiveness in a way which is useful to the industry, would be counteracted if trials were precluded which serve research and technical development. As the effect of pharmaceutical drugs produced by genetic engineering can only be ascertained by trials with human beings, it is imperative in the interest of the public good to permit clinical trials and examinations of substances with human beings insofar as the direct purpose of these trials is to gain findings. According to the Federal Court of Justice, the fact that these clinical trials are aimed at achieving the approval of a pharmaceutical drug pursuant to the relevant drugs legislation is no objection to this, as these trials are, according to the Arzneimittelgesetz (*Pharmaceutical Drugs Law*), only admissible if this is their indicated aim. 30

In this context, the Federal Court of Justice has also recognised that such a wide interpretation of the experiment privilege can lead to a substance patentee in the pharmaceutical drugs sector running the risk of being considerably impaired in the exclusive use of the patent due to the massive occurrence of trial projects. This is especially true if third parties strive for and achieve the grant of patents for use based on the results of their trials. This is, however, something the patentee must tolerate, according to the Federal Court of Justice, as the patentees of products can only be rewarded for their own contribution to technical advancement which the supply of the respective product constitutes. The Federal Court of Justice maintains that it is not justified to attribute the full reward to the patentee alone as well for those types of use of the patentee's product whose finding requires previous inventive steps of third parties. Moreover, the owner of the more recent patent for use can exclude the owner of the older product patent from proprietary use, the patent for use, however, depends on the product patent. As the owner of the more recent patent for use interferes with the scope of protection of this patent, the patent for use cannot be exploited without the consent of the product patentee. As the patent for use depends on the substance patent, the substance patent maintains its economic value, as the owner of the more recent patent needs the older patentee's consent, and as the older patent remains in full force and effect vis-à-vis third parties also concerning the use which is protected by the more recent patent. 31

This reasoning of the Federal Court of Justice does not meet with considerable constitutional reservations either. In this context, it must be assumed that patentees - like the authors (cf. BVerfGE 31, 229 <243>- have, as a matter of principle, a claim resulting from the contents of the ownership guarantee for the economic benefit of their work being associated with them if no reasons of public good take priority over the patentees' interests. Accordingly, it would be incompatible with Art. 14(1) sentence 1 GG if the patentees were not only forced to tolerate clinical trials with their patented inventions in the interest of the common good but also to renounce the economic value of their invention without a special public interest for this (cf. BVerfGE 31, 229 <243>). The direct losses suffered by the patentees due to clinical trials can, however, be tolerated as they will be limited if and insofar as actual trials are concerned. Disproportionate losses would only have to be expected if an actual commercialisation of the substance took place due to an abuse of the experiment privilege. It would be incompatible with Art. 14(1) sentence 1 GG to extend the experiment privilege to such cases of abuse. In the original proceedings there was no reason for the Federal Court of Justice to explicitly declare the preclusion of such cases of abuse from the experiment privilege. In its decision of April 17, 1997, however the court made this clear. According to this decision, an act done for experimental purposes is not admissible pursuant to Section 11 , subsection 2 PatG if the trial itself has no relation to teaching in the respective technical area or if testing takes place in such a great extent that it is no longer justified by the purpose of the experiment or if testing is carried out with the intention to disturb or prevent the distribution of the product by the inventor (cf. BGHZ 135, 217, headnote c). Whereas the patentee's economic losses due to 32

the trials as such, insofar as they do not exceed the admissible scope, will normally remain comparatively low, it would, vice versa, constitute an obstacle for further research by third parties if even a trial which uses the patented substance would only be admissible against a compensation, especially if the outcome of the trial is unknown.

What is of greater importance for the patentee are the legal consequences which may result from the grant of patents for use to third parties and their economic exploitation after the successful completion of the trials. Whereas in this case, however, the economic losses of the product patentee are ultimately - as the Federal Court of Justice has stressed as well - due to the grant of the patents for use and not directly to the permission of the trials, it is obvious that the grant of a patent for use within the duration of a product patent would not be possible without taking advantage of the experiment privilege. It must be taken into account, however, - and the Federal Court of Justice has explicitly made reference to this - that the owner of the more recent patent for use may not use it without the consent of the product patentee. Thus, the company which is the product patentee participates in the economic value of the patent for use, as it will receive a corresponding remuneration for its consent. With that, it receives at the same time a financial compensation for the fact that it had to tolerate the trials which were conducted with the intention to be granted the patent for use. Thus, the economic value of the product patent remains associated to its owner - as required as a matter of principle by Art. 14(1), sentence 1 GG (cf. BVerfGE 31, 229 <243>). From the constitutional point of view, it cannot be criticised if the third party as well is awarded a share of the economic success for such types of use which required inventive steps of this third party to be discovered, as it is this third party's activity on which the economic value of the patent for use is based. 33

The interpretation of Section 11 , subsection 2 PatG by the Federal Court of Justice does not infringe the ownership guarantee of Art. 14(1), sentence 1 GG either, due to the fact that a third party which was granted a patent for use after the completion of the trials can exclude the product patentee from acts of use which fall under the scope of the patent for use. Apart from the fact that this is only an indirect consequence of the experiment privilege as well, there would, moreover, not be any incentive for third parties, insofar as they - as it is the case with the defendants of the original proceedings -are engaged in business, to research new types of use if their patent for use was not protected vis-à-vis the product patentee as well. Especially when the fight against diseases is concerned, the public has, however, a considerable interest in such incentives for research continuing to exist. 34

Finally, it cannot be said either that the permission of clinical trials leads to a shortening of the patent duration which would be incompatible with Art. 14(1), sentence 1 GG. It is true that competitors of the substance patentee which conduct clinical trials during the patent duration making use of the experiment privilege of Section 11 , subsection 2 PatG can possibly offer competing products after the expiry of the patent duration earlier than it would be possible for them if they could carry out the neces- 35

sary trials only after the expiry of the patent duration. Independently of the question whether from the constitutional point of view, a minimum patent duration of twenty years (Section 16 , subsection 1 sentence 1 PatG) and, if necessary, a complementary five-year protection period immediately afterwards pursuant to Section 16 a PatG, are prescribed, it does not, under any circumstances, follow from Art. 14(1), sentence 1 GG, however, that the patentee must be protected from competition even after the expiry of the patent duration. The so-called factual development blocking period subsequent to the patent duration - which may be extended by the protection certificate - is a mere expectation of the patentee of being spared competition as long as possible. If this period of factual protection against competition is shortened by the fact that experimental acts are permitted during the patent term already, this does not affect the patent right protected by Art. 14(1), sentence 1 GG.

Thus, the interpretation of Section 11 , subsection 2 PatG made by the Federal Court of Justice does not contain constitutional errors of law. It is not evident either that the Federal Court of Justice, when applying the regulation which it interpreted without infringing Art. 14(1), sentence 1 GG, has failed to take the ownership right of the complainant into account. 36

Pursuant to Art. 93 d (1) BVerfGG, no further reasons are given. 37

This decision is final. 38

Papier Steiner Hoffmann-Riem

Bundesverfassungsgericht, Beschluss der 1. Kammer des Ersten Senats vom 10. Mai 2000 - 1 BvR 1864/95

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