DÜSSELDORF REGIONAL COURT

IN THE NAME OF THE PEOPLE

JUDGMENT

4 O 187/99

Pronounced on July 8, 1999
Kemper, Judicial Employee
as Clerk of the Court

In the procedure for a temporary injunction to be issued for the benefit of

1. The General Hospital Corporation, Fruit Street, Boston, Massachusetts, 02114 (US), United States of America, represented by Mr. David J. Glass, same address,

2. EPIX Medical Inc., Rogers Street 71, Cambridge, Massachusetts, 02142 (US), United States of America, represented by Mr. Michael D. Webb, same address,

Applicants,

- Counsel: Dr. Mes, Graf von der Groeben, Rother, Bühling, Verhauwen and Dr. Chakraborty, Attorneys at Law in Düsseldorf -

v e r s u s

1. Bracco-Byk Gulden GmbH, Max-Stromeyer-Strasse 57, 78467 Konstanz, legally represented by its Managing Director, Dr. Astrid Seeberg, Diploma in Biology, same address,

2. Byk Gulden Lomberg Chemische Fabrik GmbH, Byk-Gulden-Strasse 2, 78467 Konstanz, legally represented by its Managing Directors, Dr. Ulrich Sorger, a chemist, Mr.

Heinz Wolf Bull and Prof. Dr. Heinz-Werner Kurt Willi Radtke, same address,

Respondents,

- Counsel: Peter von Rospatt, Dr. Pross, Max von Rospatt, Musmann and Dr. Plesser, Attorneys at Law in Düsseldorf -

f o r patent infringement,

the 4th Civil Division of the Düsseldorf Regional Court, sitting with the Presiding Judge at the Regional Court, Dr. Meier-Beck, the Regional Court Judge Dieck-Bogatzke and the Regional Court Judge Fricke at the oral hearing of May 20, 1999,

r u l e s :

The application for a temporary injunction to be issued is dismissed.

The costs of the proceedings shall be borne by the Applicants, half each.

The judgment is provisionally enforceable.

The Applicants may ward off enforcement by furnishing security amounting to DM 42,000, unless the Respondents furnish the same amount of security before the judgment is enforced.

The security may in each case also be provided in the form of an unconditional guarantee by a bank or public savings bank located on German territory and recognised as a guarantor for amounts due to customs or tax authorities.

Facts of the Case:

Applicant 1 is the registered proprietor of European patent 0 222 886, granted with effect for the Federal Republic of Germany, *inter alia* (cf. Exhibit Ast 1; hereinafter referred to as the injunction patent), which is entitled "Hepatobiliary NMR Contrast Agents" and is based on an application filed on May 8, 1986, and published on May 27, 1987, claiming a US priority from May 8, 1985. The mention of the grant of the patent was published on September 25, 1996. The German part of the injunction patent is registered at the German Patent and Trade Mark Office under file number 36 50 572 (cf. Exhibit Ast 2).

Applicant 2 holds an exclusive licence to the subject matter of the injunction patent.

The injunction patent, which is in force in the territory of the Federal Republic of Germany, relates to contrast agents for imaging the hepatobiliary system by means of NMR. The Applicants have applied for a temporary injunction requiring the Respondents to cease and desist from infringing the injunction patent.

The registered Claim 1 of the injunction patent, which is drafted in English, the language of the proceedings, is worded as follows:

> The use of a complex consisting of a paramagnetic ion and a single multidentate organic chelating ligand in the preparation of a hepatobiliary NMR contrast agent for decreasing the NMR relaxation times (T_1 or T_2) of water protons in contact with liver tissue during NMR imaging of a human patient, said complex being characterized by
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> (1) a formation constant of at least 10^{10} M^{-1};
> (2) at least one aryl ring; provided that when the paramagnetic ion is gadolinium (III), the

chelating ligand is not 1,2-diphenylethylene diaminetetraacetic acid.

For the wording of Claims 2 and 5 of the injunction patent, reference is made to the injunction patent specification.

The Italian company Bracco S.p.A. filed an opposition with the European Patent Office against the grant of the injunction patent (cf. Exhibits AG 2/AG 3, Ast 1/Ast 2). In the course of the opposition proceedings, which have not yet been completed, Applicant 1 filed amended claims with its letters of May 22, 1998, and August 10, 1998, in which it included a disclaimer in Claim 1 of the injunction patent.

In a communication dated November 2, 1998 (Exhibit Ast 5), the Opposition Division of the European Patent Office informed the parties to the opposition proceedings that, taking account of the arguments presented by the parties, it had arrived at the provisional conclusion that the injunction patent essentially met the requirements of the EPC, though it did not consider the disclaimer added to Claim 1 of the injunction patent to be acceptable in that form. For the remaining details of the communication from the Opposition Division of November 2, 1998, reference is made to Exhibit Ast 5.

In a letter to the European Patent Office dated January 7, 1999, Applicant 1 took account of the reservations expressed by the Opposition Division regarding the disclaimer added and filed an amended Claim 1 with a newly worded disclaimer (cf. Exhibit Ast 3). The restricted Claim 1 of the injunction patent, which is asserted here by the Applicants in this version, reads as follows when retranslated from German:

> The use of a complex consisting of a paramagnetic ion and a single multidentate organic chelating ligand in the preparation of a hepatobiliary NMR contrast agent for decreasing the NMR relaxation times (T_1 or T_2) of

water protons in contact with liver tissue during NMR imaging of a human patient, said complex being characterized by

(1) a formation constant of at least 10^{10} M^{-1};
(2) at least one aryl ring;

provided that when the paramagnetic ion is gadolinium (III), the chelating ligand is not 1,2-diphenylethylenediaminetetraacetic acid and further provided that the chelating ligand is not N,N,N'-tris-carboxymethyl-N'-benzylethylenediamine when the paramagnetic ion is manganese (II).

The Respondents offer and distribute in the Federal Republic of Germany a contrast agent called "MultiHance", which is manufactured in Italy by Bracco S.p.A. As evidenced by the information on its use submitted by the Applicants as Exhibit Ast 8, this product is a paramagnetic contrast agent for liver diagnosis purposes using magnetic resonance tomography in order to detect focal liver lesions in patients with known or suspected liver carcinoma (e.g. hepatocellular carcinoma) or metastases.

The market launch of "MultiHance" was published in issue 46/98 of "Pharmazeutische Zeitung", which appeared on November 12, 1998 (cf. Exhibit AG 16), the relevant specialist journal for announcing the new introduction of pharmaceutical products.

Since about the middle of 1995, in view of the intended manufacture of the "MultiHance" product, discussions had been in progress between the Applicants and Bracco S.p.A. regarding the grant of a licence to the injunction patent, but these did not lead to a successful conclusion. In the first half of 1998, there were even negotiations on a licence, but these likewise did not lead to any agreement.

In a letter dated January 18, 1999 (Exhibit Ast 13), the Applicants warned the Respondents to stop infringing the

injunction patent and set them a deadline of March 1, 1999, by which they should, *inter alia*, provide a declaration that they would cease and desist. After that, on January 20/21, 1999, Applicant 2 repeated its offer of a licence to Bracco S.p.A., which the latter had previously rejected. A meeting was thereupon arranged for January 29, 1999, but it did not lead to an agreement. In a letter from Merck KGaA dated February 3, 1999 (Exhibit Ast 14), the Applicants were informed that their warning letter had been forwarded by Merck KgaA - which, according to the content of that letter, had a 50 % holding in Bracco S.p.A. as a "joint venture" via Merck AG/Switzerland - to Bracco S.p.A. for their comments, and that they would return to the matter, without the need for a reminder, as soon as they had received "Bracco's" comments. On February 23, 1999, Bracco S.p.A., together with the Respondents and other distribution companies in Italy, filed an action against the Applicants with the Tribunale di Milano, requesting, *inter alia*, a declaration that the injunction patent was not infringed by the manufacture of the "MultiHance" contrast agent in Italy and its distribution in all the designated contracting states. The action was served on the Applicants on February 24, 1999.

On March 4, 1999, the Applicants for their part thereupon filed an action against the Respondents with the court seized of the case, suing them for infringement of the injunction patent (in that case: the patent in suit) and requiring them to cease and desist, render account, provide information, destroy the infringing substances and pay damages. That case, which is likewise pending before the present Court under file number 4 O 125/99, has in the meantime been suspended by an order of the Court of April 20, 1999, in view of the action for a negative declaration filed by the Respondents in Italy, until the jurisdiction of the Tribunale di Milano has been definitively decided.

After the action in the 4 O 125/99 case had been filed, the Respondents made the Applicants a further offer on March 15, 1999, which the Applicants turned down.

With their motion filed with the Court on April 1, 1999 - after the filing of which Applicant 2 once again approached Bracco S.p.A. with a faxed letter of April 26, 1999 (Exhibit AG 15), unsuccessfully offering to conclude a licence agreement on modified terms -, the Applicants have now requested that a temporary injunction be handed down against the Respondents.

They regard the act of offering and distributing the "MultiHance" product as an infringement of the injunction patent. According to the Applicants, the fact that the product is manufactured in Italy by the affiliate, Bracco S.p.A., without the participation of the Respondents, does not alter the fact that the injunction patent is being infringed, because Claim 1 of the injunction patent is a process claim, as a consequence of which Section 9 sentence 2 no. 3 of the German Patent Act (PatG), in combination with Articles 2 and 64 of the European Patent Convention, applies. The Respondents' product is a direct product of the process and therefore constitutes an infringement of the patent.

The Applicants go on to state that the other conditions for the issuing of a temporary injunction are likewise met, because the validity of the injunction patent is sufficiently certain in view of the interlocutory decision of the Opposition Division of November 2, 1998. Grounds for an injunction exist. After learning that the "MultiHance" pharmaceutical was being distributed in the Federal Republic of Germany at the beginning of 1999, the Applicants applied for the injunction with the necessary speed for the purpose of warding off serious disadvantages. Patent infringing actions on the part of the Respondents were only clear for certain at the beginning of 1999; it was only then that they were able to lay their hands on a pharmaceutical offered and distributed by the Respondents. After obtaining cognisance of the distribution of the attacked product, they immediately warned the Respondents. In setting the Respondents the deadline, they had, *inter alia*, taken account of the fact that the

latter would in all probability need to consult the Italian manufacturer. Following their warning letter, they were first of all delayed by the letter from Merck KGaA. The response promised in that letter then took the form of the action for a negative declaration filed with the Tribunale di Milano. It was only after February 24, 1999, the time when the action for a negative declaration was served on them, that they thus had any knowledge of the Respondents' defence against the allegations of infringement raised in the warning letter. It was only after that time that it became clear that they would not be able enforce their legal rights without having recourse to the courts. On March 4, 1999, they then filed the suit in the main cause of action, whereupon the Respondents presented their further offer on March 15, 1999, which, however, was unacceptable to them. It was thus only after March 15, 1999, that it became finally certain that the licence negotiations had no prospects of success. Since that time, or since the early preliminary hearing in the main cause of action (4 O 125/99) on April 20, 1999, at which a stay of proceedings in the main cause of action was ordered, it has now become clear that the patent infringement case which they filed against the Respondents before the court seized of the case is blocked by the action for a negative declaration filed by the Respondents in Italy and that they - the Applicants - will be prevented for years from enforcing their rights to a cease and desist order in Germany under the injunction patent. In view of the great importance of granted patents, this is not acceptable. This alone is enough to show that grounds for an injunction exist. This is all the more valid when we consider the fact that the action for a negative declaration before the Tribunale di Milano was filed for reasons which constitute an evident abuse of the law in view of the practice of the courts there. In view of the remaining term of the injunction patent until 2006 and the fact that the attacked product has only just been introduced, it must be assumed that it will be impossible to make good the damage that will be caused in the next few years.

The Applicants initially based their application for a temporary injunction to be issued on Claims 1 and 2 of the injunction patent as modified in the opposition proceedings, and "in particular" asserted the dependent claim 5 of the injunction patent (cf. pages 2 to 3 of the file). At the hearing on May 20, 1999, however, they no longer maintained their application for an injunction based on Claim 2 (motion I. b) (page 91 of the file).

The Applicants now request that

> the Respondents be prohibited, upon pain of an administrative fine of up to DM 500,000 (five hundred thousand German marks) payable for each case of culpable non-compliance with the alternative of administrative detention of up to 6 months, or administrative detention of up to 6 months, and, in the event of repeated non-compliance, of up to 2 years,
>
> in the German scope of application of the European patent 0 222 886 B1, from offering, placing in circulation or using pharmaceutical preparations, especially the pharmaceutical preparation "MultiHance", or importing or possessing them for the above-mentioned purposes,
>
> if a complex is used in them consisting of a paramagnetic ion and a single multidentate organic chelating ligand in the preparation of a hepatobiliary NMR contrast agent for decreasing the NMR relaxation times (T_1 or T_2) of water protons in contact with liver tissue during NMR imaging of a human patient, said complex being characterised by
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> (1) a formation constant of at least 10^{10} M^{-1},
> (2) at least one aryl ring,
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> provided that when the paramagnetic ion is gadolinium (III), the chelating ligand is not 1,2-diphenylethylene diamine tetra-acetic acid and further provided that when the paramagnetic ion is manganese (II), the

chelating ligand is not N,N,N'-tris-carboxymethyl-N'-benzylethylene diamine (Claim 1 of EP 0 222 886 B1),

in particular if

a complex is used which is characterised by a formation constant of at least 10^{20} M^{-1} (Claim 5 of EP 0 222 886 B1).

The Respondents request

that the application for a temporary injunction be dismissed.

They deny infringing the injunction patent. In this respect, they assert that mere distribution actions are not covered by the injunction patent, because the injunction patent claims what is referred to as a second medical indication, for which a number of special features have to be borne in mind according to the case law of the Enlarged Board of Appeal of the European Patent Office. While the Enlarged Board of Appeal did recognise the patentability of a second medical indication in principle, it nevertheless - unlike the Federal Court of Justice - ruled out the granting of claims directed purely towards the use of the substance for a medical procedure, instead taking the view that the second medical indication could only be protected by a claim to the use of a substance or composition for the preparation of a pharmaceutical for a specific therapeutic application. Since then, the European Patent Office has only granted patents for a second medical indication if they have been worded in the patent category of a double use claim ("use of a substance or composition X for the preparation of a pharmaceutical Y for a specific new therapeutic application Z"). The injunction patent claims protection for a second medical indication of precisely this kind. When filing the application for the injunction patent, the applicant went along with the case law of the European Patent Office,

which also applies to substances used in medical diagnosis. Accordingly, it filed and prosecuted claims which contained not only the use of the substance itself, but also the use of a complex for the preparation thereof. They - the Respondents - do not, however, implement this latter feature. On the other hand, the Applicants could not claim that the feature of using a complex to prepare an NMR contrast agent pursuant to Article 62 para. 2 of the European Patent Convention or Section 9 no. 3 of the Patent Act could be replaced by the contrast agent as such, because this would lead to a claim which the European Patent Office does not consider patentable. If the (first) use of the substance X for the preparation of the pharmaceutical Y is replaced by the pharmaceutical Y as the direct product of the process, the claim again takes on the same meaning of a claim to the use of pharmaceutical Y for a specific therapeutic application Z, which the European Patent Office does not consider patentable. By wording the claim in the way it did, the applicant claimed patent protection which did not comprise the direct product of the process, because that was a precondition for obtaining the grant of the patent. The Applicants cannot now subsequently claim protection under the injunction patent for the use of a substance for a diagnostic method.

A further point, according to the Respondents, is that the injunction patent is not valid. The subject matter of Claim 1 and of the claims dependent on it lacks novelty both over the German published patent application OS 34 01 054 (Exhibit AG 7) and over the European Patent Application 0 230 893 (Exhibit AG 9). At all events, the teaching of the injunction patent lacks any inventive step. Furthermore, the claimed teaching is not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

Finally, there are no grounds for an injunction, either. This is for the simple reason that, by their behaviour, the Applicants have given every indication that they do not consider the matter to be urgent. The Applicants have

in fact been aware of the attacked product for several years from the relevant publications, which they have now endeavoured to bring in as evidence in support of the facts of infringement. As a result of the licence negotiations with "Bracco", the Applicants also knew that it was intended to launch the "MultiHance" product on the market in 1998. And the product was indeed launched on the market in Germany in mid-October 1998. Since the introduction of the product was published on November 12, 1998, the Applicants had knowledge of all the circumstances of the infringement situation by no later than November 1998. Moreover, since the opposition proceedings had already been pending since June 1997, it would easily have been possible for the Applicants, allowing them a month to process the matter, to have filed their application for a temporary injunction by the end of 1998/ beginning of 1999. Instead, the Applicants first of all sent the Respondents a warning letter, giving them six weeks in which to respond, and, after that deadline had passed, they first filed their action. This conduct on the part of the Applicants can be explained by their primary interest, which is to conclude a licence agreement with the manufacturer of the attacked product; the procedural steps adopted were intended to put increasing pressure on "Bracco" so that the latter would ultimately feel it had no choice but to agree to Applicant 2's unacceptable licence terms.

Moreover, when the respective interests are weighed up, as they must be in this case, the result favours the Respondents. As can be seen from the above comments, the Applicants are not interested in obtaining an injunction imposing a cease and desist order as requested, but are merely aiming at a licence agreement with the manufacturing company. The financial reason behind this is that the Applicants do not themselves have any competing product on the market and are not marketing the injunction patent by way of licences, either. Nor are there any prospects of their exploiting the injunction patent, because there are no corresponding products about to obtain pharmaceutical marketing approval. If, on the other hand, an in-

junction imposing a cease and desist order were to be issued, they - the Respondents - would suffer considerable disadvantages, which would go far beyond the loss of sales and profits incurred as a result of the withdrawal of the attacked contrast agent. The withdrawal of a product (for reasons based on patent law) which has only been introduced a good six months previously always results in a considerable loss of confidence and image. Furthermore, experience in the pharmaceutical sector has shown that a product which is no longer available on the market for a period of six to nine months can never be reintroduced again. The action for a negative declaration filed in Italy does not constitute an abuse of the law, because the international jurisdiction of the Italian court is justified.

The Applicants dispute these submissions.

For the further details regarding the facts of the case and the arguments, reference is made to the content of the briefs submitted by the respective parties as recited, together with the various exhibits filed.

Reasons for the decision:

The application for a temporary injunction to be issued is admissible, but is unsuccessful on the merits.

The Applicants' request is unjustified at least for the reason that there are no grounds for an injunction.

I.

The injunction patent relates to the use of certain complexes for the preparation of NMR contrast agents intended for imaging the hepatobiliary system.

The contrast agents concerned are used in "nuclear spin tomography", i.e. a method of making visible (imaging) structures inside the body by measuring electromagnetic signals. This method is also referred to as "NMR tomography" ("nuclear magnetic resonance") or "MRI" ("magnetic resonance imaging"). All these terms are synonymous. Hereinafter, in accordance with the usage of the injunction patent, the term "NMR" will be used.

What is meant by nuclear spin tomography is described in more detail in Pschyrembel, Klinisches Wörterbuch (1994), pages 775/776, a photocopy of which has been submitted by the Respondents as Exhibit AG 4. This explains that it is a computer-assisted method of tomography based on the principle of magnetic resonance. Unlike conventional x-ray diagnosis and computed tomography, no ionising radiation is used in the process, but instead the energy is measured which emerges from the body in the form of electromagnetic waves under the influence of a magnetic field applied externally with relaxation of the nuclear spin incited by a high-frequency pulse. By superimposing a homogeneous main magnetic field with a gradient field, it is possible to measure the magnetic resonance, in the course of which the resonance signals, which depend on the field strengths, can also be used to draw conclusions about the place where they arise. The signals from a transverse body layer scanned from different recording positions can then be put together with the aid of a computer to form a two or three-dimensional image of the layer, and at the same time it is possible to calculate frontal and sagittal section images. Using superconductive magnets, which are suitable for generating stable magnetic fields, it is possible to obtain a very high resolution and to image small anatomical structures in a way which is usually superior to computed tomography. The contrast in the images can be varied by physical factors

which determine the contrast (proton density, T_1 and T_2 relaxation times) and provides an indication of the morphology. Fluids and pathological structures, for example, appear with a weak signal in T_1-weighted images but with a strong signal in T_2-weighted images. The special importance of the method consists, *inter alia*, in the fact that it is in this way possible to display different types of tissue which differ not in their density or their capacity to absorb ionising radiation (e.g. bones/soft tissue), but in their proton density and their chemical binding properties (e.g. soft tissues of similar densities).

In this method, the signals come from the hydrogen atoms in the water in the body tissue. In order to perform the NMR tomography, the patient is first of all exposed to a powerful magnetic field. Under its influence, the nuclei of the hydrogen atoms in the water present in the body tissue align themselves evenly, parallel to the magnetic field. In order to produce measurable signals which can be converted into an image, the nuclei of the hydrogen atoms, which are aligned evenly, are deflected from their position by means of radio frequency pulses. As a consequence of being deflected, they begin to orbit about an axis parallel to their original alignment in a plane perpendicular thereto. The deflection of the hydrogen atoms from their original position within the magnetic field gives rise to electromagnetic signals in a receiver coil which are used to generate the image.

Since a large number of signals are needed, the deflection of the hydrogen atoms from their original position within the magnetic field must be effected several times in succession. The next signal in each case can only be generated effectively when the hydrogen atoms have largely returned to their position at rest within the magnetic field (known as "relaxation"). The time constant characteristic of the return to the rest position is referred to as "T_1" (T_1 relaxation), whereas the time constant for the decay of the measurable signal is referred to as "T_2" (T_2 relaxation).

In order to enable the image to be generated within an acceptable time scale, i.e. in order to permit the signals to be generated by deflecting the hydrogen atoms in the rest position in as rapid a succession as possible, it is desirable to increase the relaxation, i.e. to reduce the relaxation times. This is the purpose of the NMR contrast agents referred to in the injunction patent. Agents of this kind contain paramagnetic ions, which act on the hydrogen nuclei in the body tissue in such a way that they return more quickly to their original position within the magnetic field acting on the body from outside.

In particular, NMR contrast agents have the function of shortening the T_1 relaxation time and thus of permitting a more rapid succession of radio frequency pulses to deflect the hydrogen atoms from their rest position in the electromagnetic field; while shortening T_2 at the same time leads to a more rapid decay of the signal, this effect is nevertheless not so important, and it can in any case be minimised by adopting appropriate metrological measures.

To express it in simple terms, these NMR contrast agents thus serve the purpose of reducing the time taken by the procedure and of generating more powerful images, though if the contrast agent is distributed evenly throughout the body, no significant enhancement of the image contrasts between the various organs is achieved.

It is possible to make certain organs stand out more clearly on the image by using contrast agents which are preferably absorbed by specific body structures and accumulate there. The different concentrations of the respective contrast agent in the organs lead to an enhancement of the image delineation (the contrast) of the organs concerned compared to the surrounding tissue. In an extreme case, organs which are not full of contrast agent appear as black patches on the image, whereas organs

filled with contrast agent stand out clearly in different shades of brightness.

In the introduction, the injunction patent states that the German patent 3 129 906 describes NMR contrast agents consisting of a paramagnetic ion complexed with a chelating agent and a base or acid, e.g. the di-N-methyl glucosamine salt of manganese chelated with EDTA. J. Comput. Assist. Tomogr. 9(3), 431-438 and WO-A 8 602 005 describe contrast agents for the NMR imaging of the liver or the bile duct, such as Fe (EHPG) and various paramagnetic DTPA diester compounds suitable for use in MRI imaging. EP-A 0 165 728 teaches NMR contrast agents containing anilide derivatives for imaging the hepatobiliary system. All the complexes listed in that document have a plurality of ligands or low formation constants or both. WO-A 8 602 841, according to the patent specification, describes homologues of paramagnetic DTPA diamide compounds which are suitable for magnetic resonance imaging of the hepatobiliary system. AU-B-8 633 082 (Exhibit AG 8) describes paramagnetic chelating complexes as NMR contrast agents which are useful in better delineating or localising lesions in the pancreas and liver, and also tumours and haemorrhaging in the head region. Example 13 discloses the manganese complex N,N,N'-tris-carboxymethyl-N'-benzyl ethylene diamine-Mn^{2+}. In addition, EP-B-0 133 603 discloses MR contrast agents which could bind selectively to an organ of interest, such as the biliary tract. FEBS Letters 168(1) (1984), 70-74, contains a disclosure of paramagnetic metalloporphyrins which apparently increase the relaxation rate ($1/T_1$) of water, though there is no disclosure of how to perform any imaging. Finally, DE 34 01 052 (Exhibit AG 7) proposes the use of conjugates or chelates inserted in liposomes as a liver contrast agent (cf. Exhibit Ast 2, page 1).

The invention to which the injunction patent relates is based on the technical problem of providing a contrast agent which is intended to improve and/or facilitate NMR imaging and NMR measuring results, and is suitable for that purpose.

In order to solve this problem, the injunction patent proposes, in Claim 1 in the version of the opposition proceedings as asserted here (Exhibit Ast 3), the use of a complex for the preparation of a contrast agent for imaging the hepatobiliary system ("hepatobiliary NMR contrast agent") comprising the following features:

1. The use of a complex

   a) consisting of a paramagnetic ion and a single multidentate organic chelating ligand

   b) in the preparation of an NMR contrast agent

   c) for imaging the hepatobiliary system

   d) for decreasing the NMR relaxation times (T_1 or T_2) of water protons in contact with liver tissue during NMR imaging of a human patient,

2. said complex having a formation constant of at least 10^{10} M^{-1}

3. and having at least one aryl ring,

4. provided that when the paramagnetic ion is gadolinium (III), the chelating ligand is not 1,2-diphenylethylene diamine tetra-acetic acid,

5. and further provided that the chelating ligand is not N,N,N'-tris-carboxymethyl-N'-benzylethylene diamine when the paramagnetic ion is manganese (II).

This means that, according to the teaching of the injunction patent, In order to prepare an NMR contrast agent, a complex is used consisting of a paramagnetic ion and a single multidentate organic chelating ligand, the complex being characterised by having the formation constant specified in feature 2, which refers to the minimum necessa-

ry stability of the complex, and, according to feature 3, at least one aryl ring, certain complexes being excluded from the extent of protection by means of disclaimers (features 4 and 5).

The paramagnetic ion referred to in feature 1 a) is responsible for the imaging properties, whereas the chelating ligand (complexing agent) enveloping the ion determines the reduction in toxicity and also the distribution and dwell time of the complex in the body.

As the injunction patent explains (cf. Exhibit Ast 2, page 3, 2nd paragraph, and pages 7/8), paramagnetic ions are highly toxic. In contrast agents of the kind under discussion, the toxic paramagnetic ions are therefore enveloped in a chelating ligand. This has a number of binding sites (teeth) by means of which it can engage in the electron envelope surrounding the paramagnetic ion and can bind firmly to the ion in this way (cf. Exhibit Ast 2, page 8). The intended use of the complexes makes it necessary for them to have a certain minimum stability in order to ensure that the ligand and ion do not separate in the body, thus causing the "protective effect" of the ligand to be lost.

Feature 2, which is directed towards the formation constant, draws attention to the minimum stability which the complex needs to have. It is a measure of the minimum stability needed by the complex for the purpose of its intended use (cf. Exhibit Ast 2, page 2, section headed "Toxicity", 1st paragraph).

According to feature 3, the complex is further characterised by the fact that it has at least one aryl ring. Aryl rings are organic ring compounds; in particular, the term comprises the phenyl rings shown in the formulae of the injunction patent (cf. Exhibit Ast 2, page 8).

The chelating ligand enveloping the paramagnetic ion in the complex of the patent is therefore characterised solely by the fact that it has a number of binding sites

(teeth) which can interact with the central paramagnetic ion to be surrounded, and by the fact that it has at least one aryl ring.

As stated in the injunction patent (Exhibit Ast 2, page 4), the contrast agents prepared in accordance with the invention must possess properties which lead to a selective absorption or binding to the target organ, i.e. the hepatobiliary tract. Since these properties are determined by the chelating ligand (cf. Exhibit Ast 2, top of page 8), and since the latter is characterised solely by the presence of at least one aryl ring, the presence of the aryl ring is supposed, according to the injunction patent, to be responsible for the selective absorption or binding by the hepatobiliary system of the complex used in the preparation of the contrast agent.

II.

It is irrelevant whether the Applicants are entitled to the claim to a cease and desist order against the Respondents under Patent Act (PatG) Sections 9, 139 para. 1 in combination with Art. 64 of the European Patent Convention (EPC) on the grounds of offering for sale and distributing the attacked contrast agent, "MultiHance".

In this context, it is in fact undisputed that the attacked "MultiHance" product is distributed by the Respondents as an NMR contrast agent for imaging the hepatobiliary system. Nor is there any dispute between the parties that the attacked contrast agent - by Bracco S.p.A. - is prepared using a complex that is covered by the wording of Claim 1 of the injunction patent. What is, however, questionable is whether the Respondents, who are not involved in the preparation of the product, make use of the subject matter of the injunction patent merely by distributing that product, because, according to its wording (feature 1 b), Claim 1 requires the "use of the complex in the preparation of an NMR contrast agent". As far as the Court can tell, there has not yet been any decision in the case law regarding the question of what forms part of the protected subject matter (extent of

protection) of a claim in a European patent which is drafted in accordance with the case law of the Enlarged Board of Appeal of the European Patent Office regarding the patentability of the second medical indication (decision of December 5, 1984, OJ EPO 1985, 60, Exhibit AG 1 = GRUR 1985, 273 - Second Medical Indication) - according to which a European Patent cannot be granted with claims directed to the use of a substance or compound for therapeutic treatment, but can be granted with claims directed to the use of a substance or compound for the preparation of a medicament for a specific new and inventive therapeutic application. In so far as this question is dealt with in the authorities, the opinion can be found that the protective effects of a claim of this kind are no different from the protective effects of the use claim ("*use of substance X in treating disease Y*"), which, according to the Federal Court of Justice (cf. GRUR 1983, 729 - Hydropyridin), is permitted for the second indication in the case of a German Patent (e.g. Utermann, GRUR 1985, 813, 818/819, 820; cf. also Benkard/Ullmann, Patentgesetz/Gebrauchsmustergesetz, 9th edition, PatG Section 3 no. 91). The use claim permitted by the Federal Court of Justice protects the patent proprietor against a third party who tries, on a commercial basis, to prepare in Germany the substance which is to be put to therapeutic use, when he does so for the purpose of that use; that third party is also prevented from offering it for sale or placing it in circulation in Germany, and is similarly prevented from offering for sale or placing in circulation in another country on a commercial basis a substance prepared for that use (BGH GRUR 1983, 729, 731 - Hydropyridin; Benkard/Bruchhausen, loc. cit., PatG Section 9 no. 50). With regard to the question of the extent of protection conferred by the claim permitted by the European Patent Office, the authorities also draw attention to PatG Section 9 sentence 2 no. 3 and express the opinion that the medicament is a direct product of the process, the use of which is reserved to the patent proprietor alone according to PatG Section 9 sentence 2 no. 3 (Hirsch/Hansen, Der Schutz von Chemie-Erfindungen, page 310; cf. also Utermann GRUR 1985, 813, 819). Whether that

opinion can be accepted does not, however, need to be decided in the context of this case, because the Applicants' request for an injunction is at least not established, for the simple reason that the Applicants have not shown and provided credible evidence of the existence of a ground for an injunction.

Pursuant to ZPO (Code of Civil Procedure) Sections 940, 936, 920 para. 2, the issuing of a temporary injunction requires not only that the entitlement to an injunction must be shown, but also that the existence of a ground for an injunction must be shown. This also applies in patent cases, where the special regulation of UWG (Law on Unfair Competition) Section 25 does not apply (OLG Düsseldorf, Mitteilungen 1980, 117; GRUR 1983, 79, 80 - AHF-Konzentrat; Benkard/Rogge, loc. cit., PatG Section 139 no. 153; Berneke, Die einstweilige Verfügung in Wettbewerbssachen, nos. 62 and 429 with further references). On the other hand, there is no principle which says that a temporary injunction is generally out of the question in patent cases, or only in very rare exceptional cases.

One must not, however, disregard the fact that, in patent cases, it is typical for special difficulties to arise from the fact of having to assess the extent of protection and the patentability of the patent within a short time and without preparation in the form of briefs corresponding to the procedure in the main cause of action. On the other hand, issuing an injunction usually interferes in a very drastic manner in the commercial activities of the Respondent and means that the claim asserted is met for the duration of the injunction (OLG Düsseldorf, GRUR 1983, 79, 80 - AHF-Konzentrat; cf. also this Court, Mitteilungen 1988, 14, 15 - Polohemd [Polo Shirt]).

As a result, the grounds for an injunction must be examined with special care in patent cases (cf. OLG Düsseldorf, GRUR 1983, 79, 80 - AHF-Konzentrat; Benkard/Rogge, loc. cit., PatG Section 139 no. 153 a; Berneke , loc. cit., no. 429). In such cases, it is only conceivable to issue a temporary injunction pursuant to ZPO Section 940

if the specific measure required really appears "necessary" in order to ward off "major disadvantages" which the patent proprietor can incur as a result of infringements of the injunction patent. For this purpose, there not only needs to be "urgency" in a purely temporal sense, but there also needs to be a substantive justification of the requirement to issue a temporary injunction on the basis of the impending disadvantages for the patent proprietor if the court does not intervene (cf. OLG Düsseldorf, GRUR 1983, 79, 80 - AHF-Konzentrat; Mitteilungen 1996, 87, 88 - Captopril; this Court, Mitteilungen 1988, 14, 15 - Polohemd; decision of October 1, 1998, 4 O 296/98, Decisions 1998, 101, 103 - WC-Körbchen [WC Basket]; decision of April 29, 1999, 4 O 133/99, Decisions 1999, 36, 38 - Slee-P). An examination of these disadvantages also requires - as the Court assumes in accordance with its constant practice - that the interests of the Respondent must be taken into account, which need to be weighed up against the interests of the Applicant (cf. also OLG Düsseldorf, GRUR 1983, 79, 80 - AHF-Konzentrat; Benkard/Rogge, loc. cit., PatG Section 139 no. 153 a, with further references). A major role in the context of this weighing up of interests is played by doubts regarding the patentability of the injunction patent, even if that has to be respected *per se* (cf. OLG Düsseldorf, GRUR 1983, 79, 80 - AHF-Konzentrat; Mitteilungen 1996, 87, 88 - Captopril; OLG Karlsruhe, GRUR 1988, 900 - Dutralene; OLG Hamburg, GRUR 1984, 105 - Früchteschneidemaschine [Fruit Cutting Machine]; cf. also Benkard/Rogge, PatG Section 139 no. 153 a). The requirements to be placed on the validity of the patent will depend on each individual case; there are thus no fixed requirements regarding validity. Rather, there is an interaction between the various aspects of the injunction patent.

Applying these principles to the case in dispute leads to the conclusion that the existence of a ground for an injunction has not been credibly demonstrated.

1.
Reasonable doubts do exist regarding the validity of Claim 1 of the injunction patent, because it appears questionable whether the subject matter of Claim 1 in the version of the opposition proceedings as asserted here is novel over the cited prior art. This applies in particular in view of the German published patent application OS 34 01 052 (D 1; Exhibit AG 7), even though that citation was already taken into account in the grant procedure.

The German published patent application OS 34 01 052 discloses contrast agents for use in NMR tomography (cf. Exhibit AG 7, page 12, 2nd and 4th paragraphs), which contain, as their active components, complexes of a paramagnetic ion and a single multidentate organic chelating ligand (cf. Exhibit AG 7, page 39, 4th paragraph). The fact that the complex only contains a single ligand can be seen from the total molecular formula. According to Claim 2 of the German published patent application OS 34 01 052, the complexes can contain phenyl groups or benzyl groups, i.e. aryl rings (cf. Exhibit AG 7, page 2, 1st paragraph beneath the formula). According to Claim 4, the diagnostic agents of Claim 2 contain a paramagnetic ion (an element with the atomic numbers 21 to 29, 42, 44 or 58 to 70) and are provided for use in NMR diagnosis.

Example 33 (Exhibit AG 7, middle of page 49) in combination with Example 10 (Exhibit AG 7, pages 38, 39) of the citation describes the preparation of a gadolinium III complex of 1,2-diphenylethylene diamine tetra-acetic acid (cf. also Exhibit AG 7, page 15, 3rd paragraph; page 57, Example 56), i.e. a complex whose chelating ligand bears two aryl groups. According to the arguments of the Respondents, which appear plausible, further suitable complexes can be prepared with the paramagnetic ions specified at the top of page 13 of the citation. Thus, the man skilled in the art could probably realise that the compound prepared in Example 33 in combination with Example 10 can also be prepared with other paramagnetic ions in addition to Gd^{3+}.

The German published patent application OS 34 01 052 also mentions the use of the disclosed complexes for liver examinations (cf. Exhibit AG 7, page 14, last part of 2nd paragraph), attention being drawn there to the possibility of forming conjugates or inclusion compounds of the complexes with liposomes, though this does not seem to be described as being obligatory, because it says on page 14, 2nd paragraph: "the complexing acids can ... as conjugates". In addition, on page 15, it says at the end of the 1st paragraph that whenever the complexing acids are not bound to biomolecules, they will in particular carry a "single central ion", i.e. a paramagnetic ion such as Gd^{3+}.

Even if one were to assume that the citation did not teach the possibility of using the complex for it to be accumulated "selectively" in the hepatocytes, this would probably say nothing about the novelty of the teaching of the patent in suit, because the use of "imaging the hepatobiliary system" is also taught by the citation.

Finally, the German published patent application OS 34 01 052 also discusses the aspects of stability (Exhibit AG 7, bottom of page 22), it being pointed out that the agents proposed possess surprisingly high stability *in vivo*, so that a release or exchange of the ions which are not covalently bound in the complexes and are actually toxic only takes place extremely slowly over a period of 24 hours, in which time - as has been shown by pharmacological studies - the contrast agents are excreted again completely. In the opposition proceedings before the European Patent Office, Bracco S.p.A. argued that the agents disclosed in the German published patent application OS 34 01 052 and also proposed for use in liver examinations have formation constants above the minimum range required in feature 2 of the injunction patent (cf. Exhibit AG 2a, page 5).

The German published patent application OS 34 01 052 discloses complexes for use in the preparation of NMR con-

trast agents, *inter alia* for liver examinations which implement the features of Claim 1 of the injunction patent.

In the grant procedure, the Applicant tried to establish the novelty of the teaching of the patent in suit over the subject matter of the German published patent application OS 34 01 052 by means of the disclaimer according to feature 4, which excludes the specific compound of Example 10, middle of page 39 (gadolinium III complex of 1,2-diphenylethylene diamine tetra-acetic acid) from the extent of protection of Claim 1. Whether, however, a disclaimer is suitable in the present case for establishing the novelty of the teaching of the injunction patent appears questionable because, according to the case law of the Boards of Appeal of the European Patent Office which the Respondents have referred to, a disclaimer serves in particular to exclude "chance disclosures" in publications from technical fields which are not connected with the technical field of the invention (cf. decision T 857/91 cited by the Respondents). The citation at issue, however, is a document which relates to the same technical field (preparation of NMR contrast agents using complexes of paramagnetic ions and chelating ligands) and from which it is also possible to learn the envisaged use (use of the disclosed complexes for liver examinations). From the decision T 290/86, which has also been cited by the Respondents (OJ EPO 1992, 414), it can also be learnt that whenever the teaching of a document is broader than the disclosure of an example, the novelty of a claim can not be established by amending the claim by including a disclaimer for the specific example. That is very important in the present case because the teaching of the German published patent application OS 34 01 052 seems to go beyond the individual compound excluded by the disclaimer of feature 4 with regard to the use of complexes with the claimed properties.

Nor will Applicant 1 be able to rely on the fact that the use of the complexes described in the German published patent application OS 34 01 052 for liver examinations is only disclosed in inclusion compounds with liposomes,

because, on the one hand, the teaching of the German published patent application OS 34 01 052 does not seem to exclude the use of the complexes in a free form for the purpose specified and, on the other hand, the injunction patent does not exclude the possibility, according to the wording of Claim 1, that the complexes are bound to biomolecules or included in liposomes in the process of using the claimed complexes to prepare an NMR contrast agent.

Even in view of the cited German published patent application OS 34 01 052, there are therefore already reasonable doubts about the novelty of the subject matter of the patent in suit, so that there is no need to discuss the other citation AU-B 86330/82 (D 3; Exhibit AG 8), because of which Applicant 1 included the further disclaimer in feature 5 of Claim 1 in the opposition proceedings in order to establish the novelty of that claim by excluding the specific compound disclosed in Example 13 of citation D 3. In the course of this case, the Applicants have not been able to resolve the doubts regarding the validity of the injunction patent, because they did not submit anything regarding the prior art in their initial brief of April 1, 1999, requesting an injunction, and it was only on the day before the oral hearing that they submitted the response to the opposition of Respondent 1 of May 22, 1998 (Exhibit Ast 19).

While one must not disregard the fact that the German published patent application OS 34 01 052 - like AU-B 86330/82 - was already taken into account by the Opposition Division in the communication of November 2, 1998 and was not regarded there as being novelty-destroying, that was only a provisional assessment by the Opposition Division, and the parties to the opposition proceedings still have an opportunity to comment on it. Furthermore, the reasons given by the Opposition Division are extremely brief. The communication from the Opposition Division does not therefore justify disregarding the reservations which exist concerning the validity of Claim 1 of the injunction patent.

The Applicants cannot successfully rely on Claim 5 of the injunction patent, which they assert "in particular", for the simple reason that they have not provided sufficient evidence to show that the complex used to prepare the attacked contrast agent has a formation constant of at least 10^{20} M^{-1}. The Respondents have denied that this feature of Claim 5 is implemented by referring to the "MultiHance basic brochure" which they submitted. It is apparent from the brochure submitted (cf. page 7) that the logarithm of the equilibrium constant of "MultiHance" is supposed to amount to 18.4 (= $10^{18.4}$).

2.
Apart from the doubts regarding the validity of the injunction patent, a further argument against issuing a temporary injunction here is the fact that it is undisputed that the Applicants themselves do not have any competing product on the market, and they have not been able to assert credibly that marketing approval for a product of their own can be expected in the near future. While the Applicants submitted at the oral hearing that there was a product undergoing examination, they did not provide any more details on the subject or provide evidence in support thereof. Nor, quite apart from that do these submissions indicate that a pharmaceutical marketing authorisation can be expected in the near future.

Nor is the injunction patent currently being marketed by means of any other licences. On the contrary, it is merely intended to exploit the injunction patent by issuing licences, which is why corresponding licence negotiations have been conducted with Bracco S.p.A. Someone who in any case only exploits his patent by issuing licences or someone who simply intends to exploit them in this way can more readily be expected to have the situation clarified in the proceedings in the main cause of action, where he may be found to be entitled to damages, than someone who is specifically interested in exploiting a monopoly position (Benkard/Rogge, loc. cit., PatG Section 139 no. 153a; Rogge, Festschrift for von Gamm, pages 461,

469), because his interest is essentially only directed towards obtaining an appropriate monetary reward. A further point in the case at issue is that the Applicants have already conducted concrete licence negotiations with the Italian manufacturer of the attacked product, which shows that they are even willing in principle to grant that company a non-exclusive licence to the subject matter of injunction patent.

3.
Even if the Respondents do not themselves manufacture the attacked product, it must also be taken into account in their favour that any interruption of distribution, even if it were only temporary, would have a negative effect on the future market prospects of the product, which was only launched approx. seven months ago. Apart from the loss of confidence and harm to the company's image which could be expected in the event of a temporary injunction, it also appears convincing that, in the pharmaceutical sector, if a product is no longer present on the market for a period of six to nine months, it will be difficult to introduce again at all and, if it is possible, it would involve very considerable difficulties. Whereas the Applicants argue against this and object that, on the contrary, it must be taken into account in their favour that, because of habit on the part of users in the pharmaceutical sector, it is difficult to displace the Respondents from the market, the Court cannot accept these arguments. If the Applicants were able successfully to enforce their claim to a cease and desist order in the main cause of action, so that the Respondents then had to take their product off the market, it is in fact the case that there would then be a demand precisely for a new contrast agent, which the Applicants would be able to meet with a product of their own.

4.
Weighing up the interests of the Respondents with the opposing interests of the Applicants in preventing any (possibly) patent infringing actions until a judgment is handed down in the main cause of action, the interests of

the Respondents must take precedence here. This is true despite the fact that the Respondents have filed an action for a negative declaration against the Applicants in Italy so that, in view of Article 21 of the Brussels Convention on the Enforcement of Judgments in Civil and Commercial Matters (ECEJCCM), the proceedings pending before this Court in the main cause of action between the parties (4 O 125/99) have therefore been stayed by order of the Court of April 20, 1999, until the jurisdiction of the Tribunale di Milano, which the Respondents first had recourse to, has been established (regarding the stay of proceedings under ECEJCCM Article 21, cf.: this Court, order of February 27, 1998, 4 O 127/97, Decisions 1998, 44 = GRUR Int. 1998, 804 = Mitteilungen 1998, 397 - Impfstoff [Vaccine]).

The fact that an action for a negative declaration has been filed in one contracting state for non-infringement of that part of a European patent which is valid in a different contracting state, with the consequence that the patent infringement dispute pending before the court later seized of the case is stayed, cannot, in isolation and in principle, establish the grounds necessary for a temporary injunction to be issued. The ECEJCCM assumes not only that the courts in the contracting states are of equal standing, but also that an action for a negative declaration is of equal importance to an action for performance. In ECEJCCM Article 21, it lays down that whenever actions concerning the same claim between the same parties are made pending before courts in different contracting states, the court later seized of the case must stay the proceedings *ex officio* until the jurisdiction of the court first seized of the case has been decided. This also applies in the relationship between an action for a negative declaration and an action for performance; unlike German procedural law, the action for a positive order does not enjoy priority (cf. ECJ, NJW 1989, 665 - Gubisch/Palumbo; JZ 1996, 616 - Tatry/Maciej Rataj; BGH, NJW 1995, 1758; NJW 1997, 870; also Neuhaus, Mitteilungen 1996, 257, 261/262; Geimer/Schütze, Europäisches Zivilverfahrensrecht, Article 21 nos. 31 f.; Kropholler, Euro-

päisches Zivilprozessrecht, 6th ed., Art. 21 nos. 7 f.). In the process, the court later seized of the case must not examine whether the court first seized of the case has jurisdiction for the decision. On the contrary, this decision must be made solely by the court first seized of the case (this Court, order of February 27, 1998, 4 O 127/97, Decisions 1998, 44 = GRUR Int. 1998, 804 = Mitteilungen 1998, 397 - Impfstoff; cf. also Kropholler, loc. cit., Article 21 no. 16). This means that according to the European law of civil procedure, the alleged patent infringer can file an action for a negative declaration in one contracting state relating to the non-infringement of the part of a European patent which is valid in a different contracting state and can thus block a patent infringement action by the patent proprietor in the other contracting state. The ECEJCCM tolerates this. ECEJCCM Article 24 does in fact lay down that the temporary measures provided for in one contracting state, including those which are directed towards securing claims, can be applied for before the courts of that state even if, because of the Convention, the court of a different contracting state has jurisdiction to decide on the main cause of action. The only conclusion to be drawn from this is that a German court can issue a temporary injunction for infringement of a German patent or the German part of a European patent even if it would not have jurisdiction over the main cause of action - especially because the jurisdiction of a court in a different contracting state has been established earlier pursuant to ECEJCCM Article 21. ECEJCCM Art. 24 does not, however, obviate the need for grounds for an injunction, which are necessary under the German law of civil procedure if a temporary injunction is to be issued. Proceeding on this basis, it is the Court's opinion that the filing of an action for a negative declaration in another contracting state is not in itself sufficient to constitute grounds for an injunction. On the other hand, it likewise does not mean that no importance is to be attached to it at all, because in connection with the need to weigh up the respective interests, significance can certainly also be attached to the fact that an applicant may be unlikely,

for certain reasons, to obtain protection for his rights in the proceedings of the action within a reasonable time. It goes without saying that the interests of the applicant in a provisional order to cease and desist is all the greater, the longer he must wait for a decision in the main cause of action. For this reason, it appears conceivable that the issuing of a temporary injunction in a case in which the "urgency" (the grounds for the injunction) could not in fact be acknowledged according to conventional criteria will have to be judged differently if an applicant who had not initially applied for provisional protection for his rights, in the expectation that he would be able to enforce his rights in the proceedings of the action within a reasonable period, has been disappointed by the filing of an action for a negative declaration where the duration of the proceedings is unforeseeable, such as, for example, when there are several different patents and numerous embodiments (in this connection, see also this Court, Decision of January 27, 1998, 4 O 418/97, Decisions 1998, 46 = GRUR Int. 1998, 803; Mitteilungen 1998, 316 - Kondensatorspeicherzellen [Capacitor Storage Cells]). The Applicants have not, however, provided credible evidence that this is the case here.

Nor is it possible to establish that the action for a negative declaration relating to the non-infringement of the German part of the injunction patent, which has been filed in Italy by the Respondents together with the Italian manufacturer of the attacked product, is an "evident" or "unambiguous" abuse of the law. Irrespective of the question of whether the court seized of the case is in any way authorised to make any prediction about the jurisdiction of the court first seized of the case, this Court feels that it is prevented from making any such observation here, at least because, so far, no decision has been handed down by the European Court of Justice on the questions that arise in patent cases of this kind in the context of ECEJCCM Art. 5 no. 3 and Art. 6 no. 1. Furthermore, the Applicants cannot successfully assert that the Respondents cannot raise any serious defence in

the Italian proceedings against the accusation that they have infringed the German part of the injunction patent, because the Respondents could also plead in the Italian legal dispute that mere distribution actions are not covered by the injunction patent.

No grounds for an injunction therefore exist, which is why the application for the granting of a temporary injunction must be dismissed.

III.
The ruling on costs is based on ZPO Sections 91, para. 1 and 100, para. 1.

The decision on provisional enforceability ensues from ZPO Sections 708, no.6, 711, sentence 1, and 108, para. 1.

The value of the litigation is DM 2 million.

Fricke

The Presiding Judge at the Regional Court, Dr. Meier-Beck and the Regional Court Judge Dieck-Bogatzke are on vacation and are therefore absent, so that they are unable to sign.

Fricke