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Can diagnostic data be protected as “direct product” of a process?

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Owners of diagnostic method patents had in the past and still have a hard time in Germany to enforce their patents against the importer of results produced abroad under application of their patented diagnostic method. The recent Supreme Court Case in X ZR 124/15 regards diagnostic methods as “working processes” and not as “methods of preparation” with the consequence that the result obtained by the diagnostic method does not qualify as a “direct product” as obtained by a ”method of preparation”. Rather the result of a working process, such as a diagnostic method, results in “information” only.

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Protection conferred by a process claim to a direct product

Protection for products directly obtained from a process has been part of German as well as European jurisdiction. In particular, Section 9, Sentence 2, No. 3 of the German Patent Act (GPA)[1] specifies that any third party shall be prohibited from (underlining added)

> *[…] offering, placing on the market or using a product which is produced directly by a process which is the subject-matter of the patent, or from either importing or possessing such a product for the purposes referred to*.

The European Patent Convention (EPC) provides a similar regulation for determining the scope of protection of a patent under Art. 64(2), which stipulates that (underlining added)

> *If the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process.*

These regulations are conforming to Art. 28 (b) TRIPS as well as with Art. 5quater of the Paris Convention.

Both the German and the European patent law provide an independent protection for products and processes. The *ratio legis* behind the additional protection conferred for direct products of a process is to strengthen the rights of a patent owner. This additional protection shall in particular apply when the patented process is performed abroad, where there is no patent protection for the respective process, while the products as the result of the process performed abroad are imported back to the country where the process is patented.

Such circumvention of patents shall be prevented by the additional protection of the "direct product of the patented process" (in the following "direct product") which thus enables the patent owner the complete exhaustion of the invention's economic value[2].

The protection for the direct product does not consistently apply to any results of a patented process. Rather, in order to enjoy the protection, the process in question must be a "process of preparation" and the result of the patented process has to be "a product" which is "directly" produced by the patented process.

According to the well-established case law, there is no requirement that the direct product of a process must be patentable per se. In other words, the product of the patented process does not have to be novel or inventive itself. Accordingly, protection is also conferred to products which have been produced applying a patented process, even if the products are not new and can also be produced by an alternative process.

It is further required that the product results from a process of preparation. German case law distinguishes between processes of preparation ("Herstellungsverfahren") and working processes ("Arbeitsverfahren"). There still is some gray zone between these two concepts. Some examples of a pure working process which does not give rise to protection of its results include: testing procedures, screening and diagnostics processes, surface processing procedure such as polishing. On the other hand, a

[1] *In German language „Patentgesetz", abbreviated as PatG*

[2] *A. Keukenschrijver, "Busse Patentgesetz" commentaries of the German Patent Act, 7th edition, 2013; Section 9, No. 98; Schulte, "Patentgesetz mit EPÜ" commentaries of the German Patent Act and the European Patent Convention, 9th edition, 2014, Section 9, No. 88.*

process of preparation is generally expected to provide a product, such as a chemical compound, mechanical device etc..

This distinction according to the well-established case law, allows protection for the following direct products: tubes freed from gas, colored textiles, product of a chemical reaction, medicament produced from a pharmaceutical active ingredient.

However, protection as a direct product is not provided for instance for: repaired machine parts, results of cleaning or polishing, measuring, tiding, transporting, etc.

The requirements for a result of a process to be acknowledged as the direct product have been somewhat softened in the recent years. According to the recent case law, the physicality of the result of a process is no longer required for a direct product[3].

For those products resulting from a process which are excluded from patentability or not interpreted as direct products, patent protection of processes can easily be circumvented by performing the process in a whole or partly in a country in which the corresponding patents are not in force and shipping the result to the country where the process is patented. In view of globalization, a patented process becomes powerless if the result is not protected as a direct product.

While the softening of the criteria for protection of the direct product could be observed in the field of communication technology (case X ZR 33/10), recent decision in the case X ZR 124/15 in the field of medical diagnostics rendered by the Supreme Court appears to go in an opposite direction.

In the following we provide an overview on both cases and discuss the different view of the Supreme Court on these cases as well as potential consequences on patent practice.

[3] *BGH X ZR 33/10, MPEG-2-Videosignalcodierung*

Supreme Court Case X ZR 33/10

As stated above German patent law protects under Section 9, Sentence 2, No. 3 GPA products, which are the direct result of a patented process, in a manner similar to the protection of a product by a product patent. A case dealing with the question of whether or not the product of a patented process qualifies as a product covered by Section 9, Sentence 2, No. 3 GPA or is only considered to represent pure information is decided in Supreme Court case X ZR 33/10, referred to in the following as “MPEG-2” case.

Supreme Court case X ZR 33/10 results from a litigation based on European patent No. 0 620 157. The European patent relates to the encoding and decoding of video data.

Claim 11 of the granted patent relates to the encoding method of video data:

> *11. A method for encoding video data representative of successive frames of video images, the video data for each frame …*
>
> *[…]*
>
> *(h) providing signals representing the second field of the current frame, the best mode motion vector data, and the pixel error data.*

Claim 25 of the granted patent relates to the decoding method of video data:

> *25. A decoding method for encoded video data representing a sequence of frames of video images, the video data for each frame […], the method comprising the step of (a) receiving encoded video data for successive frames …*
>
> *[…]*
>
> *(f) generating the current frame of video image data from the predicted first filed of the current frame and the second field of the current frame separated from the received encoded video data.*

The encoding together with the correspond-

ding decoding process is part of the well known coding standard MPEG-2 which has been standardized by the International Standardisation Organisation (ISO). The licensing of the patents covering this standard is handled by the patent pool MPEG LA. MPEG LA grants standardized pool licenses to companies for making use of the MPEG-2 standard.

The defendant is a company located outside Germany manufacturing in and distributing from Greece optical video storage media (DVDs). The defendant did not sign such a standardized pool license agreement. The infringement proceedings are based on a test order initiated by the plaintiff to manufacture 500 DVDs which had been shipped back to Germany. The European patent underlying this case did not directly protect a DVD or any other storage media for video data. The plaintiff could only use the patented processes relating to the encoding and decoding of video data for this purpose, i.e. argue for contributory infringement of the process claim based on the decoding claim or argue for infringement of § 9, sentence 2, Nr 3 GPA protecting the direct product, based on the encoding claim. The plaintiff tried both, namely to argue for infringement of the encoder claim and the decoder claim.

Based on the decoding claim the plaintiff argued that the encoded video data on the DVDs form an essential part for contributory infringement when used together with a decoder in Germany. In contrast to the Appeal Court decision, the Supreme Court could not find a contributory infringement in this matter. According to the Supreme Court, the sequence of encoded video data stored on the DVDs is only processed during decoding as a working process and does not contribute to decoding rules. Hence, contributory infringement of the decoding claim by decoding the data stored on the DVD was rejected by the Supreme Court.

Additionally, the plaintiff used the encoding claim to argue for direct infringement of the product resulting from the encoding process, namely that a shipment of the encoded data stored on the DVDs to Germany infringes Section 9, Sentence 2, No. 3 GPA as a direct product of the encoding process. For the question of a possible infringement, the Supreme Court had first to decide whether or not a sequence of encoded video data is a direct product in the sense of Section 9, Sentence 2, No. 3 GPA.

Firstly, the Supreme Court discussed the question of physicality of the encoding result, i.e. the data stored on the DVDs. The Supreme Court found that neither for the data processing nor for the court decision it makes a difference if the video data are present on a DVD or transmitted via Internet. This means the product protectable under Section 9, Sentence 2, No. 3 GPA has not to be a physical substrate but may be an immaterial processing result, for instance, a sequence of video data.

However, the Supreme Court distinguished the sequence of encoded video data from other immaterial process results like electricity, heat, light or acoustic waves. The Supreme Court considered that the sequence of video data could be made perceivable like a physical substrate any number of times by employing a decoding means.

The Supreme Court also confirmed that further requirements exist for a result of a process to be acknowledged as a direct product. In particular, the Supreme Court found that the encoded video data are the direct processing result of the encoding process as the encoded video data possess particular information and recording structures in accordance with the coding standard. Further, the Supreme Court considered the identity and characteristic of the data structure of the encoded video data to remain unamended even if stored on different storage media and implemented on a DVD in form of “pits” and “lands”.

Hence, the transfer of encoded video data as a result of the process of claim 11 into Germany is not seen as the transfer of pure information but as a transfer of a direct product protected under Section 9, Sentence 2, No. 3 GPA.

In other words, the "MPEG-2" decision acknowledged protection for a de facto abstract data structure being a result of a patented coding process; as such data structure can be materialized on any storage[4].

Supreme Court Case X ZR 124/15

This Supreme Court decision results from a litigation based on European Patent No. 959132, which was maintained in an amended form after a separate invalidation proceedings before the Federal Patent Court and the German Supreme Court (BGH), where by decision X ZR 141/13 "Rezeptor-tyrosinkinase," *inter alia*, the following claims were upheld:

> *1. A nucleic acid molecule of a tandem duplication mutant encoding FMS-like tyrosine kinase 3 (FLT3), wherein said nucleic acid molecule has a nucleotide sequence corresponding to:*
>
> *(a) a tandem duplication mutation in the amino acid sequence of juxtamembrane of FLT3, or*
>
> *(b) a tandem duplication mutation in the nucleotide sequence of a region comprising exon 11 or exons 11 to 12 of FLT3 without a change in the reading frame.*
>
> *7. A method for detecting the nucleic acid molecule of claim 1, or the nucleic acid molecule of claim 2, comprising the steps of:*
>
> *(a) subjecting a nucleic acid sample from a human to a gene amplification reaction, wherein a nucleic acid fragment comprising exon 11 or exons 11 to 12 of the FMS-like tyrosine kinase 3 (FLT3) gene and having a tandem duplication mutation in the juxtamembrane is amplified, which can be found in the FLT3 gene;*
>
> *(b) detecting the presence of the tandem duplication mutation in the nucleic acid fragment of step (a).*

As an interesting side note on the above case, "Rezeptortyrosinkinase," the claims were, *inter alia*, attacked for being directed to a "discovery only" namely a naturally occurring gene variant. The German Supreme Court rejected such an attack and also made specific reference to the U.S. Supreme Court case, "*Mayo v. Prometheus*," and their criteria for "eligible matter." In the BGH's opinion, to qualify as patentable matter, it is only required that the patent teaches that the natural product in question can be used as part of a technical teaching. In order to become "eligible matter," it is not required that the natural product contains an "inventive surplus" compared to the product as it exists in nature. Of course, to become patentable, the product in question must also be based on an inventive step and fulfill the further patentability requirements as any kind of inventions.

The fact pattern underlying the litigation in X ZR124/15, as discussed herein below, was as follows:

The defendant isolated cells from patient samples and isolated nucleic acids from said isolated cells. The thus prepared nucleic acids were sent to the Czech Republic, to another defendant in the present case, where the nucleic acids were analyzed for the presence of the tandem duplication mutation as defined in the claims. After finishing the analysis, the test results produced in the Czech Republic were sent back into Germany to the party having performed the first isolation steps of the process, namely the isolation of cells and nucleic acids. The plaintiff saw in the importation of the test results produced in the Czech Republic into Germany a violation of Section 9, Sentence 2, No. 3 of the GPA.

As a note aside, the plaintiff did not argue for an infringement of § 9, Sentence 2, No. 3 GPA in using the process partly in Germany and partly in the Czech Republic. According to established case law, such as in "Prepaid-Telephone-Chip" of the Appeal Court in Düsseldorf, splitting of a process into steps performed in Germany and steps performed abroad can, as a whole, be attributed to the party in Germany, so that infringement of § 9,

[4] *MPEG-2 decision, paragraphs 23, 24*

Sentence 2, No. 2 GPA can still be given, although the process is only partly performed within the country.

The Supreme Court did not see an infringement of § 9, Sentence 2, No. 3 GPA in the defendant's activities for the following reasons:

According to § 9, Sentence 2, No. 3 GPA, products which are the direct result of a patented process are protected in a manner similar to the protection of a product by a product patent, as has been explained above. However, § 9, Sentence 2, No. 3 GPA is applicable only to a result of a process if the process produces a product which shows characteristics imparted to it by the claimed process. Therefore, the protected process must lead to something which, itself, could in principle be the subject of a product patent, so the court's considerations.

The above considerations applied to the present fact pattern means that the test results produced in the Czech Republic were not regarded by the Court as a direct product in the sense of § 9, Sentence 2, No. 3 GPA, but merely constituted "information" which, as such, cannot be protected as a product as such by a product patent, but rather is excluded from patent protection under Section 1, Sentence 3, No. 4 GPA.

Thus, even though general patentability is not required for the direct product to enjoy protection under § 9 GPA, it must not be excluded from patentability. Under German patent law, the exclusion from patentability applies to (cf. Section 1, Sentence 3 GPA):

- *discoveries, scientific theories and mathematical methods;*
- *aesthetic creations;*
- *schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;*
- *presentations of information.*

In the Court's opinion, the process of claim 7 of EP 0 959 132 results in biochemical data which informs the skilled person about the presence or absence of a tandem duplication mutation, which, itself, is an indicator for Leukemia. Only such information/knowledge was sent to Germany. Since information itself cannot be protected by a product patent – neither under the EPC, nor under German Patent Law – information does not constitute a matter which could qualify as the direct product of a process in the sense of § 9, Sentence 2, No. 3 GPA.

The information obtained according to the patented process of claim 7, as shown above, did not qualify as a direct product like the "data package" according to the "MPEG-2" case discussed above. The Court saw the difference between the two cases in the fact that the "data package" in the "MPEG-2" case was the direct result of the claimed process and because the data package showed a structure being conferred to it by the patented process it was regarded as a "direct product" and not merely information. The Court in the "MPEG-2" case found that the data package, in principle, could also be protected by a product patent.

In the present case of X ZR 124/15, in the Court's view, the data obtained by the process of claim 7 did not show "technical characteristics" such as a "new structure," which were conferred to them by the process of claim 7. Rather, the result was nothing more than the finding of whether a tandem duplication within the gene is present or not. Hence the result of the claimed process constituted information only.

Therefore, the transfer of the data as the result of the process of claim 7 as pure information into Germany, although it was obtained by a patented process abroad, did not constitute a use of the claimed invention, in the Court's view. § 9, sentence 2, Nr 3 GPA was not infringed by sending the test results to Germany

The Supreme Court appears to be rather strict in this decision.

The result of the patented process for detecting the nucleic acid molecule in a

patient sample which includes detecting the presence of the tandem duplication mutation therein was considered to be a mere information which is not technical and thus not eligible under German patent law rather excluded from patent protection under § 1 GPA. Consequently, according to the well-established case law, such result of the patented process was not considered to be protected as a direct product of a process.

The downside if this classification of the results of the genetic testing is that anyone is allowed to economically exploit direct results of a diagnostic process in the country in which the process is patented, as long as the process is performed in another country. This appears to weaken or even take away attractiveness of patenting inventions in the field of detection methods such as diagnostic methods. Moreover, it does not appear to be in line with the original reason behind the additional protection for the direct product of a process under § 9, Sentence 2, No. 3 GPA, namely enabling of the exhaustion of the economic value of a patented invention by the patent owner himself only.

In particular in view of the protection conferred on one hand to the non-physical products such as data structures and even their copies, the lack of protection for other kind of products such as the results of detection methods and a diagnosis based thereon appears to be questionable.

It is true that presentation of information is excluded from patentability under Section 1, Sentence 3 GPA. However, a result of detection methods is not a mere *presentation* of information. The claimed process does not define, how information is to be presented but rather how the particular detection result is obtained by technical means. The corresponding direct product is the result whether or not there is a tandem duplication mutation in a given patient sample. Hence, it appears questionable that § 1 GPA provides a proper basis for depriving the results of a detection method the protection under § 9, sentence 2, Nr 3GPA.

Practical consequences

In view of decision X ZR 124/15, one may wonder how to provide an applicant with the best way to avoid circumvention of his patent when preparing a patent application.

Since the reasoning of the Supreme Court not to apply § 9, sentence 2, Nr 3 GPA to the results obtained by the claimed detection method relied on the exclusion of the process results as pure information from patentability under § 1 GPA, particularly striking could be the approach of drafting a “process of preparation” claim by adding a further step of producing a data medium storing the results of the detection method. Since neither novelty nor inventive step are necessary for the additional protection conferred to a direct product of a process, it appears that such formulation of a claim could confer protection under § 9, Sentence 2, No. 3 GPA to such a claim and, hence, might be more difficult to get circumvented by performing the process abroad but shipping the result into Germany.

As discussed above, the scope of protection of a process claim conferred to its direct product is currently limited to products not excluded from patentability, in other words to products which in principle could be protected by a product claim. This implies that a product of a process, such as information obtained by a detection method, currently may be used in Germany by anyone even though the corresponding process is patented.

This limitation seems to be unsatisfactory, at least for owners of diagnostic method patents and in contradiction with the original aim of the additional protection for the direct products of processes of preparation. Especially in view of the protection conferred to products of coding processes, not conferring protection for other products such as electricity, light, heat, results of detection processes and the like does not seem to be justified. It is noted that it may be difficult to prove that the particular product actually is a product of a particular process. However, the difficulty of proof is no criterion for the application of § 9, Sentence 2, No. 3 GPA.

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