Process patents and the partial outsourcing of individual procedural steps into patent-free foreign countries – opportunity or risk? A view from practice

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Introduction

In the case of cross-border situations, the question arises as to whether a patent-infringing act of use can be assumed if, in the case of a process patent, only a part of the procedural steps are carried out in the domestic patent-protected country, and other procedural steps are transferred to a patent-free foreign country. The precise answer to this question is of great practical importance, especially in the face of progressing global and economic division of labour. From the patent proprietor's point of view, it is important that their protective rights provide the best possible protection and on the part of the person wishing to make use of the patent protected object, it is essential that they can do so without infringing any third-party intellectual property rights. While in the literature diverse opinions are expressed, the jurisprudence to date is clear. Accordingly, the need for legal counselling with regard to this question is correspondingly significant. Only recently, in the field of a prenatal diagnostic procedure consisting of several procedural steps, we have obtained a judgment before the District Court Düsseldorf,[2] which fortunately provides more clarity.

The importance of the principle of territoriality

The principle of territoriality is of fundamental importance in patent law and in answering the question raised. The substance of this principle is that a patent exerts its substantive effects only in the territory in which it was granted.[3] A procedural patent which was granted in the Federal Republic of Germany, respectively, a European patent which was granted for this jurisdiction also only has a material effect in the Federal Republic of Germany. A sufficient connection to the territorial scope of protection is therefore decisive.[4] Consequently, the IPR does not prohibit the implementation of the entire process in patent-free foreign countries. The execution of all procedural steps in a patent-free foreign country would then not constitute a patent infringement.[5]

> [...] THE INDIVIDUAL PROCEDURAL PARTS OR STEPS THAT CONSTITUTE THE ACTUAL CORE OF THE INVENTION MUST BE IDENTIFIED[1]

Using a process patent as an act of use

Process patents do not provide protection for a specific product, but rather for a specific technical instruction.[6] Process patents are regularly composed of several procedural steps. In principle, a process patent grants the proprietor the sole right to use or offer the patented process (section 9 sentence 2 no. 2 and 3 German Patent Law). When evaluating partial procedures carried out abroad, the alternative to usage are of particular relevance.

Usage within the meaning of Patent Law has occurred if all procedural steps are applied domestically, that is to say they are carried out or used as intended.[7] The manifest arrangement of a device in order to apply the patented method does not constitute usage in this sense.[8] If individual process steps are carried out by a third party in a patent-free foreign country, the central question is whether the partial steps carried out abroad can be attributed to the persons acting domestically and what the requirements are for these to be attributed to them. The prerequisite for their being no presumption of domestic patent infringement, in the case of partial outsourcing of individual procedural steps abroad, would therefore be that the procedural steps carried out in a patent-free foreign country cannot be attributed to the parties who are carrying out the other procedural steps that are also part of the patented procedure.[9] In that case, the implementation of the

patented procedure as a whole would be regarded as usage in a patent-free foreign country.

Criteria for establishing attribution

In some cases, the possibility of attribution and thus of patent infringement is presumed from the fact that the first procedural step is carried out domestically, irrespective of the intensity of that partial act.[10] In other cases, on the other hand, the focus is on whether the act is domestically successful.[11] Here it depends on whether the offender acting domestically takes ownership of the procedural steps implemented abroad, in Germany. According to the Prepaid Phone Card decision of the Higher Regional Court of Düsseldorf, an "economic-normative approach" is required as a necessary corrective.[12] This requires a targeted approach to the domestic market, and must therefore directly concern the same.[13] Others, in turn, focus on the focal point or core of the inventive method.[14] Accordingly, "the entire procedure must be considered and the individual procedural parts or steps that constitute the actual core of the invention must be identified."[15] If the focal point of the actions realised is on the procedural steps carried out domestically, then an infringement of the patent has occurred. The aforementioned views all relate to objective criteria relating to the procedure. In the end, a subjective approach is sometimes employed, according to which the focus, at least in the case of a manufacturing process, is on a conscious and intentional collaboration between the parties who act domestically and abroad.[16]

Current developments in jurisprudence

The Regional Court Düsseldorf has recently decided, with regard to a prenatal diagnostic method, that what is relevant is whether the procedural step in question is an essential element of the invention.[17] The case being decided by the Regional Court Düsseldorf concerned a non-invasive prenatal test to determine the risk of foetal chromosomal disorders, which is achieved by analysing cell-free DNA from the mother's blood. In this way, serious diseases, such as trisomy 21, can be detected at an early stage. The patented process essentially involves 4 process steps; namely providing a maternal blood sample (i), separating the sample into a cellular and non-cellular fraction (ii), detecting the presence of a nucleic acid of foetal origin in the non-cellular fraction using the method of any one of claims 1 to 17 (iii) and providing a diagnosis based on the presence and/or quantity and/or sequence of the foetal nucleic acid (iv).[18]

The mere extraction of samples from the pregnant woman is carried out by gynaecologists in Germany. The samples are subsequently transferred to a laboratory in the USA, where no patent protection exists, to perform process steps (ii) to (iv). In line with our argument, the Regional Court Düsseldorf stated that the decisive factor is whether the provision of samples in Germany is a step that is essential to the invention. Here, the Düsseldorf Regional Court emphasises the importance of the principle of territoriality. It explains that the infringement of a procedural patent is excluded when merely the first procedural step is carried out domestically, which only produces a primary product, which is subsequently transferred to a patent-free foreign country where the remaining and essential procedural steps are carried out by third parties.[19] In fact, in such a case, the procedural step carried out domestically is attributed to the party acting abroad, with the result that the entire procedure must be regarded as usage abroad.[20] This principle should only be departed from if the reverse case exists, i.e. if only a primary or intermediate product is produced in the patent-free foreign country, while the remaining and essential procedural steps are carried out in the patent-protected domestic country.[21] In the case being decided, the Regional Court Düsseldorf assumes that the extraction of samples in Germany (step (i)) is comparable to the case where only a preliminary product is being produced domestically.[22] The implementation of the method to determine the risk of chromosomal disorders and the making of a diagnosis, which take place in the patent-free foreign country, on the other hand, represent essential procedural steps.[23] The core of the invention is thus beyond the scope of the patent protection, with the effect that the procedural steps carried out in the USA cannot be attributed domestically.[24]

Conclusion

In principle, the infringement of a procedural patent can only be assumed if all procedural steps are single-handedly applied.[25] If some steps of a procedural patent are transferred to a patent-free foreign country, of relevance for the question of attribution on the basis of relevant case law, is where the process steps that are essential to the invention take place, respectively, where merely an insignificant primary product or intermediate product is produced.[26] With regard to this issue and the relevant practical implications, as a consequence, fortunately more clarity and thus legal certainty has been achieved in the field of process patents.

1 Free translation of the authors; cf. Haupt, GRUR 2007, 187, 191:„*Es ist […] der […] Verfahrensteil oder -schritt herauszufinden, der den eigentlichen Kern der Erfindung ausmacht*"."
2 District Court Düsseldorf, judgement dated 20.12.2016, 4c O 62/16 – not legally valid.
3 Benkard/*Scharen*, Patent Law (PatG), § 9 note 8 et seq., 11. Ed. 2015.
4 Kraßer/Ann, Patent Law, § 33 note 43, 7. Ed. 2016.
5 Higher Regional Court Düsseldorf Judgement dated 10.12.2009, 2 U 51/08, BeckRS 2010, 12415 – Prepaid-Telefonkarte.
6 *Benkard/Scharen*, PatG, § 14 note 47, 11. Ed. 2015; cf. concerning the breaking down of process patents, Mes Patent Law, § 1 note 195 et seq., 4. Ed. 2015.
7 BGH GRUR 1990, 997, 999 – Ethofusemat; Kühnen, Patentverletzung, A.V.7. note 270, 9. Ed. 2016.
8 BGH GRUR 2005, 845, 847 – Abgasreinigungsvorrichtung.
9 Higher Regional Court Düsseldorf judgement dated 10.12.2009, 2 U 51/08, BeckRS 2010, 12415 – Prepaid-Telefonkarte.
10 *Busse/Keukenschrijver*, PatG, § 9 note138, 8. Ed. 2016; Kraßer/Ann, Patent Law, § 33 note 139, 7. Ed. 2016, whereby the conditions that should be fulfilled for an attribution are not mentioned.
11 Hölder, Jubilee publication for 10 years of studies "International Studies in Intellectual Property Law", 2009, p. 181, 192.
12 Higher Regional Court Düsseldorf judgement dated 10.12.2009, 2 U 51/08, BeckRS 2010, 12415 – Prepaid-Telefonkarte.
13 ibidem.
14 Haupt, GRUR 2007, 187, 190 ff.; Kühnen, patent infringement, A.V. note. 271, 9. Ed. 2016; Regional Court Munich, GRUR-RR 2015, 93, 99 - FLT3 Gene test using the terminology "essential".
15 Haupt, GRUR 2007, 187, 191.
16 *Benkard/Scharen*, PatG, § 9 note 10, 11, Ed. 2015.
17 Regional Court Düsseldorf, judgement of 20.12.2016, 4c O 62/16 – not legally valid.
18 Cf. the German part of the European Patent 0 994 963 B2.
19 Regional Court Düsseldorf, judgement dated 20.12.2016, 4c O 62/16 – not legally valid; Kühnen, patent infringement, A.V. note. 271, 9. Ed. 2016.
20 Ebd.
21 Higher Regional Court Düsseldorf judgement dated 10.12.2009, 2 U 51/08, BeckRS 2010, 12415 – Prepaid-Telefonkarte.
22 Regional Court Düsseldorf, judgement dated 20.12.2016, 4c O 62/16 – not legally valid.
23 ibidem
24 Ibidem. In the field of prenatal diagnostic procedures, the Federal Supreme Court has also recently confirmed that investigation results obtained in a patent-free foreign country on the basis of a patented process do not constitute direct procedural products within the meaning of section 9 sentence 2 no. 3 of the German Patent Law; cf. the judgment on 27.09.2016 - X ZR 124/15, BeckRS 2016, 111826 - FLT3 (Gene Test). According to this, third parties are prohibited from offering, placing on the market or making use of a product directly produced through a patented process. In the relevant case, samples were collected in Germany, nucleic acids extracted and sent to the Czech Republic to carry out the disputed procedure. The test results were then sent back to Germany.
25 Kühnen, patent infringement, A.V. note. 269, 9. Ed. 2016.
26 Terminologically comparable "key concepts" and "Focal Point Area".