



Process patents – paper tigers or effective protective rights?

Thoughts on “sufficient likelihood” in the sense of section 140c German Patent Act (PatG)

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When process patents are infringed, patent owners are often faced with considerable problems of providing proof of infringement. Effective enforcement is further impeded by the strict requirements set by German case law for inspection proceedings. In order not to let the protection by process patents run empty, a rethinking is necessary with regard to the requirements for “sufficient likelihood”, says Stephan Neuhaus.

Starting Point

In the field of biotechnology and the pharmaceuticals and chemicals industries in particular, innovations in manufacturing processes can trigger significant progress. An innovative manufacturing process can, for instance, significantly increase the yield of a desired drug substance in the course of production (cf. ruling by the German Federal Supreme Court (Bundesgerichtshof; BGH) dated 3 April 2012, X ZR 90/09, BeckRS 2012, 12375, margin no. 18 – Gemcitabin). In return for disclosing their invention,

the inventor deserves a reward, which is granted to them in the form of a temporary exclusive right to use the invention (BGH, GRUR 1969, 534, 535 – Skistiefelverschluss; Rogge/Melullis in: Benkard, PatG, 11th ed., introduction, margin no. 1). In practice, however, the question of whether this protection is even worth the paper on which the patent specification is printed is often raised.

The owner of a process patent is often faced with particular difficulties in terms of receiving a reasonable reward for their invention, not only in theory but also in practice. This is in particular the

case if application of the protected process by a (potential) infringer cannot be identified by analysing the product that has been manufactured and distributed, because where the manufactured product itself is not new, the reversal of the burden of proof provided for in section 139 (3) sentence 1 of the German Patent Act (Patentgesetz; PatG) does not offer any assistance and the patentee will bear the entire onus of proving that the defendant used the protected process. It will, however, be impossible to furnish such evidence without being able to inspect the manufacturing process itself or at least related documentation.

Understandably, no company will (voluntarily) grant third parties, and in particular competitors, access to its production systems. And the corresponding documentation, which must be prepared and submitted to the competent authorities in the context of having drugs and their manufacturing processes approved, for instance, represent trade and business secrets and as such are subject to stringent protection measures. In common law jurisdictions, a certain degree of relief where patentees encounter such difficulties in furnishing evidence is provided in the context of a more or less comprehensive “discovery” process (for information on the US discovery process, see Pfeiffer, GRUR Int. 1999, 598, for instance). Since the Directive on the Enforcement of Intellectual Property Rights (2004/48/EC, Enforcement Directive) was adopted, the inspection and document presentation procedure codified in section 140c PatG has offered the possibility of a court-monitored process for securing evidence in Germany. In practice, however, performance of such inspection procedures has so far represented the exception rather than the rule and has seldom succeeded – an injustice in itself.

The requirement of a “sufficient likelihood” of a patent infringement under German law

According to section 140c (1) sentence 1 PatG, the inspection procedure or the obligation to present a document is conditional upon the respondent to an application for an inspection order having committed a patent infringement “with sufficient likelihood”. The

question of what constitutes “sufficient likelihood” is a question of merits which courts must assess on the basis of objectively determinable, supportive facts (decision passed by the Higher Regional Court (Oberlandesgericht; OLG) of Frankfurt/Main dated 27 November 2019, 6 W 100/19, Juris margin no.3). While in past rulings on the question of inspection pursuant to section 809 of the German Civil Code (Bürgerliches Gesetzbuch; BGB) the BGH still required a “significant level” of likelihood (BGH, GRUR 1985, 512, 2nd sentence of headnote – Druckbalken), it would now appear that at least a “certain level” of likelihood may suffice, provided the requirements that are not affected by the inspection and document presentation procedure have been clarified (BGH, GRUR 2018, 1280, margin no. 16 – My Lai [re a claim pursuant to section 809 BGB in connection with personality rights]; Regional Court (Landgericht; LG) of Munich I, PharmR 2018, 268, 270; Kühnen, Handbuch der Patentverletzung (Manual of Patent Infringement), 13th edn. 2021, margin no. B.26). The OLG Frankfurt/Main offers a “practical indicator” of a sufficient degree of likelihood, namely if the patent infringement is more likely than not, i.e. the degree of likelihood can be placed at at least greater than 50% (decision passed by the OLG Frankfurt/Main dated 27 November 2019, 6 W 100/19, Juris margin no. 3).

Examples of supportive facts on which the grounds for sufficient likelihood of patent infringement can be based include the qualities of parallel products distributed in other, patent-free jurisdictions, for instance, or information provided by the party obliged to permit inspection in promotional material indicating that the product has particular qualities, or industry standards with which the respondent may be assumed to have complied (Kaess in: Busse/Keukenschrijver, PatG, 9th edn. 2020, section 140c margin no. 8; Kühnen, Handbuch der Patentverletzung, margin nos. B.28-31). The effect of the assumption set out in section 139 (3) PatG is also included here.

The lack of evidence for an infringement of a process claim

The supportive facts specified in the relevant legal literature are, however, often of little practical use to the owner of a process patent. If the product in

question could be manufactured using processes that are not protected by the patent, for instance, an examination of the finished product, whether in Germany, where the patent applies, or in another jurisdiction where it does not, is of no use. Unauthorised users of the patented process will avoid making public statements on their manufacturing processes. If the manufactured product itself is not new as compared to the state of the art, section 139 (3) PatG does not help either, not least since in a case pursuant to section 139 (3) PatG an inspection process would appear to be rendered unnecessary, since the effect of the assumption and consequent reversal of the burden of proof pave the way for a substantiated claim to be asserted in such situations.

There may be cases where it is possible to obtain expert confirmation that, for instance, the product may theoretically be manufactured without using the patented process but this would not really be economically feasible as compared to using the protected process, and that it would thus be impossible to offer a product at the competitor's prices in practice. Such clear cases are likely to be the exception, however. Often, while the patented process is substantially more economical, the product manufactured by the respondent can also be manufactured using patent-free processes, albeit for a substantially lower profit margin, which is naturally unknown to the party applying for the inspection order. Past rulings place very strict requirements on evidence demonstrating sufficient likelihood of patent infringement by such means (cf. decision passed by the OLG Frankfurt/Main dated 27 November 2019, 6 W 100/19, Juris margin no. 4; LG Munich I, PharmR 2018, 268, 272). This has so far typically caused applications for inspection orders to be rejected.

In such circumstances, it is practically impossible for patentees to substantiate the "sufficient likelihood" of patent infringement. Since they are not able to secure evidence by way of an inspection procedure, they are unable to enforce their protective rights. Do process patents therefore constitute worthless paper tigers in such cases?

Interpretation in conformity with European law

The solution lies in an interpretation of the term "sufficient likelihood" in compliance with European law, combined with the possibilities for protecting trade and business secrets under the so-called "Duesseldorf procedure".

The purpose of section 140c PatG in requiring "sufficient likelihood" is to ensure that applications for inspection orders are not simply submitted "on the off-chance", while taking into account that the question of unlawful activity can ultimately remain open (Kühnen, Handbuch der Patentverletzung, margin no. B.26; Kaess in: Busse/Keukenschrijver, PatG, 9th edn. 2020, section 140c margin no. 8). Section 140c PatG serves to implement Articles 6 and 7 of the Enforcement Directive (BR-Drs. 64/07 pp. 62, 65). The Enforcement Directive establishes a minimum level of harmonisation (BR-Drs. 64/07 p. 56 para. 4, Art. 2(1) Enforcement Directive). The right to inspection granted under section 140c PatG thus cannot be subject to stricter requirements than those specified in Article 7 of the Enforcement Directive. From the outset, however, Article 7(1) of the Enforcement Directive does not make the granting of a right of inspection conditional on "sufficient likelihood", but rather requires that the applicant presents "all reasonably available evidence to support his/her claims that his/her intellectual property right has been infringed or is about to be infringed". The requirement of "sufficient likelihood" as set out in section 140c PatG should be interpreted on this basis.

Moreover, under the Enforcement Directive member states are obliged to provide for measures to preserve relevant evidence in respect of the alleged infringement which are effective, subject to the protection of confidential information. The aim is to enable patentees to enforce their protective rights. It is thus not permitted to render it practically impossible for the patentee to enforce their rights by imposing stricter requirements on substantiating the likelihood of patent infringement.

50:50 = sufficiently “likely”?

How “likely”, therefore, must the infringement be before a right to inspection is granted? Since it is ultimately a subject which the court must weigh up, percentages are not particularly helpful here. But even an assessment on the merits can encounter difficulties in individual cases. In a case where two equally available manufacturing processes are possible, only one of which is protected by the process patent in suit, it will generally (i.e. in the absence of additional indicators) be impossible to assume that use of the protected process is “more likely than not” (see the decision by the OLG Frankfurt/Main cited above). Viewed from the opposite perspective, however, it is equally not “more likely than not” that the protected process is not being used. If, in such case, one were to permit the argument that the respondent would, in the event of doubt, act in a lawful manner and respect third-party protective rights as a rule, i.e. if in doubt would select an available, patent-free process (even if it were slightly less suited), the patentee would have no possibility of enforcing their protective right. Even in a hypothetical case where patents have been granted to two separate patentees for two potential and equally viable manufacturing processes, such patents would be effectively worthless. Neither patentee would be able to provide prima facie evidence vis-à-vis a third-party manufacturer that it is more likely that their process is being used than that of the other patentee.

If, therefore, one is to take the protection of process inventions seriously, the option of an inspection must be available also in the event that the court cannot already conclude on the basis of the available evidence that it is more likely than not that the protected process is being used (i.e. if the 50% threshold has not been exceeded). It is not clear, however, whether or not this is expressed in the specification of a “certain degree” of likelihood, as is sometimes cited in past rulings and legal literature (see above). Practical application is not eased by the various different terms used in relation to likelihood.

Inspection to be ordered if all “reasonably available evidence” (Art. 7 Enforcement-Directive) is presented

Thus, the question must be raised as to whether, when passing a decision on an application for an inspection order, it would not be better to place greater emphasis on the requirement specified in the Enforcement Directive, namely that the applicant must provide all “reasonably available evidence” in support of the alleged patent infringement. The patentee may in this context be expected to invest reasonable efforts, such as comprehensive tests, if they may be expected to substantiate the facts of the case. The LG Braunschweig, for instance, (arguably correctly) refused to grant an inspection order on the grounds that the patentee had reasonable options of its own available to investigate the matter. The adversary in that case had made a specimen available which the patentee could have analysed in order to derive the required facts (judgment passed by the LG Braunschweig dated 5 August 2016 – 9 O 2539/15). If, by contrast, the patentee has exhausted all possibilities for obtaining reasonably available evidence, it must certainly still be given the opportunity to substantiate the facts of the case by way of an inspection procedure.

Protection of business and trade secrets of the respondent by way of the “Dusseldorf Procedure”

The primary concerns against granting (more) generous inspection rights relate to the fear that such practice could lead to random applications for inspection orders being filed “on the off-chance” (Kühnen, Handbuch der Patentverletzung, margin no. B.26). But German law does not allow petitions to procure evidence by way of “fishing-expedition” (decision by OLG Frankfurt/Main dated 27 November 2019, 6 W 100/19, Juris margin no. 3). This is primarily due to the legitimate concern that merely by making an assertion claiming a vague possibility of patent infringement, a patentee could secure access to the respondent’s trade and business secrets.

Achieving a fair balance between protecting the alleged infringer's trade and business secrets on the one hand while honouring the patentee's exclusive right laid down in Article 14 of the German Basic Law (Grundgesetz) thus remains elusive. Such balance can and must, however, be possible without patentees being stripped of all possibilities for enforcing their claims. The flexible application of confidentiality mechanisms by way of the "Duesseldorf procedure" offers a solution in this context (cf. Deichfuß, GRUR 2015, 436, for instance). Under the Duesseldorf procedure, the applicant itself is prohibited from participating in the inspection, and in a first step only their legal counsel and patent attorney they have instructed are granted access to the subject of the inspection, besides the expert appointed by the court. The applicant is granted access to the results of the inspection only at a later date, in the form of an expert opinion that has been cleared through clearance proceedings, if the indications of infringement have been corroborated. It is, however, equally possible that only the court-appointed expert is granted access to the process to be inspected or to the corresponding documents, with only their report being disclosed to the applicant's legal counsel, who in turn are subject to a duty of confidentiality towards their client. It is thus possible to first have sensitive documents, such as whole modules of the confidential dossier, approval documents under medicinal products legislation or production batch reports, "filtered" down to the key facts by the court-appointed expert on the basis of the party's submission relating to the alleged infringement. Any ambiguous issues can be clarified by way of applications to supplement the expert report. It is thus possible to ensure maximum protection of the respondent's confidential information. The Duesseldorf procedure therefore enables the flexible development of a solution depending on the "likelihood" of a patent infringement which protects the respondent's potential trade secrets without rendering it impossible for the applicant to enforce their protective right from the outset.

Conclusion

The patentee's application for an inspection order should generally be granted if the patentee has no

other reasonably available opportunity to procure evidence. The decision should not be based on weighing up the definition of a "sufficient likelihood" in the sense of "prevailing likelihood". The respondent's legitimate interests in securing their trade and business secrets may be taken into account by applying a version of the Duesseldorf procedure that has been tailored to the individual case. The legislature has also acknowledged the advantages of the Duesseldorf procedure's flexible structure in its government bill relating to section 145a PatG, according to which the provisions of the German Business Secrets Act (Geschäftsgeheimnisgesetz; GeschGehG) expressly do not apply to independent proceedings for the taking of evidence (cf. p. 65 of the government bill) because, in contrast to the Duesseldorf procedure, it is not possible under sections 16 et seq GeschGehG to completely rule out the possibility of the adversary gaining knowledge of information that should be subject to confidentiality (cf. section 19 (1) GeschGehG).

The concern that such an approach could lead to unlawful discovery activities or even that courts could face a flood of unjustified inspection applications is likely to be unfounded. A patentee would not risk the substantial time and costs involved in an inspection procedure without plausible grounds (even if their suspicion of a patent infringement may not breach the threshold of "more likely than not"). Moreover, if no infringement is confirmed, the applicant is obliged under section 140c PatG to compensate any damage suffered as a result of the inspection. The court may also make the inspection conditional on the provision of a corresponding security. An application for an inspection order, therefore, represents a not insignificant financial risk for the patentee if, for instance, production has to be suspended during the inspection, and would thus not be filed lightly. Where inspections can be conducted without affecting production in daily operations by the targeted removal of specimens or simple observation (or documents being inspected by the court-appointed expert), the respondent in turn has no protected interest relating to any potential impact on production. Their legitimate interest in maintaining the confidentiality of their business

secrets can, as set out above, be taken into account by tailoring the procedure to the needs of the individual case (duty of confidentiality imposed on the applicant's legal counsel or inspection by court-

appointed expert only, accompanied by a member of the court etc., as necessary, and communication of the inspection report only to the applicant's lawyers, who are subject to a duty of confidentiality).

Key points/1 minute read/Summary

For the enforcement of (manufacturing) process patents, patent owners are often dependent on information from the actual manufacturing process or from confidential (regulatory) documents of the purported infringer. The inspection procedure under Sec. 140c PatG offers an effective method of obtaining evidence in Germany - a legal system that lacks a "discovery" procedure. However, when issuing inspection orders, the courts apply strict standards and require factual indications that a patent infringement is "sufficiently probable". When this is the case is judged differently in the case law. If there are alternative (possibly even patent-free) possibilities for production, the inspection request often remains unsuccessful. Stephan Neuhaus argues for an interpretation in conformity with European law, according to which a request for inspection is to be granted if "all available evidence" has been submitted, but the facts of infringement nevertheless remain unclear. Otherwise, process patents, the protection of which is expressly provided by the legislator, are practically devalued. Justified interests of the respondent in the inspection proceedings in the protection of his trade and business secrets can be taken into account by the flexible design of the so-called "Düsseldorf procedure".

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