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‘Launch at risk’ – Article 9 (7) of the Enforcement Directive interpreted by the CJEU in C-688/17 (Bayer), concluding that when a patent is subsequently revoked it does not automatically follow that the preliminary injunction was unfounded

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The injunction gap is a frequently discussed characteristic of those European jurisdictions, Hungary being one such country, whose patent litigation systems are bifurcated. In a preliminary injunction proceeding in Hungary the court does not assess the validity of the patent in suit, at least not simply at the level of arguments, although decisions on invalidity which have already been made are to a certain extent relevant. Consequently, following the decision on the request for preliminary injunction, the main patent infringement action is suspended for the duration of revocation/opposition proceeding, which may and indeed sometimes does give rise to the patent, on the basis of which the preliminary injunction was ordered, being subsequently revoked.

This is the context of the case in which the referral in C-688/17 (Bayer) was made by the Metropolitan Court of Budapest, Hungary.

The parties are Bayer Pharma AG (Bayer) vs. Richter Pharma Nyrt. (Richter) and Exeltis Kft. (Exeltis). The patent in suit covers an oral contraceptive pharmaceutical preparation. Although the patent was still pending when the generic products came onto the market, once the patent had been granted Bayer immediately filed a request for preliminary injunction while Richter initiated a revocation action against the patent. Following the Metropolitan Court’s positive finding on the likelihood of patent infringement taking place, a preliminary injunction was ordered and the main infringement suit suspended in line with the practice of bifurcation.

The preliminary injunction was, however, subsequently lifted by the Metropolitan Appeal Court for reasons unrelated to the previous findings concerning the likelihood of patent infringement. Some months later the Hungarian Intellectual Property Office (HIPO) revoked the patent. In Hungary, the first instance decision of the HIPO is followed by two judicial instances, as well as the possibility of an extraordinary judicial review, on questions of law, by the Curia (Supreme Court). At the end of the revocation proceeding the patent was revoked with final effect.

Both Richter and Exeltis have filed lawsuits for the compensation of the losses they have suffered as a consequence of the preliminary injunction.

In course of this suit the Metropolitan Court referred questions to the CJEU regarding the interpretation of Article 9 (7) of the Enforcement Directive, since it found that in the absence of specific provisions in Hungarian legislation corresponding to this Article the general provisions of the national Civil Law on liability and damages shall apply in accordance with the Directive. The Court sought interpretation as to the scope of Art. 9 (7) and also whether the national court is precluded from taking into account the behaviour of the defendants and particularly their own contribution to any damage suffered.

Essentially the question addressed here was whether it is only the patentee that bears the risks of a preliminary injunction and therefore has to provide full and entire compensation to the defendant when the patent was valid at the time of the injunction being granted but subsequently revoked or whether the defendant's own act of launching at risk can be taken into account and thereby affect whether and to what extent compensation may be awarded.

In addition to receiving observations from all parties involved and the EU Commission, and a hearing in Luxembourg, the Court also obtained the opinion of Advocate General Pitruzzella (AG). Noting the almost identical wording of Art. 50 (7) of the TRIPS Agreement and that of Art. 9 (7) of the Enforcement Directive, the AG started by pointing out that it is not the intention of Union Law to provide a higher level of harmonisation than the TRIPS Agreement, so the Directive leaves room for Member States to determine that national substantive legislation governs the right to compensation of the enjoined defendants in line with Art. 9 (7).

The AG was further of the opinion that it would be contrary to the aim of the Directive if the compensation of defendants could be routinely refused when they do not wait for the revocation of the enjoined patent and this would in fact encourage the misuse of preliminary injunctions. However, the AG moderated his opinion by stating that national courts are still not precluded from considering the behaviour of the defendant when awarding compensation under Art. 9 (7), especially in the event that the defendant has launched a product without first challenging the patent. The AG emphasised that, even though launching at risk is not a circumstance that would necessarily preclude compensation, the national court can take this, among other relevant circumstances such as the characteristics of the patent and the particular market, into account.

While many would say that the CJEU tends to follow the opinion of the AG, the present case shall be remembered as one of the exceptions to this, given that [the judgement of the Court published on 12 September 2019](#) adopted a very different approach to the questions raised.

The Court started by stressing that "appropriate compensation", as it appears in Art. 9 (7) of the Directive, is an independent notion of Union Law, requiring uniform interpretation in the EU. To determine the meaning of "appropriate compensation" at the level of Union Law is also justified by the aims of the Enforcement Directive, which are express in recitals 7, 8 and 10. Allowing Member States to establish the essence of "appropriate compensation" on their own would run against the principles of equivalence and homogeneity which Union Law desires.

Testing its own findings against the TRIPS Agreement, the Court pointed out that the TRIPS Agreement acknowledges Member States' right to ensure a higher level of protection in their national legislation and that this is precisely the aim of the Enforcement Directive, and as such the Court's interpretation is not in violation of the TRIPS Agreement.

Turning to Art. 9 (7), the Court declared that even when the preconditions for the application of

Art. 9 (7) are met before a national court, i.e. that provisional measures are revoked or lapse due to any act or omission by the applicant (patentee), or where it is subsequently found that there has been no infringement or threat of infringement, it shall not mean that the national courts would automatically and in any event be obliged to order the claimant (patentee) to pay compensation for any damage suffered by the defendant as a result of those measures.

Here the Court referred to recital 22 of the Directive, on the basis of which Art. 9 (7) serves as a guarantee against unjustified requests. The same recital contains that measures are particularly justified where any delay would cause irreparable harm to the right holder. Thus, the Court continued, one may say that an injunction was unjustified where there was no threat that it would cause irreparable harm to the right holder in the event that the injunction was ordered with a delay.

Paragraph 63 and 64 of the judgement contain the key finding that in the event a defendant markets a product in such a situation where there is a patent application or a granted patent that prohibits its distribution, such distribution is *prima facie* an objective sign of causing irreparable harm to the patentee. Therefore, in such circumstances a request for preliminary injunction cannot be *a priori* regarded as unjustified in the context of Art. 9 (7).

Reiterating that the products in the basic case were considered infringing in the preliminary injunction proceeding, the Court concluded that the fact that in the basic case the preliminary injunction was lifted, even though it fulfills the precondition of applying the court's competence to awarding compensation to the defendant under Art. 9 (7), does not, as such, prove that the preliminary injunction was unfounded.

The Court reaffirmed that a contrary conclusion would, in circumstances similar to those in the basic case, lead to right holders being deterred from seeking the measures provided by the Directive and would thus be contrary to its aims. As a restriction to its interpretation the Court also noted, with reference to Art. 3 (2) of the Directive, that national courts must ensure that the measures encompassed in Art. 9 of the Directive are not misused. Courts must therefore establish that the request for preliminary injunction is not a misuse of rights.

Even though at first glance it might seem that the judgement of the CJEU is merely filling a gap in Hungarian legislation, its significance may go well beyond the basic case in determining the content of 'appropriate compensation' as an autonomous notion of Union Law, requiring uniform interpretation throughout the EU and in doing so making it clear that 'launching at risk' may indeed be the risk of the defendant and not that of the patentee. In what may be considered food for thought for future cases, the decision appears to rule out automatic compensation within the context of Art. 9 (7) while also setting down the necessary safeguards against the misuse of provisional measures. The judgement may consequently impact judicial practice not only in Hungary but also in other jurisdictions and will probably be particularly relevant in countries that apply bifurcation in patent litigation.

Disclaimer: the author represented Bayer before the CJEU; the present article contains the author's personal views.

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