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Preliminary injunctions – a view from Young EPLAW

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June 2023 has just passed, and the newly minted Unified Patent Court is of course still on everyone's lips. But, of course, there are many reasons why the novel court system might not be the perfect fit for your next preliminary injunction: You just manage to submit your opt-out without the CMS crashing halfway through, and withdrawing the opt-out doesn't fit your strategy? The proceedings may be expensive? Or perhaps you just want to see others go through the tunnel first?

Even if you want to go down the "UPC road", the competent UPC division might want you to briefly discuss and summarize national requirements (at least with respect to some UPC member states) for obtaining a PI in the UPC system. Hence, all the more reason to take a quick look at the PI requirements in four leading patent litigation jurisdictions.

Following our panel discussion on preliminary injunctions relating to patents at Young EPLAW 2023, we summarize the main takeaways, focusing on recent developments from our jurisdictions (UK, Germany, Italy and Belgium). We cover three topics: conditions to obtain a preliminary injunction, potential liability when enforcing that injunction, and looking ahead on preliminary injunctions, including in the UPC context.

Conditions to Obtain a Preliminary Injunction

So, you have got your patents – now you have to decide where to use them!

When considering where to apply for a preliminary injunction, patentees have to consider differences in national practices. While similar conditions may apply, such as the need for urgency, or prima facie assessments of validity and infringement, courts can (and do) come to different conclusions.

UK

While generally similar to practices on the European Continent, the UK approach to preliminary injunctions is a little different. The UK court assesses PIs by asking three (or four depending how you break them down) questions (arising from *American Cyanamid)*: (1) is there a serious issue to be tried / is there an arguable case? – this is a low bar that is often met; (2) are damages an adequate remedy for the patentee (if so, no PI is likely to be granted), are they adequate for the

defendant?; and (3) where does the balance of convenience lie (or what is the path of least injustice)? – this is where questions of the *status quo*, urgency and "clearing the way" can come into play. The UK authorities are clear – a PI is not a mini-trial. As such, questions of validity raised by the defendant are highly unlikely to prevent a PI being granted. If a PI is going to fail, it will typically be because damages are an adequate remedy for the patentee; the main exception to this is pharmaceutical cases where it is often accepted that generic launches will lead to irreparable and/or unquantifiable damage to the patentee. If a PI is to be granted, the patentee will be required to give a cross-undertaking in damages (i.e., an undertaking to the court to compensate the defendant (and other parties) for loss caused by the order, should any PI be ultimately found to have been wrongly granted).

Recently, a slight question mark has appeared over the general view that for pharmaceutical PIs damages will not be an adequate remedy for the patentee. Although the Court of Appeal was clear, in *Neurim v Generics* [2020] EWCA Civ 793, that deciding to uphold the lower court's decision not to grant a pharmaceutical patent PI was based on the specific facts of that case, the Patents Court has subsequently refused two further pharmaceutical PIs (*Neurim v Teva* [2022] EWHC 954 (Pat) and [2022] EWHC 1641(Pat), and *Novartis v Teva* [2022] EWHC 959 (Ch)). The fact patterns of these cases are, however, atypical and it is unlikely that this represents a sea-change in the general approach. It is also a salient reminder of the importance for parties to explain why damages are not an adequate remedy in the circumstances of their case.

Belgium

Patentees often look at Belgium because it is traditionally an injunction-friendly jurisdiction. While it remains a key forum for obtaining injunctions, especially in the pharma sector, the current trend is towards a more detailed assessment of validity and infringement. When the patentee does not present a clear-cut case, the balance of all stakeholders' interests plays a growing role. One case between Biogen and Mylan is worth mentioning. In January 2023, the Court of appeal confirmed the refusal to grant an injunction to Biogen based on EP 2 653 873. Among other considerations, the Court found prima facie that the patent lacked inventiveness and that the balance of interested played against the injunction notably because Mylan's damage in case an injunction was granted would be more difficult to establish that that of Biogen if no injunction was granted but the patent was later found valid and infringed. Mylan could also lose the "first mover effect".

Germany

If you are looking for a patent-friendly European jurisdiction, you will certainly consider Germany, because the outcome of infringement proceedings is relatively predictable thanks to experienced, specialised judges, and more often than not courts grant a permanent injunction, the costs are rather low by international standards, and you get all that within a very reasonable timeframe.

But when it comes to *preliminary* injunctions, surprisingly, infringement courts at major patent litigation venues tend to be somewhat hesitant: Besides having a strong case on infringement, in PI proceedings, as a traditional benchmark, the patent's validity must be sufficiently ensured. According to long-established case law, the patent would usually have to have "survived" first-instance contradictory opposition or nullity proceedings. In its leading *Harnkatheterset* decision (April 29, 2010, I-2 U 126/09), Düsseldorf Higher Regional Court had emphasised this rule but also pointed to a respectable (non-exhaustive) list of exceptions. The threshold for obtaining a PI may be high, but it is well possible to show sufficiently ensured validity without contradictory

nullity or opposition proceedings.

Beyond the widely accepted *Harnkatheterset* exceptions, the Courts also recognize special circumstances of the individual case: To name only one common constellation, in pharma cases against generics manufacturers, experience shows that the damage to the originator's pricing is done once the generic drug hits the market. Courts recognise that under circumstances like this, a quick decision is crucial, and, weighing interests, they consider it sufficient that in prima facie assessment, the better arguments speak for validity or that the question of validity at least remains unsolved: The Court would regard the granted patent valid until proven otherwise.

However, the traditional "surviving patent" approach according to *Harnkatheterset* is now under some scrutiny: A referral to the CJEU by Munich I Regional Court resulted in the decision C-44/21 *Phoenix Contact v Harting*, in which it was held that a "surviving patent *only*" approach is incompatible with the Enforcement Directive. Several practitioners, including senior justices, have argued that Munich I Regional Court, in its referral, did not correctly reflect the exceptions and the *Phoenix Contact* decision would not affect German case law. Nonetheless, Munich I Regional Court will likely pursue a more generous approach in the future. While the Düsseldorf courts will likely stick to *Harnkatheterset* for the time being, it remains to be seen whether other courts will follow Munich I Regional Court's lead.

Italy

Italy is a very specialized jurisdiction when it comes to interim proceedings, especially in IP cases. To obtain interim measures the very well-known requirements of prima facie likelihood of success and danger in delay must be met. A certain degree of interplay exists between these two requirements, in that a high degree of likelihood of success can be accompanied by a lower degree of danger in delay, whereas the opposite could not.

Italian Courts firstly conduct a summary assessment as to the basis on which the interim measure has been requested, assessing if it is likely that the subsequent proceedings on the merits will result in the patent being found valid and infringed. Thus, the applicant has to allege facts and provide evidence on the basis of which it may be presumed that there is a strong likelihood that they have an entitlement to the claim.

It is worth considering that the patentee profits from Art. 121 of the Italian Intellectual Property Code which places on the alleged infringer the burden of proving that the patent is invalid and from which Courts have become increasingly inclined over the years to imply a presumption of validity of the patents.

However, it should be borne in mind that if the respondent claims the patent's invalidity, which is very common, the presumption of validity of the patent will not be sufficient. In these situations, given that Italian judges do not have any technical background, the Court in most cases will appoint a technical advisor (Court Technical Advisor, CTA), which is a quite peculiar aspect of Italian jurisdiction, if compared to the UK, Germany and Belgium.

The assistance of the CTA makes the proceedings a bit longer (it can take up to 12 or 18 months), but it also makes the examination of the patent's validity and the alleged infringement more thorough. CTAs are usually asked to answer general questions (e.g., whether the patent satisfies the validity requirements being challenged and whether the patent is infringed by the respondent's product/process), and sometimes can also be asked to better describe the respondent's

product/process and to carry out specific laboratory tests or analyze tests submitted by the parties.

Interestingly, the Court of Milan appointed a CTA in about 70% of the patent interim proceedings over the last three years. Almost all the remaining cases (i.e., those without a CTA report) resulted in the Court refusing the PI application. These data confirm the experience that the presence of CTAs is the rule in Italian interim proceedings, and that Courts do not appoint them only when, for example, the patent's validity is not contested at all or when the prima facie case is clearly groundless.

Another aspect to be careful about is the presence of the danger in delay, especially in relation to the timeframe within which to start interim proceedings. Even if Italian law does not provide any time limit, case law usually considers that too much time passed, and that the danger in delay is not met, when the conduct that the applicant is challenging dates back more than a year before the proceedings are started. Thus, the ideal time to start interim proceedings is approximately 6-12 months after the filing party becomes aware of the opposing party's conduct. Other situations in which the danger in delay could be considered weak or absent occur for example when: (a) the patentee delayed action without an objective justification; or (b) the alleged infringer can provide stringent reason to carry on their business (i.e., that the business, once stopped, cannot restart easily); or (c) the parties don't operate in the same sector or geographical area; or (d) the infringing activities stopped. Conversely, the danger in delay requirement is considered met even if the patentee doesn't have a product on the market which embodies the patented invention, because the infringement could in any case lead to the diversion of customers, which is a damage that can never be entirely restored by an award of damages.

Potential Liability when Enforcing the Preliminary Injunction

Oh dear – your patent was ultimately found invalid or not infringed, what now?

Things can go wrong for the patentee, including when the patent on which the preliminary injunction was granted is revoked or when the patent is ultimately found not to be infringed by the defendant. When injured parties wish to seek compensation from the patentee, national practices differ.

In the UK, when obtaining a PI, the patentee is required to give the cross-undertaking described above. If the PI is ultimately found to be wrongly granted, the defendant can rely on that cross-undertaking to commence an inquiry into the damages suffered. Typically, the defendant and related companies are named in such cross-undertakings. However, the court is required to consider other parties that may suffer loss when defining the terms of the cross-undertaking. To that end, parties in the UK are required to notify the National Health Service of any PI that would affect dealings in a pharmaceutical product or medical device purchased by the NHS. In recent years, the NHS has started to pursue significant claims for compensation see, for example, *Servier v NHS* and *Warner-Lambert v Dr Reddy's*. With the NHS pursuing such claims, it is not inconceivable that other third party stakeholders in the medical device / pharmaceutical space might decide they too should be entitled to a slice of that compensation pie.

Such an up-front requirement to agree to compensate does not exist in Germany, Italy and Belgium. The Court of justice of the European Union seems to exclude no-fault liability of the patentee in case Bayer C-688/19. There is a pending referral on this issue before the same Court in the case Mylan C-473/22, which also asks the question of when assessing the existence of liability,

can it be taken into account that the patent has been found invalid *ab initio* (the UK Patents Court said “no” to a similar question of whether that fact can be taken into account when assessing damages in an inquiry pursuant to a cross-undertaking).

In a decision of 11 October 2022, the Court of Appeal of Brussels rejected a claim for compensation in a case involving Mylan and Novartis where EP 0 948 320 was revoked after the PI was enforced, thereby confirming the high threshold to hold the patentee liable under Belgian law in such a situation. Mylan appealed the decision before the Supreme Court. Italy adopts a similar approach to Belgium.

From a compensation point of view, injured parties are better placed in Germany. Patentees must compensate for any damage caused by enforcing a PI if the injunction is overturned. Sec. 945 of the German Code of Civil procedure orders a no-fault liability for damages which arise from the enforcement of a PI, with the sole requirement that such PI has been overturned for turning out to be “unjustified from the outset”. This does not only apply for PIs for patent infringement if overturned on appeal but also if the patent is nullified. Discussions of whether this statutory liability is in line with the *Bayer* decision are still at the very beginning and seem not to have made it into case law until now.

Italy has never implemented Art. 9 of the Enforcement Directive through specific rules and has never applied strict liability. The positions and the interests of the parties are balanced by virtue of two main measures: security and abuse of process.

As to the first one, Art. 669-*undecies* of the Italian Civil Procedure Code stipulates that the Court, in the order granting the interim measure, “*having considered all circumstances*”, and especially the request of the respondent, may impose a security on the applicant in the event they are ordered to pay damages. It is up to the Court to determine the amount of the measure, which is usually based on a discretionary assessment of the possible damage that the enforcement of the PI order would cause the respondent, if that order were subsequently revoked. This means that the applicant is not automatically required to provide the security, which in fact is not commonly imposed by Courts.

The risk of compensation for damage if a PI is subsequently revoked, must be framed also within the concept of abuse of process under Art. 96(2) of the Italian Civil Procedure Code, which, stating that “*A judge who ascertains the non-existence of a right for which a precautionary order has been executed […] shall, at the damaged party’s request, order the claimant […], who acted without ordinary prudence, to pay compensation for damage*”, rules out strict liability. The application of Art. 96(2) does not require gross negligence on the applicant’s part, which means that any form of negligence is sufficient. Very few decisions have applied Art. 96(2) CPC since it is very rare that the respondent manages to prove the applicant’s negligence (i.e., absence of ordinary diligence and caution), which could happen, for example, in cases where the applicant acted being aware of the patent’s invalidity or of its expiration.

However, it appears a rule of strict liability has now been introduced through Art. 132(5)-*quater* of the Italian Intellectual Property Code, which implements EU Directive 2016/943 on the protection of trade secrets and which states that “*[…] if protective measures adopted to protect trade secrets become ineffective because proceedings on the merits are not commenced […] or lose their effectiveness because of an act or omission on the applicant’s part, or if it is subsequently established that the unlawful acquisition, use or disclosure of those trade secrets did not exist, the*

applicant shall pay compensation for the damage caused by the adopted measures".

Notably, the wording used to implement this Directive is very similar to Art. 9(7) of the Enforcement Directive, despite the latter not having been implemented by the Italian legislator when Italy's IP legislation was reformed to implement the Enforcement Directive. This is because, at that time, the Italian Government believed that the general rules of Italian law (i.e., Art. 96(2) of the Italian Civil Procedure Code) were already compliant with the obligations under Art. 9(7) of the Enforcement Directive. Given that Art. 132(5)-*quater* specifically concerns trade secrets, it can be assumed that it will not be extended to cases involving other IPRs. Moreover, it is uncertain whether this provision will be interpreted as introducing a strict liability system that derogates from the general liability provisions of Art. 96(2) of the Italian Civil Procedure Code or interpreted as a specific application of Art. 96(2) (and therefore proof of negligence will be considered necessary also to apply Art. 132(5)-*quater*), also in light of the Bayer decision.

Looking ahead on preliminary injunctions including in the UPC context

Time (and more importantly the first UPC Court of Appeal decision) will tell how PI proceedings are handled in the UPC context. Until then, since no detailed test, e.g., on how to weigh the interests of the parties (see R. 211 (3) RoP), is prescribed in the UPCA or RoPs, national interpretations may come into play. Hence, it is advisable to look beyond the horizon of the respective national practices when arguing a PI case in front of the UPC context, trying to make use of national practices in UPC member states beneficial to one's position. For this, the UPC judges should be informed by the parties of the respective national practice, to allow the court to review and potentially adapt such practices for the UPC system.

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