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# **IP Litigation System in Czech Republic, Poland, Hungary and Slovakia**

- Report for Japan External Trade Organization -

February 28, 2022

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## Report

### 1. CZECHIA (CZ)

#### 1.1 What is the forum for the conduct of patent litigation?

The City Court in Prague is the only court with jurisdiction to hear patent related disputes at first instance. All appeals are heard by the High Court in Prague. Extraordinary appeals are heard by the Supreme Court. Constitutional complaints are heard by the Constitutional Court (a complaint may be filed without an extraordinary appeal being heard first).

The City Court proceedings are heard before panels of judges ('senates'). The Court has a number of IP specialised senates; however, the judges are all lawyers; there are no technically trained judges. The courts rely on court experts to resolve technical issues. In Preliminary injunction matters filed before full action on merit proceedings are begun a single judge (in the role of the president of the senate) rules on the PI application.

The High Court sits in panels on IP cases. All judges are lawyers without technical experience. The Supreme Court and Constitutional Court judges have no IP specialisation.

The Industrial Property Office 'IPO' is the only body able to cancel, i.e. revoke a patent. It is also possible to seek a (non)infringement opinion from the 'IPO', where the IPO rules on whether a described object/process falls within the scope of protection of a patent or not. In both cases the 1st instance decision is made by a technically trained IPO officer.

The decision can be appealed to the President of the IPO. The president decides based on the advice of a panel of 5 IPO officers, of whom one is legally trained and the remainder technically qualified. A judicial review application can be filed against the decision of the President of the IPO to the City Court in Prague (administrative division) and is heard by an IP specialised senate.

The appeal ('cassation complaint') is heard by the Supreme Administrative Court, which has an IP specialised senate, however, at both instances the judges are all lawyers with no technical expertise.

A constitutional complaint may be filed to the Constitutional Court.

#### 1.2 What is the typical timeline and form of first instance patent litigation proceedings?

Infringement and invalidity proceedings are bifurcated. Only the Industrial Property Office can cancel, i.e. revoke a patent. (The courts theoretically have the power to

decide that the patent was not properly granted and decide to disapply the patent – however, this is very rare.) Typical validity proceedings before the IPO involve 2 instances and then 2 instances of judicial review. The judicial review does not stay the enforcement of the challenged IPO decision. Each instance at the IPO level can be expected to take 9-18 months. The first instance of the judicial review takes 2-4 years, with the second instance taking around 1-3 years.

Infringement proceedings before the City Court take 15-36 months to reach judgment. The court generally requires technical assistance from experts. Generally, experts from the field of ‘Patents and Inventions’ newly renamed “Industrial Property” are relied on, but experts in other fields, such as ‘chemistry’, ‘machinery’ etc. can also be asked to assist. The parties can ask experts to prepare expert reports directly. An expert in the field of Patents and Inventions/Industrial Property is usually relied on to carry out the patent claim construction. The court can disagree with the experts’ claim construction.

Damages claims are not common, permanent injunction claims are more common. The total sum claimed in damages (which includes lost profit, and the sum of unjustified enrichment and the sum for reasonable compensation for immaterial harm caused) must be specified at the outset. In practice the plaintiff should be in position to prove that damage occurred, and its level without further assistance of the court. It is very rare for the court to examine the issue of infringement in an interim judgment and only then to proceed to quantify the damages. This can realistically only occur if a permanent injunction or some other non-pecuniary claim (such as an apology) is made. It must also be noted that until the plaintiff formally claims the full sum in court the limitation period continues to apply to the unclaimed amount.

**1.3 Do the courts/government bodies deal with infringement, invalidity and unenforceability simultaneously or must invalidity and/or unenforceability actions be brought in separate proceedings?**

Infringement is ruled on by the courts. The courts can address the issue of whether a patent is valid, but this is extremely rare. In such a case, the court will refuse to provide protection to the patent or its invalid part; it cannot order its removal from the patents register.

To fully revoke a patent and have it removed from the register an application must be filed with the IPO.

The court can wait for the IPO decision on validity, but not in all circumstance and never in preliminary injunction proceedings. The court can also decide to resolve the validity issue itself.

The court must wait for an IPO decision in utility model matters before ruling in favour of the right holder, or itself decide that the utility model is valid, because there was no

substantive examination at the IPO before its grant. This is not the case in the case of preliminary injunctions, where validity is presumed.

The validity proceedings and infringement proceedings proceed at their own pace – the system is bifurcated. If a final infringement decision is made in favour of the right holder and the patent is later revoked, the infringement proceedings can be reopened.

#### **1.4 Which acts constitute direct patent infringement?**

Direct infringement is defined as: the manufacture, offering, introduction onto the market, use, and importation, storing or other dealing with a patent protected product for those purposes, in s. 13 of the Act no. 527/1990 Sb., on Inventions and Rationalisation Proposals, as amended. The same applies to a product obtained through a patented process, where identical products are presumed to infringe, if it is highly probable that the product was manufactured through a process which is subject to a patent and the patent owner was, despite reasonable efforts, unable to identify the manufacturing process used, until the opposite is proved. The presence of the rather vague term “other dealing” means the scope of protection is very wide. The use of a patented process or its offering is also actionable.

#### **1.5 Do the concepts of indirect patent infringement or contributory infringement exist? If so, what are the elements of such forms of infringement?**

Indirect infringement is defined in s. 13a of the Act on Inventions as follows: (1) No one may, without the permission of the patent owner, supply or offer to supply to another person, other than a person entitled to utilise a patented invention, the means relating to a substantial element of the invention and serving in that respect for its realisation, if with regards to circumstances it is clear that the means are capable of realisation of the patented invention and are intended for it. (2) Subsection 1 will not apply if the means are products which are common on the market, unless the third party influenced their recipient to engage in conduct prohibited by s. 13. (3) Persons carrying out activities under s. 18 letters c) to e) (passing craft, individual drug preparation, non-commercial use, and the experimental exceptions) are not regarded as persons entitled to use the invention, within the meaning of subsection 1.

Contributory infringement can amount to conduct in unfair competition.

#### **1.6 What are the key defences to patent infringement?**

The defendant can raise several defences to infringement.

First it can claim that it is a prior user of the right. In such a case the right is not effective against it. The exact scope of such right remains unexplored, e.g., it is unclear whether use must be continual, whether improvements extinguish the right and how it can be assigned, if at all.

Second, patent rights could have been exhausted, as once the right holder places the product onto the market in the EU or EEA, the patent can no longer be enforced in relation to that product. This permits free movement of goods within the EU and EEA.

A compulsory licence can allow an infringer to use the right, but only after such compulsory licence is granted by the IPO.

There is still no local case law on reasonable and non-discriminatory (FRAND) agreements in standard essential patents, and whether injunctions are unavailable if the right holder does not engage in genuine negotiations. Given that existing EU case law has not created hard rules, it is difficult to know whether a right holder will be unable to seek an injunction in such cases, if it does not engage in genuine negotiations.

### **1.7 What are the key grounds of patent invalidity?**

A patent or utility model can be revoked on application to the IPO. Any person can seek to revoke a patent or a utility model. Revocation proceedings can be begun even after a right has expired, however, in that case the applicant must show a valid legal interest in doing so.

The courts cannot revoke a patent. However, it can decide that the right is invalid and refuse to grant it protection.

Patent revocation can be based on the argument that:

- the conditions for patentability were never present (lack of novelty or inventiveness over the prior art, lack of industrial applicability, the subject matter is not patentable for lack of technical nature or excluded from patentability – e.g., surgical or medical treatment);
- the invention is not described so fully or clearly to enable the person skilled in the art to practice it;
- the patent contains added matter over the scope of the application; and
- the patent owner is not the inventor or legal successor.

### **1.8 Can a patentee seek to amend a patent that is in the midst of patent litigation?**

Yes. It must be borne in mind, however, that validity and infringement are bifurcated. In practice therefore the plaintiff has no reason to limit its patent in the infringement proceedings, and the defendant would challenge the patent before the IPO. The amendments would then be made in the IPO proceedings. The plaintiff could in some circumstances concede that the patent is partially invalid, and the court would then examine only the limited scope of the patent for infringement. The plaintiff can also apply to limit its own patent at the IPO; however, it would have to argue lack of novelty,

inventive step or another reason for the limitation to succeed; partial surrenders are not possible. Third parties cannot ordinarily intervene in the IPO proceedings. A 3<sup>rd</sup> party intervention is possible in infringement proceedings.

### **1.9 How are technical matters considered in patent litigation proceedings?**

Experts are relied on to resolve technical issues, as the judges are not technically trained. The regional courts maintain a list of ‘appointed experts’ for various fields, such as ‘chemistry’, ‘electronics’, ‘economics’ etc. Any person with qualifying education and experience in the field can apply to be appointed as an expert in the field by one of the regional courts. The court and the parties can then approach this expert. One of the fields in which an expert can be appointed is “Patents and Inventions” newly renamed to “Industrial Property”.

Such experts regularly prepare reports on whether a product or process falls within the scope of a patent. The court can appoint an expert to prepare an expert report to resolve a technical question. The technical findings of the expert are binding on the court, however, if the court is of the opinion that the findings are not correct it can appoint a further expert to answer the same question or to review the expert report.

An expert report prepared for one of the parties is binding on the court if it satisfies the necessary legal requirements and is accompanied by a declaration of the expert that he/she is aware of the criminal sanctions for a knowingly incorrect report and the report is not clearly incorrect. In every case the court should summon the expert to an oral hearing where the expert is cross examined by the court and the parties. The expert, even if commissioned by one of the parties, must remain impartial and objective; its duties are to the court.

### **1.10 Is some form of discovery/disclosure and/or court-mandated evidence seizure/protection (e.g. saisie-contrefaçon) available, either before the commencement of or during patent litigation proceedings?**

It is the court which leads all evidence, and it should acquire the evidence the parties identify and then rule on its admissibility. In practice the parties are required to present all evidence they can acquire themselves and only where there are good reasons for them being unable to acquire evidence, can they request assistance from the court, such as where evidence is in the possession of a third party. The parties can request that evidence is seized in a preliminary manner, if there is a risk that it will not be obtainable later or only with great difficulty.

A request for preliminary seizure of evidence can be made during or before the action on merit proceedings are begun. The court can seize a sample of a product, material used to manufacture or disseminate it, and documentation relating to it, if it is suspected of infringing a patent. To carry out the seizure of evidence generally or the



product sample and related machinery or documents, the court must be convinced that the applicant has a patent right and that it is likely infringed. The courts will refuse fishing expedition requests. Discovery and inspection, as understood in common law jurisdictions, are not available. While there is a right to information about products and their distribution channels from a defendant, in practice this is only ordered once infringement has been proved.

**1.11 Is there a system of opposition proceedings? If so, how does this system interact with the patent litigation system?**

A granted patent can be revoked at the IPO (or EPO) only. Any person can apply to cancel a patent. This application can be made even after the patent's expiry if valid legal reasons for this exist. The EPO opposition period closes 9 months after patent grant publication and the patent can then only be cancelled through the IPO. The IPO will stay a local patent cancellation action if EPO opposition is filed or pending. Where the plaintiff agrees the courts will stay the pending patent infringement proceedings to await the IPO or EPO validity decision.

**1.12 What are the key procedural steps that must be satisfied before a patent action can be commenced? Are there any limitation periods for commencing an action?**

The plaintiff must file a front-loaded claim with the appropriate court, the City Court in Prague, identifying the plaintiff, its right and the defendant and the infringing conduct. However, additional argumentation and evidence can be presented and identified until the end of the 1<sup>st</sup> oral hearing in the matter. For damages claims this must be done within 3 years of infringement or becoming aware of the damage for which monetary compensation is claimed. If the plaintiff wishes to seek costs of the proceedings against the defendant, it must send a prelitigation demand to the defendant's last known address at least 7 days before the claim is filed in court. Failure to send the letter does not impact on the chances of success. Costs may be awarded in some cases even though this pre-litigation letter was not sent.

**1.13 What options are open to a patent holder when seeking to enforce its rights in your jurisdiction? (especially the Border measures)**

Apart from litigation, a right holder can register a customs watch for the external market or for the internal market, or both. The customs will then aim to seize product being imported into the EU market (external market watch) or product already on the Czech/EU market (internal market watch). The right holder can identify shipping routes, importers and locations where products are stored. If customs seize product and the defendant does not voluntarily agree to its destruction the right holder has to initiate legal proceedings.

**1.14 Which parties have standing to bring a patent infringement action? Under which circumstances will a patent licensee have standing to bring an action?**

The patent owner can enforce. A licensee can enforce once the licence is registered by the IPO and if the licence authorises the licensee to enforce, or where the licensee informs the owner of the infringement/threat of infringement and the owner does not begin enforcement within 1 month of such notification.

**1.15 Are interim injunctions available in patent litigation proceedings?**

Interim and preliminary injunctions 'PI' are available in patent disputes. The court must rule on the application within 7 days and no hearing can be held. In practice most cases are thus decided ex parte. However, the defendant may attempt to submit a defensive brief, written defence and evidence. The PI application must be accompanied by a 50,000CZK statutory bond. The court can increase the bond of its own motion before deciding (which is rare) or after grant on application of the defendant. There is no upper limit on the size of the bond. The PI bond in no way limits the liability for damage which the law applies on the PI applicant in relation to all persons to whom damage is caused by the PI. The unlimited strict liability, which can only be avoided if the damage would have occurred regardless of the PI, can only be avoided if the PI applicant succeeds in the action on merits or if its rights are satisfied.

If the PI is rejected or refused the defendant is not informed. An ordered PI is enforceable upon service on the defendant. The court will order the PI if the existence of the patent right and its infringement are established and there is a need to adjust the position of the parties or there is a threat that the enforcement of a future decision would be jeopardised. In practice the courts look to the patent's formal registration only and do not form their opinion about the patent's validity. It can be enough to merely argue infringement, but in technically complex matters an expert report finding that a product or process falls within the scope of protection of the patent is recommended. The need for the interim injunction can be established where the presence of the product on the market is causing ever-increasing damage, or where the threat of infringement is such as to threaten to cause irreparable harm.

PIs are readily available in patent cases, with the courts being patentee-friendly, however, the courts are less prepared to grant injunctions where the right is close to expiry, the product is not present on the market (and there isn't conclusive evidence of an imminent launch) or there is a lack of urgency. The decision can be appealed as-of-right; however, the order remains enforceable pending the appeal decision. The appellate court must restrict itself to the evidence presented at first instance, i.e. no new evidence can be presented by the defendant, who must restrain itself to arguing that the PI should not have been ordered based on the evidence available to the court at first instance.

**1.16 What final remedies, both monetary and non-monetary, are available for patent infringement? Of these, which are most commonly sought, and which are typically ordered?**

The court can order any injunction it deems appropriate. The most common orders are injunctions prohibiting dealing with a patented product as well as recalls of products from commercial channels, as well as materials, tools and other devices used to infringe, as well as remedy of the infringing situation.

Destruction of infringing products, materials etc. can be requested, but the court does not have to order destruction if it were to be disproportionate. The plaintiff can request that the defendant publishes an apology. The law also allows the plaintiff to demand confirmation of the right to publish the judgment at the defendant's expense. The plaintiff can seek damages which include actual damage and lost profit. The plaintiff can seek surrender of unjustified enrichment. The plaintiff can seek reasonable compensation of immaterial, i.e. noneconomic, harm. The court uses its discretion to set the level of this compensation, as by its nature its level cannot be calculated. These can be claimed either at actual levels or as a lump sum payment calculated using a licence analogy, i.e. at a level amount to at least twice the level of a licence that would have authorised the infringement. In the case of an unknowing infringement there is no multiplication of this licence. Damages claims are not common. It is unclear whether damages and unjustified enrichment can both be claimed, or the plaintiff has to select one.

Permanent injunctions and product recalls are often sought and granted. Destruction is often sought but sometimes not granted. Damages are sought rarely, as is unjustified enrichment. Reasonable compensation for immaterial harm is sometimes sought and generally granted, although the awards are modest.

**1.17 On what basis are damages for patent infringement calculated? Is it possible to obtain additional or exemplary damages?**

The experts, usually from the field of economics, are relied on with the court having a limited role in directing the calculation process. There is little judicial guidance given the low number of decided and reported cases and the variation in approach between experts. Additional and exemplary damages are not available; however, the licence analogy does require at least doubling of the fictitious licence, with the court being able to set the multiplication factor higher, perhaps to serve as additional and exemplary damages.

**1.18 What avenues of appeal are available for a defeated party and on what basis?**

Appeals in industrial property matters proceed under ordinary rules of procedure.

In the case of patent, SPC and utility model appeals, the High Court in Prague has exclusive jurisdiction and sits in three member panels/senates. All judges are legally trained and specialise in intellectual property.

The appeal proceedings allow for a review of both fact and law; however, new evidence cannot be presented as a general rule, unless it can be shown that one of the exceptions, such as that the evidence did not exist at the time of first instance judgement, or to undermine the credibility of evidence relied on in the judgment, or to prove errors of procedure etc.

**1.19 How long do patent infringement proceedings typically last?**

A PI decision must be issued within 7 days of the application being filed. The appeal usually takes 3-6 months to reach a decision. A 1<sup>st</sup> instance action on merit judgment can be expected within 15-36 months. The as-of-right appeal usually reaches judgment within 12-24 months. Extraordinary appeals take 6-24 months to be resolved. Constitutional complaints take 12-36 months.

**1.20 What level of cost should a party expect to incur to take a case through to a first instance decision, preliminary injunction proceedings and appeal proceedings?**

The costs range widely depending on the type of patent and the plaintiff and defendant. Expert report costs, laboratory testing, translations and legal fees form the major expenses. Apart from legal fees these expenses are likely to be recovered in full on success. Legal fee recovery is at c. USD 1.000 per instance per defendant. We would expect the first instance proceedings to cost between USD 50.000 to USD 100.000 and around USD 50.000 on appeal. Complex cases can incur much higher costs, simple cases less.

Court fees are minimal unless damages are claimed. A damage claim also affects the calculation of recoverable legal fees.

Similar costs can be expected for the preparation of the PI application, although the appeal proceedings usually do not exceed USD 30.000. The preparation of the PI application means that the action on merit submissions then require only a minimum time to prepare.

## **2. HUNGARY (HU)**

### **2.1 What is the forum for the conduct of patent litigation?**

In accordance with Article 104 of the Hungarian Patent Act (Act XXXIII of 1995 on the Patent Protection of Invention), the Budapest Metropolitan Court shall have exclusive competence and shall sit in a chamber in all litigation concerning the infringement of an invention or of a patent.

For revocation actions it is the Hungarian Intellectual Property Office (HIPO) that has competence at first instance while the Metropolitan Court acts as appeal forum. However as of 1<sup>st</sup> January 2022, the defendant of a patent infringement action may also choose to file the revocation request directly in the infringement lawsuit as counterclaim rather than a separate action starting in front of the HIPO. In this case the same judicial forum is competent as for infringement and the two actions are decided in a unified proceeding.

### **2.2 What is the typical timeline and form of first instance patent litigation proceedings?**

#### *a) Current practice, strict bifurcation until 31<sup>st</sup> December 2021*

Under the current practice it typically takes 1-3 months to obtain a first instance decision on preliminary injunction and further 1-3 months to obtain a second instance ruling. Importantly, however, this practice has developed under such rules of patent litigation that have been amended as of January 1<sup>st</sup>, 2022. Before that it was the consistent practice of the court that it did not consider invalidity arguments in preliminary injunction proceedings. However, under the new rules, the court is obliged to take into account invalidity arguments as well which suggests that the timeline may get somewhat longer.

In main actions the first instance infringement proceedings normally take 1 to 2 years depending on the complexity of the case and the need for hearing of witnesses/experts. If there is opposition at the EPO or a separate revocation action pending in front the HIPO the infringement lawsuit is routinely suspended for the duration of that. The duration of revocation proceedings initiated before the HIPO generally takes at least 3 years to go through all instances (HIPO, first instance court, second instance court) but in more complex pharma cases it is often much longer than that and can be even 5-7 years. During this time the decision on infringement is delayed because of the stay of the proceedings.

#### *b) Potential future practice, semi (optional)-bifurcation after January 1, 2022*

As of 1<sup>st</sup> January 2022, the defendant of a patent infringement lawsuit has the option to file a revocation request directly as a counterclaim in the lawsuit. In this case the revocation action has a shorter duration since the HIPO level is skipped and according to

the new rules the court should act in an accelerated manner. What this will mean in practice is yet to be seen but we do expect that it will be at least a year faster to get a final decision on both validity and infringement.

### **2.3 Do the courts/government bodies deal with infringement, invalidity and unenforceability simultaneously or must invalidity and/or unenforceability actions be brought in separate proceedings?**

As stated above, as of 1<sup>st</sup> January 2022 the Hungarian system is semi-bifurcated, as opposed to the previously applied strict bifurcation rules. If Revocation actions are infringement-independent actions they must be initiated at the HIPO going up to the Metropolitan Court and then the Metropolitan Appeal Court as appeal instances. However, if it is the defendant of a patent infringement lawsuit that wishes to invalidate the patent they can choose (as of 1<sup>st</sup> January) between starting the revocation action “traditionally” i.e. before the HIPO – in this case the infringement court will not deal with invalidity questions and instead it will suspend the lawsuit and resume once the revocation action is over. The defendant’s other option that became available as of this year is to file a revocation action as a direct counterclaim in the infringement proceeding. In this case the Metropolitan Court will decide on both infringement and invalidity in the same proceeding.

### **2.4 Which acts constitute direct patent infringement?**

Under Article 19 of the Patent Act:

- making, using, putting on the market or offering for sale a product which is the subject matter of the invention, or stocking or importing the product for such purposes;
- using a process which is the subject matter of the invention or, where such other person knows, or it is obvious from the circumstances, that the process cannot be used without the consent of the patentee, from offering the process for use; or
- making, using, putting on the market, offering for sale or stocking or importing for such purposes a product obtained directly by a process which is the subject matter of the invention

are the acts that constitute a direct infringement of the exclusive right without consent. In practice, courts interpret the forms of exploitation listed in this article of the Patent Act strictly, and no other activity is infringing.

## **2.5 Do the concepts of indirect patent infringement or contributory infringement exist? If so, what are the elements of such forms of infringement?**

The concept of indirect patent infringement does exist in the Patent Act, on the basis of which the patentee shall also be entitled to prevent any person not having his consent from supplying or offering to supply a person, other than a person entitled to exploit the invention, with means (instruments, appliances) relating to an essential element of the invention, for carrying out the invention, when such person knows, or it is obvious from the circumstances, that those means are suitable and intended for carrying out the invention.

It is to be noted that there is hardly any judicial practice with contributory patent infringement so there is no judicial source guiding the interpretation. It is however clear that the supplied thing must relate to an essential element of the invention and the knowledge of the contributory infringer about the intended infringing use is also a determining factor.

## **2.6 What are the key defences to patent infringement?**

We are going to list below several possible defences against patent infringement, but we must note that in most cases it is only the invalidity of the patent that is used in practice, and on a few occasions the research exemption and enjoying a license/authorization was also argued – the rest have not yet occurred in practice.

### *1) Invalidity*

The most typical defence occurring in practically 100% of pharma cases is the invalidity of the patent. As stated above until 1<sup>st</sup> January 2022 the Hungarian system was strictly bifurcated and invalidity arguments could not affect the decision on infringement and were taken into account only to a limited extent even in preliminary injunction cases. As of this year, however, it is possible to file revocation actions as a direct counterclaim in patent infringement lawsuits and the new rules allow more room for invalidity arguments to be taken into account with a greater weight in PI proceedings as well (importantly we mean mere arguments of invalidity, because if there is already a first instance decision ruling on the revocation or relevant limitation of the patent in suit that excludes the issuing of a PI). Regarding PI proceedings, however, despite the new rules the applicable short decision making deadlines have not been adjusted, so it is our team's preliminary view that only in the case of very obvious invalidity arguments, e.g. in the event of clear novelty destroying evidence the court will probably consider this as a circumstance effectively rendering the PI request unjustified. Again, if there is a first instance decision stating invalidity preliminary injunctions will not be issued or even if granted before they cannot be maintained any longer.

## 2) *Non-infringement action*

According to Article 37 of the Patent Act, any person believing that proceedings for patent infringement may be instituted against him or her may file a non-infringement procedure before the HIPO, requesting a decision ruling that the product or process exploited or to be exploited by them does not infringe a particular patent. Importantly, such a non-infringement action can only be filed with the HIPO if there is no infringement action pending against the applicant. If the non-infringement action is filed first the court may (and in practice several times did) suspend the infringement proceeding until the final decision in the non-infringement procedure.

## 3) *Research Exemption/Bolar Exemption*

The research exemption rule in Art. 16 (1) of the Patent Act has also been modified as of 2022 and provides now a pharma sector specific exemption as well, stating that the exclusive right of exploitation shall not extend to acts done for experimental purposes relating to the subject matter of the invention, including experiments, studies and related tasks necessary for obtaining an authorization to place a pharmaceutical product on the market in the EEA or in a third country, in particular manufacturing, use, distribution, offer for sale, storage, importing or exporting – irrespective of the fact if these acts are done by the applicant of the marketing authorization or another person in commercial relationship with the applicant for this purpose. This exemption is however rarely referred to in patent cases. Earlier judicial practice has made it clear that the mere act of applying for or obtaining a marketing authorization for a pharmaceutical product is not an act of patent infringement and not even the direct threat of it.

## 4) *License*

Although never occurred in a pharma case, in other fields there have been cases in the past where the defendant successfully argued that they in fact enjoyed authorization by the patentee with only the amount of royalty being disputed. In such case the court has refused to declare infringement.

## 5) *Compulsory license*

Compulsory licenses are available in Hungary based on four legal titles: (i) non-genuine use of the patent, (ii) dependency of patents, (iii) under Regulation 816/2006/EC and (iv) for public health. The latter has been added in 2021 with respect to the Covid19 pandemic. It should be noted that compulsory licences have a very limited practice in Hungary. As far as we are aware it is only under the pandemic related public health compulsory licensing (Art. 33/B of the Patent Act) that compulsory licenses have been granted by the Hungarian Intellectual Property Office. Consequently, while it would be possible for the defendant to ask for a compulsory



license as a counter claim in an infringement proceeding (at least based on non-genuine use and if the same court as the one dealing with infringement actions is competent for the grant) there is no practice for such defenses.

6) *Private Prior Use and Continued Use in the context of EP patents*

The prior use of the invention is also treated as a limitation of the exclusive rights of the patent holder, if someone in good faith – before the date of priority, in the territory of the country and within the framework of his economic activities – had begun making or using the subject matter of the invention. This defence has not yet been raised before the court in patent litigation, to the best of our knowledge.

Furthermore, a special rule for continued use may be relevant regarding European patents validated in Hungary. Namely the Patent Act allows the possibility for the patentee or applicant to correct the translation of the claims or the specification, or to file a Hungarian translation of the specification even if it was originally not required for validation. This is especially significant if the translation before the correction ensured a narrower scope of protection. After the publication of the correction, the wider scope (i.e., which was originally granted in the language of the given European patent) shall apply. However, the Patent Act grants the right of continued use to any person who had begun to make or use the subject matter of the invention or had made serious preparations for that purpose within the framework of his or her economic activities in good faith, before the date of publication of the correction, in the territory of the country, provided that such exploitation would not have infringed the earlier (narrower) scope of protection determined by the earlier translation. This rule seems to be becoming more and more relevant as EP patent litigations are becoming dominant, rather than litigation based on national patents.

7) *Exhaustion*

Exhaustion is also a possible defence, and Hungary applies regional exhaustion, i.e. the exclusive right of exploitation conferred by patent protection shall not extend to acts concerning a product put on the market in the territory of the European Economic Area by the patentee or with his or her express consent, except where the patentee has legitimate interests in opposing the further marketing of the product (Article 20 Patent Act). The interpretation of this provision has been rarely dealt with in patent cases, so it is not yet clear what shall be accepted as express consent or legitimate interests. The Patent Act contains specific provisions related to the exhaustion of biotechnological patents and plant variety protection.

8) *Farmer's Privilege, Transit Traffic*

Farmer's privilege (the sale or other form of commercialization of plant propagating material to a farmer by the patentee or with his express consent implies

authorization for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm) and transit traffic (subject to reciprocity, patent protection shall have no effect with respect to means of traffic and transport transiting in the territory of the given country or to foreign goods not intended to be put on the market in the given country) are also possible defenses against infringement but we are not aware of any case where they have actually been brought up.

## **2.7 What are the key grounds of patent invalidity?**

In line with the EPC the Patent Act provides for the following key ex tunc revocation grounds:

- the subject matter of the patent does not satisfy the requirements laid down in the Patent Act (lack of novelty, inventive step, industrial applicability, exclusion from patent protection);
- the description does not disclose the invention in a clear and complete manner (insufficiency);
- the subject matter of the patent extends beyond the content of the application as filed at the date of filing or – in the case of division – beyond the content of the divisional application (added matter); or
- it was granted to a person who was not entitled to it.

## **2.8 Can a patentee seek to amend a patent that is in the midst of patent litigation?**

In line with Article 72 of the Patent Act, the amendment of description, claims and drawings can only be initiated until the day on which the decision on the grant of the patent is delivered. Therefore, the patentee itself cannot seek any post-grant proceeding to amend the scope of the issued patent, but during invalidity action initiated by a third-party patentee has the right to limit the scope of the patent. As the patentee-offered limitation takes the form of a statement of defence (i.e. a request to only limit the scope rather than fully invalidating the patent as requested by the applicant) procedural time limits for changing the statement of defence must be observed (in practice such limitation shall be made before the HIPO or before the court of first instance).

## **2.9 How are technical matters considered in patent litigation proceedings?**

In patent infringement proceedings the Metropolitan Court which is competent for hearing cases at first instance proceeds with a panel of 2 technical judges. There is strong technical expertise of the patent currently in pharma cases as the judge rapporteur is a chemist and the head of the senate has both legal and technical (biology)

qualifications. The first instance court is however free to appoint judicial technical experts and also accepts expert opinion provided by the parties. At the second instance court as well as in front of the Curia (Supreme Court) there are only legal judges. In exceptional cases the Appeal Court also appoints technical experts. It is common that the parties are represented by a team of lawyers and patent attorneys, with patent attorneys arguing technical questions. Patent attorneys and lawyers have equal rights of representation before the courts and the HIPO in patent litigation.

If the patent revocation action starts at the HIPO, both the examiner of the case and the head of the senate have technical expertise. It is very common before the HIPO for both parties to file their own expert opinions, but it is rare that the HIPO appoints a forensic expert, it usually decides based on the evidence and its own expertise. At the judicial appellate levels, the same evaluation of technical questions applies as described above as the same judicial panel is competent for both patent infringement and revocation cases (and there is only one patent panel at the court).

**2.10 Is some form of discovery/disclosure and/or court-mandated evidence seizure/protection (e.g. saisie-contrefaçon) available, either before the commencement of or during patent litigation proceedings?**

There is no saisie-like pre-trial discovery proceeding in Hungary. The general rules of civil procedure and the Patent Act both provide for exceptional cases where due to urgency the party can ask the court to obtain/preserve evidence before the commencement of the main lawsuit, but the preconditions are so strict that this has never been applied and in practice parties must obtain evidence in their own capacity. During the lawsuit the defendant may be obliged to present documents or objects if the plaintiff successfully proves that such items are not in their possession, and they have acted duly to present all evidence to the extent available. Again, this is a provision with scarce practice.

**2.11 Is there a system of opposition proceedings? If so, how does this system interact with the patent litigation system?**

No, there is no opposition for patents in Hungary. Following the grant of the patent revocation action is the only type of invalidity action.

**2.12 What are the key procedural steps that must be satisfied before a patent action can be commenced? Are there any limitation periods for commencing an action?**

There is no special limitation period for patent matters; the general five-year limitation applies as for all civil law claims. However, judicial practice confirmed that the right to certain remedies such as the declaration of infringement and cease-and-desist orders is tied to the property-like character of registered intellectual property rights and thus such claims are not subject to limitation.

If the plaintiff is unable to start an action for a reason that is not their fault, the limitation period is stayed. Also, there are certain acts that interrupt the limitation period and cause it to recommence, such as the initiation of a lawsuit if it is concluded on the merits. Importantly, a mere warning letter does not interrupt the limitation period.

There is no obligation for the patentee to send warning letter or attempt settlement before initiating court proceeding.

**2.13 What options are open to a patent holder when seeking to enforce its rights in your jurisdiction? (especially the Border measures)**

There are both civil law and criminal law sanctions to patent infringement. The Patent Act further states that in the event of patent infringement the patentee may, according to the provisions of specific legislation, request action by the customs authorities to prevent alleged infringing goods coming on to the market in line with Regulation 608/2013/EC.

The most extensive practice has developed in civil law claims as the criminal and customs authorities have more difficulty in dealing with the technical character of patents and thus patentees usually opt for the civil route.

**2.14 Which parties have standing to bring a patent infringement action? Under which circumstances will a patent licensee have standing to bring an action?**

Patent holders and under certain circumstances patent applicants as well as licensees registered in the HIPO's patent registry have the right to bring a patent infringement action. The applicant whose invention enjoys provisional protection may institute proceedings for patent infringement; however, the proceeding shall be suspended until the decision to grant the patent has become final. Regarding the patent licensee, provided that the patentee despite the licensee's invitation to take appropriate action fails to take it within thirty (30) days and the licensee is recorded in the Patent Register, may initiate proceedings for patent infringement in his own name. In practice licensees may act as plaintiff alone or as co-plaintiffs next to the patentee.

**2.15 Are interim injunctions available in patent litigation proceedings?**

Yes, a request for a preliminary injunction may be filed either prior to or simultaneously with the main action. Ex parte proceeding may be requested but in practice the court has never granted it and served the complaint on the defendant. Preliminary injunction proceedings are usually conducted without a hearing, and the judges decide based on documentary evidence provided by the parties. The most common type of preliminary injunction is a cease and desist order as well as seizure and withdrawal of the infringing product from commerce. Provision of information is never ordered in a preliminary injunction as it is considered by the court to be contrary to the reversible nature of preliminary injunctions. The preliminary injunction is often subject to the deposition of a

security bond by the plaintiff. The amount is determined by the court based on the submissions and arguments of the parties regarding the expected losses of the defendant during the term of the PI.

**2.16 What final remedies, both monetary and non-monetary, are available for patent infringement? Of these, which are most commonly sought, and which are typically ordered?**

If the court finds the patent to be infringed, it makes a declaratory order as well as it may order a final injunction. Injunctive relief may include a cease and desist injunction as well as seizure, the transfer to a specific person, the recall and the definitive removal from the channels of commerce, or destruction, of the infringing products, as well as of the means and materials exclusively or principally used for infringement.

In addition, the court may order the provision of information by the infringer relating to the distribution chain, ( e.g. number of infringing items sold, distribution partners, as well as well as revenue achieved – i.e. information that are further needed to claim compensation or identify further infringers). The court may also oblige the infringer to provide satisfaction to the patentee, this typically takes the form of the publication of the decision in newspapers or magazines, or on the internet (e.g. on the infringer's website) at the expense of the infringer,

Importantly, the court may only order such remedies that were contained in the statement of claims of the patentee; even in that case, the court may not order it in a form that was not specifically requested by the plaintiff.

As to monetary remedies, the patentee may request the return of any enrichment (typically the profit) gained through the infringement of the patent or may demand compensation for their damages in accordance with the provisions of civil liability. As it will be detailed later again at the question relating to calculations, the main difference between the return of enrichment and damage compensation is that the first one is objective and the second one depends on the infringer's liability. A special rule relating to claiming damages based on a validated EP patent is that if the patentee failed to submit the Hungarian translation of the description of the European patent as required by law, and the infringer's home address or registered office is located in Hungary, the infringer may not be liable for damages up to the point when the full patent translation is provided, unless the patentee is able to verify that the infringer should have understood the original text of the European patent even in the absence of a translation.

According to standing practice if the fact of an infringement of an effective IP right is established, the court grants an injunction automatically without considering the other facts of the case (e.g. the revenue loss of the defendant or the interest of third parties or wilful infringement), i.e. proportionality is not considered in final injunctions.

Monetary remedies, cease-and-desist obligations as well as the recall of the infringing products from the channels of commerce can be considered as the most commonly sought remedies. These remedies are the most typically ordered, however the reasons for monetary remedies shall be duly justified in order to be awarded.

**2.17 On what basis are damages for patent infringement calculated? Is it possible to obtain additional or exemplary damages?**

As already mentioned at remedies, the patentee may seek two types of pecuniary compensation. First, they can claim the return of the infringer's enrichment, which is most commonly calculated as the infringer's profit made on the sales of the infringing products. This is relatively objective and easy to calculate based on documentary evidence of revenue and costs. The other type of pecuniary compensation is the compensation of the damages of the patentee. This can be claimed instead of the profits of the infringer or to the extent it exceeds it. However, this is more difficult for the patentee to prove since the patentee must prove the amount of lost profit (i.e. a hypothetical revenue) and the link of causality with the infringing act, i.e. that the loss was not due to other, independent market reasons. For this significant difference in the difficulty of proving, patentees tend to go for claiming enrichment rather than damages. There is no legal basis for additional or exemplary damages in the Hungarian law.

**2.18 What avenues of appeal are available for a defeated party and on what basis?**

In preliminary injunction proceedings both parties can appeal the first instance decision, within 15 days from receipt however the appeal does not suspend the enforcement of it.

In a patent infringement main action, including the case of a unified infringement-revocation action, similar route and deadlines for appeal exist. I.e. the first instance decision of the Metropolitan Court can be appealed in 15 days. Unlike in PI proceedings the appeal suspends the enforcement of the first instance judgment. The second instance decision of the Metropolitan Appeal Court is final and enforceable however a request for judicial review can be filed in 45 days with the Curia (Supreme Court) regarding questions of law.

In revocation actions commenced in separate proceeding, in front of the Hungarian Intellectual Property Office, the decision of the Office can be appealed in 30 days by either party. Following this the judicial route is the same as in the case of main patent infringement actions, i.e. the first instance decision of the Metropolitan Court can be appealed in 15 days and against the final, second instance decision of the Metropolitan Appeal Court judicial review can be requested from the Curia (Supreme Court).

**2.19 How long do patent infringement proceedings typically last?**

As stated above in the context of timelines, in main actions the first instance infringement proceedings normally take 1 or 2 years depending on the complexity of the

case and the need for hearing of witnesses/experts. If there is opposition or separate revocation action pending in front the HIPO, the infringement lawsuit is suspended for the duration of that. The duration or revocation proceedings initiated before the Hungarian Intellectual Property Office generally takes at least 3 years to go through all instances (Hungarian IPO, first instance court, second instance court) but in more complex pharma cases it is often much longer than that, can be even 5-7 years, by which the decision on infringement is delayed.

## **2.20 What level of cost should a party expect to incur to take a case through to a first instance decision, preliminary injunction proceedings and appeal proceedings?**

The bulk of the costs is the parties' legal representation fee as the official duty fee of patent litigation (if there are no pecuniary claims involved) is not substantial. Thus, the costs depend to a large extent on the complexity of the case and the number of submissions exchanged, experts involved etc. The below figures are very general numbers which may be greatly influenced by the specifics of the case, numbers of patents involved, number of defendants, etc.

The overall cost of a first instance preliminary injunction proceeding may range between USD 17.000-55.000 and the second instance phase between USD 5.500-23.000.

Main infringement actions without a revocation counterclaim may reach USD 28.000-100.000 at first instance and again USD 11.000-34.000 at second instance. If a revocation counterclaim is filed, i.e. validity is also decided in the lawsuit, that may mean additional USD 34.000-100.000 depending on complexity, for two instances. If a revocation action is filed separately, meaning an extra instance at the HIPO that means USD 11.000-90.000 in front of the patent office and the same amount as mentioned before the two court instances, i.e. additional USD 34.000-100.000.

## **3. POLAND (PL)**

### **3.1 What is the forum for the conduct of patent litigation?**

Since the amendments of Polish judicial system in July 2020 there are four specialized IP courts (located in Warsaw, Poznan, Gdansk and Lublin) and two appeal courts (in Warsaw and Poznan) which have exclusive jurisdiction over:

- the protection of copyrights and related rights, industrial property rights and rights in intangible goods,
- preventing and combating unfair competition,

- the protection of personal interests in connection with scientific or inventive activities,
- the protection of personal rights in cases involving the use of goods for the purposes of individualization, advertising or promotion of an entrepreneur, goods or services

What is more, the IP Court in Warsaw has exclusive jurisdiction over matters relating to inventions, utility models, computer programs, topographies of integrated circuits, plant varieties and company trade secrets of technical nature.

Nonetheless, the invalidation matters are still dealt with by the Polish Patent Office.

### **3.2 What is the typical timeline and form of first instance patent litigation proceedings?**

Typically, court proceedings are commenced by the claimant bringing a claim containing all the statements and claims related to the circumstances of the patent infringement. The claimant must submit evidence in support of its claim. The defendant can respond to the statements and lodge evidence in support. Following exchange of the initial written statements, the parties can exceptionally present further arguments in subsequent pleadings, provided the evidence could not have been raised in the claim or in the response to the claim.

Then the court will hear both sides' motions as to the evidence provided and issue a decision as to which of the submitted evidence will be admitted. A witness can be heard orally (exceptionally – in cases where both parties are business entities), or witness evidence can consist of written statements. Expert evidence must be produced either in writing or orally during the hearing. When the evidence has been heard, the court will close the case and issue a verdict.

The decision and its reasoning can be delivered to a party on written request. Each of the parties can lodge an appeal against the first instance judgement. In first instance the proceedings may take 2-3 years, however, in appeal proceedings the case should end within 2 years.

The amendments introduced in November 2019 into the Code of Civil Procedure establish a new economic procedure that apply in matters related to civil relations between entrepreneurs within the scope of their business activities. Patent infringement cases will be covered by several more severe regulations if an entity conducting business is a party of the proceedings. The proceedings as such still will be held in accordance with the IP rules, which govern also the proceedings conducted between the parties, where one of them is an individual person. The new procedure is very onerous in terms of collection of evidence, providing for very specific time limits and numerous constraints that apply when new evidence or facts appear during proceedings.



Additionally, on the grounds of the existing law regulations the possibility of increasing the value of the claim during the proceedings between the entities conducting business, is disputable, even though generally in IP proceedings it is possible. This is a challenge for a professional representative, who will need to collect all necessary evidence/documents at the time the summons is lodged.

What is more, due to the issues caused by the COVID pandemic, the courts take advantage of the opportunity to conduct sessions via internet instead of in the court buildings. We are of the opinion that this legal option is now being treated as a rule rather than an exception. This option has both: advantages and disadvantages, as it fastens the proceedings, on one hand, but gives the parties less chances to take active part, especially when hearing witnesses. The speed of the proceedings and its effectiveness often depends on the judge hearing a particular case.

**3.3 Do the courts/government bodies deal with infringement, invalidity and unenforceability simultaneously or must invalidity and/or unenforceability actions be brought in separate proceedings?**

The IP Court in Warsaw (the only competent body for dealing with patent infringement) does not have jurisdiction to hear patent invalidation proceedings.

Invalidity actions for all IP rights (except trademarks and industrial designs) must be brought in separate proceedings before the Patent Office. An appeal against a Patent Office decision must be lodged with the district administrative courts and any subsequent appeal must be made to the Supreme Administrative Court.

**3.4 Which acts constitute direct patent infringement?**

In accordance with Article 63(2) of the Law of Industrial Property, a direct patent infringement occurs when an infringer's actions are within the scope of exclusive rights of a granted patent.

Moreover, the recently amended Industrial Property Law provides a new definition of a patent infringement: a patent holder can prohibit a third party from using the invention in a profitable or professional manner (manufacturing, using, offering, marketing, storing or warehousing a patented product, exporting or importing such product for these purposes) without his consent. This applies both to patented products and methods for obtaining the said patented products.'

**3.5 Do the concepts of indirect patent infringement or contributory infringement exist? If, so what are the elements of such forms of infringement?**

There is no precise definition of these concepts in Polish IP law. Nonetheless, indirect patent infringement may be defined as enabling a third party an infringement of

exclusive rights. This is, however, very hard to prove in a court. The court may also theoretically rule on the infringement, provided more than one party takes an active role in the infringement practice, given that there is evidence that all parties were aware of the cooperation for a clear purpose of receiving an effect (e.g. a product) that would eventually constitute an unquestioned infringement.

### 3.6 What are the key defences to patent infringement?

Possible defenses depend on each particular case. The most common way of defense includes:

- **challenging the allegations of infringement.** This can include stating that the claimant failed to submit proper evidence in support of the objections raised.
- **earlier use of the subject matter of the patent.** A person who uses an invention with goodwill in Poland before the priority of the patent has been determined can still use it free of charge in their enterprise in the same way they have always used it
- **exhaustion of rights.** It is not an infringement to import into Poland, offer, market and manufacture a product, or use the method of an invention, which has already been marketed in the territory of the European Economic Area by the patentee or with its consent
- **non-infringement of patent features.** This requires showing that the product used by the alleged infringer does not possess features protected by the patent, according to both the literal interpretation of the claims and under the doctrine of equivalents.
- **invalidation of the patent.**
- **expiry of the limitation period.** Claims for patent infringement expire after three years. The limitation period starts running on the day on which the patent holder becomes aware of an infringement and of the person who infringed the patent, separately for each infringement. However, a claim is barred five years after the date on which the patent was infringed

### 3.7 What are the key grounds of patent invalidity?

A patent can be invalidated (in its entirety or in part) if:

- the invention lacks novelty, inventive step or industrial applicability,
- the invention is not described in complete and enough manner so that a person skilled in the art is able to carry it out,
- the patent is granted for an invention not covered by the scope of the application (or the scope of the original application),

- the patent claims do not specify in a clear and concise manner the subject of the protection sought,
- the patent claims are not entirely supported by the description of the invention.

The party bringing invalidation proceedings no longer needs to specify why it has a legal interest in invalidating a matter.

### **3.8 Can a patentee seek to amend a patent that is in the midst of patent litigation?**

Yes, provided that the patent holder applied for limitation either:

- during opposition proceedings, before the response to the opposition is delivered,
- during patent invalidation proceedings, before the hearing.

Before the Polish Patent Office issues its decision, the patent holder can be requested to submit explanations and to introduce specific amendments and supplements to the patent description within a specified period. Failing to do so will result in discontinuation of the proceedings.

It is also possible to limit the scope of protection at any time by lodging a statement on the waiver of protection.

### **3.9 How are technical matters considered in patent litigation proceedings?**

The evidence in patent litigation proceedings are documents, opinions prepared by court's experts, witnesses' testimonies and inspection of premises or apparatus. There is no obligation to file original documents with the court, however, the copies must be confirmed as true and correct by the party's professional representative. Court's experts are people who are skilled in the relevant art (parties may present their own expert's opinions; however, such evidence is considered party's statement). Witnesses are usually examined during hearings but there is a possibility of presenting a written witness' statement.

### **3.10 Is some form of discovery/disclosure and/or court-mandated evidence seizure/protection (e.g. saisie-contrefaçon) available, either before the commencement of or during patent litigation proceedings?**

The patent holder can apply to secure the evidence. Such motion is heard in a closed session (the parties do not participate).

The court, in order to obtain information from the infringer or other persons, can order:

- the infringer to provide the information necessary to seek a preliminary injunction on the origin and distribution networks of goods or services that

infringe a patent (if there has been proven a significant likelihood of infringement of a patent),

- the party other than the infringer to provide the information necessary to seek a preliminary injunction on the origin and distribution networks of goods or services that infringe a patent (if there has been proven a significant likelihood of infringement of a patent) provided that the said party was found: to be in possession of the goods infringing the patent; to make use of the services that infringe a patent; to provide services used in activities that infringe a patent; to be indicated by a person referred to above as being involved in the production, manufacture or distribution of the goods or in the provision of services that infringe the patent

What is more, the infringers or the third party must have carried out the above activities to directly or indirectly gain profit or other economic benefits.

The plaintiff may also request the defendant to reveal the indicated evidence (bank, financial or any other commercial evidence) that is crucial for the plaintiff to prove some substantial facts. The defendant gets an adequate time to serve to the court the response to such motion.

**3.11 Is there a system of opposition proceedings? If so, how does this system interact with the patent litigation system?**

The opposition proceedings take place before the Polish Patent Office, whereas the infringement cases are settled before the relevant Courts. These two systems are separate and independent from each other.

**3.12 What are the key procedural steps that must be satisfied before a patent action can be commenced? Are there any limitation periods for commencing an action?**

It is recommended to attempt resolving the dispute in an amicable manner before filing for a court action - for example by sending a cease and desist letter with 14 days or one-month deadline. Such actions have influence on the overall costs awarded by the court. Such actions do not relate to preliminary measures.

The limitation period (3 years) starts running on the day on which the patent holder becomes aware of an infringement and of the person who infringed the patent, separately for each infringement. However, a claim is barred five years after the date on which the patent was infringed.

Another possibility is referring to an alternative dispute resolution tribunal or another mediator. However, in case of seeking patent action under criminal law, there is no need to begin with any sort of negotiations. If the amicable attempts on settling the matter

fail, the court's proceedings are commenced by the claimant bringing a claim containing all the statements and claims related to the circumstances of the patent infringement. Moreover, evidence supporting the claim must be filed.

**3.13 What options are open to a patent holder when seeking to enforce its rights in your jurisdiction? (especially the Border measures)**

Apart from civil and criminal proceedings, a patent holder can resort to Border measures. To do this, the patent holder or other entitled person must file an AFA (application for action) with the Director of the Chamber of Customs and Tax Administration in Warsaw. Such motion must be supported with evidence of the applicant's exclusive rights.

Goods entering Poland which are suspected by the customs authorities to infringe the patent covered by the AFA will be seized and the decision holder will be relevantly informed. After receiving such information, the decision holder can then commence infringement proceedings (civil and/or criminal enforcement action) and the goods will be seized until completion of the claim. If the proceedings are not commenced, the seized goods will be released. Finally, if the importer's consent is obtained, the Customs Enforcement Regulation provides also for a simplified procedure for the destruction of the seized goods.

**3.14 Which parties have standing to bring a patent infringement action? Under which circumstances will a patent licensee have standing to bring an action?**

Patent holder, co-owner of the patent and an exclusive licensee have standing to bring a patent infringement action. The patent licensee has standing to bring action unless the license agreement provides otherwise. However, the exclusive license agreement must be entered in the Polish Patent Office's register of patents.

**3.15 Are interim injunctions available in patent litigation proceedings?**

Yes, they are available.

Motions for interim injunctions can be filed before or at the same time as infringement proceedings are initiated. If the motion is filed before proceedings are brought, the court must set a time limit within which main proceedings must be commenced. This period cannot be shorter than two weeks and longer than one month. The injunction will expire if proceedings are not brought within this deadline.

The conditions for an interim injunction are the following:

- evidence that there is a high probability that the patent has been infringed,

- justification of claims raised, resulting from the alleged infringement,
- existence of a legal interest in seeking the injunction (for example, a risk that continuance of the infringing practice will have irreversible effects on the claimant's assets, a risk that evidence will be destroyed, or that a delay in obtaining evidence will hinder the claimant's case),
- urgency.

**3.16 What final remedies, both monetary and non-monetary, are available for patent infringement? Of these, which are most commonly sought, and which are typically ordered?**

Monetary remedies include:

- the surrender of profits,
- compensation of damages (in case of wilful patent infringement),
- payment of a sum of money corresponding to a license fee or another suitable remuneration that would be payable for the patent holder's consent to the use of the invention.

Non-monetary remedies include:

- court's order regarding the infringing products, means and materials which are in the possession of the infringer or which are used by the infringer,
- court's order to deliver up and destroy the remaining products, means and materials,
- court's order prohibiting actions that infringe the patent, such as: manufacturing the patented product; using of the product or a method consisting of the subject matter of the invention; marketing or importing a product constituting the subject matter of the invention; offering, marketing or importing products obtained directly from the patented method.

It's difficult to determine which are most commonly sought and which are typically ordered.

**3.17 On what basis are damages for patent infringement calculated? Is it possible to obtain additional or exemplary damages?**

The basis for calculating the damages for patent infringement are lost profits or reasonable royalties. The fair market value of the license can be calculated and then

multiplied by the court depending on the number of items which infringe the subject patent.

**3.18 What avenues of appeal are available for a defeated party and on what basis?**

Any appeal (on objections of fact or law) against the decision of the IP Court must be lodged with the Court of Appeal within 14 days. The appeal must be delivered to the other party, who has 14 days to file a response to the objections raised.

The Court of Appeal can carry out a limited evidence procedure, provided that the applicant can show that they were unable to file motions as to evidence in the first instance proceedings. If the value of the claim is not lower than PLN 50,000 (approx. 12.500 USD), it is possible to lodge an appeal for cassation with the Supreme Court within two months of the Court of Appeal decision.

Court decisions concerning the security for the claim are issued in the form of a court order. It is possible to lodge, within seven days from the date of receipt of the decision, an appeal challenging both the actual circumstances of the case and objections claiming erroneous interpretation or application of legal provisions. The complaint is heard during a closed session without participation of the parties. The complaint is delivered to the other party, who can address the objections raised in it and file a reply to it.

**3.19 How long do patent infringement proceedings typically last?**

Patent infringement proceedings typically last between 2-3 years (before the court of first instance). Parties can strategically delay proceedings by lodging numerous motions regarding the evidence, hearing witnesses and admission of expert opinions, however, since the COVID regime has entered into force we can observe the verdicts being issued much quicker due to conducting fewer oral hearings.

**3.20 What level of cost should a party expect to incur to take a case through to a first instance decision, preliminary injunction proceedings and appeal proceedings?**

The costs of litigation very much depend on the technology (e.g. biotech and electronic patent cases are much more expensive than pharma or mechanical) and the defendant (the size especially and the ability to hire expensive law firms which usually escalate the litigation).

In a standard case the costs of PI and first instance proceedings vary between USD 100.000 and USD 200.000 (proceedings last about 4 years). Costs on the appeal are much lower, usually around USD 30.000-50.000.

The legal fees are practically not recoverable (the statutory cap with expenses is usually around USD 10.000-20.000).

## **4. SLOVAKIA (SK)**

### **4.1 What is the forum for the conduct of patent litigation?**

The District Court Banska Bystrica has sole jurisdiction in industrial property matters at first instance. The Regional Court Banska Bystrica hears appeals.

In unfair competition litigation, either the District Court Banska Bystrica, District Court Bratislava I, or District Court Kosice has jurisdiction depending on the location of the defendant. The respective regional courts hear appeals.

The Supreme Court hears admissible extraordinary appeals.

In matters where the final decisions of the IPO or customs are being challenged through judicial review, the Regional Court Banska Bystrica administrative branch has jurisdiction. The appeal is decided by the Supreme Court.

The Constitutional Court hears constitutional complaints of the parties, or referrals by any of the courts.

A preliminary question may be referred to the CJEU on issues of EU law, by any of the courts.

### **4.2 What is the typical timeline and form of first instance patent litigation proceedings?**

First instance proceedings take one to two years to reach judgment, depending on complexity. The first hearing takes place three to nine months after a claim is filed. Usually two, and sometimes three, hearings are necessary. Each lasts a maximum of one day, usually only a few hours. There is no upper limit on the number of oral hearings.

The first hearing is often organisational and generally results in the court admitting most of the evidence presented in the matter so far and deciding to appoint an expert. At the second hearing the expert is heard, or experts are heard, and the court decides, or adjourns to fully consider the expert's evidence, or to have it reviewed by another expert.

Ordinary rules of procedure apply to industrial property and unfair competition litigation.

In cases involving trade secrets or unfair competition one of the three district courts (District Court Banska Bystrica, District Court Bratislava I, District Court Kosice I) in whose jurisdiction the defendant is located has jurisdiction.

Cases involving patents, SPCs and utility models are heard by an IP specialised judge at the District Court Banska Bystrica, which is the only court of jurisdiction.



All witnesses and experts can be cross-examined, although formally it is the court which asks the questions, in practice this often dispensed with and parties address their questions to the witness or expert directly.

The judgement can either address infringement and damages, or the court can issue an interim judgment on infringement and reserve its judgment on damages until after the appeal on infringement is heard. Damages claims are not common; most cases proceed as pure infringement cases seeking an injunction. Damages are then claimed later through separate proceedings – limitation periods must be kept in mind.

**4.3 Do the courts/government bodies deal with infringement, invalidity and unenforceability simultaneously or must invalidity and/or unenforceability actions be brought in separate proceedings?**

Infringement is ruled on by the courts. The courts can theoretically address the issue of whether a patent, SPC or utility model is valid, but they have so far refused to accept this. In such a case the court would refuse to provide protection to the right or its invalid part; it cannot order its removal from the register.

To fully revoke a right and have it removed from the register, an application must be filed with the IPO.

The court can wait for the IPO decision on validity, but not in all circumstance and never in preliminary injunction proceedings.

The validity proceedings and infringement proceedings proceed at their own pace – the system is bifurcated. If a final infringement decision is made in favour of the right holder and the patent is later revoked, the infringement proceedings can be reopened.

**4.4 Which acts constitute direct patent infringement?**

Direct infringement of a patent or utility model is:

- the manufacture, use, offering, introduction of a patent-protected product onto the market, or its storing or importing for such purposes;
- the use of a patented method/process or offering it; and
- dealing with a product made through a patented process.

There is a presumption of infringement of a process if the defendant's product is identical to that made by the patented method, where it is most likely the protected process was used, and the owner could not access evidence about the process.

#### **4.5 Do the concepts of indirect patent infringement or contributory infringement exist? If so, what are the elements of such forms of infringement?**

Indirect infringement is such conduct where the defendant does not practice the invention but supplies a key element of the invention to another or offers to do so, and the key element is not readily available on the market for a legitimate use. The supplier of the key element cannot benefit from the exemptions to patent/utility model law in particular under the non-commercial use, experimental use exemption.

The same applies to SPCs, although minor differences exist.

Other conduct, such as that aimed at assisting infringement (sometimes called secondary patent infringement or contributory infringement), can be caught under the prohibition of unfair competition as it is not moral to assist other in infringing patents, SPCs or utility models.

#### **4.6 What are the key defences to patent infringement?**

The defendant can raise a number of defences to infringement.

First it can claim that it is a prior user of the right. In such a case the right is not effective against it. The exact scope of such right remains unexplored, e.g., it is unclear whether use must be continual, whether improvements extinguish the right and how it can be assigned, if at all.

Second, patent rights could have been exhausted, as once the right holder places the product onto the market in the EU or EEA, the patent can no longer be enforced in relation to that product. This permits free movement of goods within the EU and EEA.

A compulsory licence can allow an infringer to use the right, but only after such compulsory licence is granted by the IPO.

There is still no local case law on reasonable and non-discriminatory (FRAND) agreements in standard essential patents, and whether injunctions are unavailable if the right holder does not engage in genuine negotiations. Given that existing EU case law has not created hard rules, it is difficult to know whether a right holder will be unable to seek an injunction in such cases, if it does not engage in genuine negotiations.

#### **4.7 What are the key grounds of patent invalidity?**

A registered right can be revoked on application to the IPO. Any person can seek to revoke a registered right. Revocation proceedings can be begun even after a right has expired, however, in that case the applicant must show a valid legal interest in doing so.

The courts cannot revoke a patent. The courts have ruled that they cannot address patent validity issues.

Patent revocation can be based on the argument that:

- the conditions for patentability were never present (lack of novelty or inventiveness over the prior art, lack of industrial applicability, the subject matter is not patentable for lack of technical nature or excluded from patentability – e.g., surgical or medical treatment);
- the invention is not described so fully or clearly to enable the person skilled in the art to practice it;
- the patent contains added matter over the scope of the application; and
- the patent owner is not the inventor or legal successor.

Utility models can be revoked for similar reasons.

#### **4.8 Can a patentee seek to amend a patent that is in the midst of patent litigation?**

Yes. It must be borne in mind, however, that validity and infringement are bifurcated. In practice therefore the plaintiff has no reason to limit its patent in the infringement proceedings, and the defendant would challenge the patent before the IPO. The amendments would then be made in the IPO proceedings. The plaintiff could in some circumstances concede that the patent is partially invalid, and the court would then examine only the limited scope of the patent for infringement.

The plaintiff can also apply to limit its own patent at the IPO, in such a case the IPO does not require that reasons for the limitation are provided.

#### **4.9 How are technical matters considered in patent litigation proceedings?**

The judges are all legally trained and as a result the courts rely on experts or the IPO to resolve technical issues. The court can also ask the IPO to decide whether a product or process falls within the scope of protection of a patent. The parties can present expert reports prepared by Slovak experts, and these have the same weight as those presented by experts appointed by the courts.

The courts maintain a list of appointed experts, and one of the fields of expertise is “Industrial Property”. Such experts are often retired officers of the IPO or patent

attorneys. Such experts are often called on and permitted by the courts to interpret patent or utility model claims, i.e., to determine whether a certain product or process falls within the scope of protection of the patent, SPC or utility model.

**4.10 Is some form of discovery/disclosure and/or court-mandated evidence seizure/protection (e.g. saisie-contrefaçon) available, either before the commencement of or during patent litigation proceedings?**

The right holder can generally request that the court seizes or otherwise acquires evidence which may not be available later, or only with great difficulty. This can be done even before action on merit proceedings begin.

It is possible to request preliminary seizure of a sample of allegedly infringing product and related documents before proceedings begin, or after they begin. The proceedings are the same as in interim injunction proceedings.

Third parties must generally disclose any evidence they have available in court, if the court so requests, unless they would themselves admit infringement. The defendant can refuse to testify. The defendant must produce evidence clearly identified by the court in an order.

Information about scope of infringement can be sought from the defendant, however, not in a preliminary manner, i.e., only once infringement is ruled upon will the court order the defendant to disclose such information.

**4.11 Is there a system of opposition proceedings? If so, how does this system interact with the patent litigation system?**

A granted patent can be revoked at the IPO (or EPO) only. Any person can apply to cancel a patent. This application can be made even after the patent's expiry, if valid legal reasons for this exist. The EPO opposition period closes 9 months after patent grant publication and the patent can then only be cancelled through the IPO. The IPO will stay a local patent cancellation action if EPO opposition is filed or is pending. Where the plaintiff agrees the courts will stay the pending patent infringement proceedings to await the IPO or EPO validity decision.

**4.12 What are the key procedural steps that must be satisfied before a patent action can be commenced? Are there any limitation periods for commencing an action?**

The plaintiff must file a front-loaded claim with the appropriate court, identifying the plaintiff, its right and the defendant and the infringing conduct. However, additional argumentation and evidence can be presented and identified until the end of the 1<sup>st</sup> oral hearing in the matter.

The court can only order an injunction while the infringing conduct is continuing or there is a threat of it repeating.

For damages claims this must be done within 3 years of infringement or becoming aware of the damage for which monetary compensation is claimed.

**4.13 What options are open to a patent holder when seeking to enforce its rights in your jurisdiction? (especially the Border measures)**

Apart from litigation, a right holder can register a customs watch for the external market or for the internal market, or both. The customs will then aim to seize product being imported into the EU market (external market watch) or product already on the Czech/EU market (internal market watch). The right holder can identify shipping routes, importers and locations where products are stored. If customs seize product and the defendant does not voluntarily agree to its destruction the right holder has to initiate legal proceedings.

**4.14 Which parties have standing to bring a patent infringement action? Under which circumstances will a patent licensee have standing to bring an action?**

The patent owner can enforce. A licensee can enforce once the licence is registered by the IPO and if the licence authorises the licensee to enforce, or where the licensee informs the owner of the infringement/threat of infringement and the owner does not begin enforcement within 1 month of such notification.

**4.15 Are interim injunctions available in patent litigation proceedings?**

Interim (preliminary) injunctions (PIs) are available before and during proceedings.

To succeed with a PI request, the PI applicant must prove that

- it has a valid right;
- this right is likely infringed by the defendant's conduct;
- the preliminary order sought is necessary given the general circumstances of the case; and
- the benefit of the PI order to the applicant is not exceeded by the detriment caused to the defendant.

Validity of the right, or rather the lack thereof, cannot be a reason for the court refusing a preliminary injunction.

By law, the court must decide immediately and not later than within 30 days. The defendant is not informed of the PI application, or a decision rejecting/refusing the PI application. In practice almost all cases are decided on an ex parte basis as a result.

The PI applicant has strict and unlimited liability for damage caused by the PI, if the PI fails otherwise than through the applicant's success in the action on merits. The effect of

EU law, the CJEU decision in Bayer C688/17, which appears to prohibit this form of liability, is so far unclear.

A bond can be requested by the court when ordering the PI, but this is rare.

**4.16 What final remedies, both monetary and non-monetary, are available for patent infringement? Of these, which are most commonly sought, and which are typically ordered?**

The right holder can demand that:

- the infringing conduct stops, for example, product is not made, offered, used, disposed of, stored, imported or otherwise dealt with;
- the infringing situation is remedied, i.e., any product it is withdrawn from the market, and is destroyed;
- an apology is made at the expense of the defendant;
- the damage caused is compensated (including lost profit);
- the unjustified enrichment of the infringer is surrendered;
- reasonable compensation for immaterial harm is paid;
- a court judgement is published at expense of defendant;
- information about infringement is provided by the defendant; and
- it receives costs, i.e., actual reasonable expenses incurred in the proceedings and legal expenses at statutory levels.

The court does not have to order the destruction of goods. The court decides on the wording and scope of publication of an apology, based on what it thinks is appropriate.

Permanent injunctions and product recalls are often sought and granted. Destruction is often sought but sometimes not granted. Damages are sought rarely, as is unjustified enrichment. Reasonable compensation for immaterial harm is sometimes sought and generally granted, although the awards are modest.

**4.17 On what basis are damages for patent infringement calculated? Is it possible to obtain additional or exemplary damages?**

The experts, usually from the field of economics, are relied on with the court having a limited role in directing the calculation process. There is little judicial guidance given the low number of decided and reported cases and the variation in approach between experts.

Additional and exemplary damages are not available. However, the licence analogy can be used, where the court can award more than the licence fee, but a multiple of it. It is unclear whether that is to punish the infringer, or to allow the court to award meaningful damages, as the licence fee may not be deemed adequate – since the patent owner never intended to grant a licence.

**4.18 What avenues of appeal are available for a defeated party and on what basis?**

Appeals in industrial property matters proceed under ordinary rules of procedure.

In the case of patent, SPC and utility model appeals, the Regional Court Banská Bystrica has exclusive jurisdiction and sits in three member panels/senates. All judges are legally trained and specialise in intellectual property.

The appeal proceedings allow for a review of both fact and law, however, new evidence cannot be presented as a general rule, unless it can be shown that one of the exceptions, such as the evidence did not exist at the time of first instance judgment, or to undermine the credibility of evidence relied on in the judgment, or to prove errors of procedure.

**4.19 How long do patent infringement proceedings typically last?**

A PI decision must be issued within 30 days of the application being filed. The appeal usually takes 3-6 months to reach a decision. A 1<sup>st</sup> instance action on merit judgment can be expected within 9-24 months. The as-of-right appeal usually reaches judgment within 9-24 months. Extraordinary appeals take 6-24 months to be resolved. Constitutional complaints take 12-24 months but 1-6 months in PI matters.

**4.20 What level of cost should a party expect to incur to take a case through to a first instance decision, preliminary injunction proceedings and appeal proceedings?**

The costs range widely depending on the type of patent and the plaintiff and defendant. Expert report costs, laboratory testing, translations and legal fees form the major expenses. Apart from legal fees these expenses are likely to be recovered in full on success. Legal fee recovery is at c. USD 1.000 per instance per defendant. We would expect the first instance proceedings to cost between USD 50.000 to USD 100.000 and around USD 50.000 on appeal. Complex cases can incur much higher costs, simple cases less.

Court fees are minimal unless damages are claimed. A damage claim also affects the calculation of recoverable legal fees.

Similar costs can be expected for the preparation of the PI application, although the appeal proceedings usually do not exceed USD 30.000. The preparation of the PI

application means that the action on merit submissions then require only a minimum time to prepare.



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