



The Patent Litigation Review

2024

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2024

The first edition of the IAM Patent Litigation Review casts an expert eye on some of the most pressing issues facing those involved in patent litigation in the Americas, the Asia-Pacific, and Europe, the Middle East and Africa.

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IN SUMMARY

Since the fourth amendment to the Patent Law in June 2021, the value of damages awards in patent infringement cases in China has substantially increased. This article first presents statistics illustrating this upwards trend and highlights factors that may influence whether large damages are awarded. It then discusses steps that can be taken to increase the amount of damages before concluding with examples of cases in which large damages awards were granted.

DISCUSSION POINTS

- Increase in the amount of damages
 - Keeping a balanced perspective towards increasing damages
 - Practical measures to increase damages
 - Recent patent cases with high damages
-

REFERENCED IN THIS ARTICLE

- *Spin Master v Guangzhou Lingdong*
- *Jin Minhai v Baijia Hardware Electromechanical*
- *Shenzhen Shenglida v Shenzhen Jingsheng*
- *Babyzen v Hebei New Speed*
- *Ningbo Lubao v Hebei Jitong*

Exactly two years have passed since the fourth amendment of the Patent Law became effective on 1 June 2021. The amendment officially introduced punitive damages into the patent infringement system. Since then, the damages awarded in patent infringement cases have substantially increased.

INCREASE IN THE AMOUNT OF DAMAGES

The Supreme People's Court's annual report on IP protection,^[1] published in April 2023, encouraged the intensification of efforts to increase the damages awarded from infringements. Across the Chinese judicial system, it has been recognised that the intangibility of intellectual property and the concealment of infringement are the factors that give rise to the great uncertainties and insufficiencies when calculating damages; however, given the promotion of an innovation-driven economy in China, the Supreme People's Court believes, despite the challenges in calculating damages, IP rights holders should be awarded sufficient and adequate damages, demonstrating the market-value orientation of IP rights.

The statistics for 2022 from major IP specialised courts and tribunals have shown great progress in damages awards. According to statistics released by the Beijing IP Court, which is a landmark pioneering IP specialised court in China, the average damages awarded in technical cases in Beijing increased from US\$80,000 in 2018 to US\$450,000 in 2022.^[2] Statistics released by the Shanghai IP Court, another pioneering IP court, show that 1,182 cases had damages claims of between US\$140,000 and US\$1.4 million, and 119 cases

had damages claims of over US\$1.4 million in 2022,^[3] which demonstrates the confidence that IP rights holders have in the Shanghai IP Court to award high damages. Among those cases, 22 cases involve the plaintiff requesting punitive damages.^[4] The Shanghai IP Court has demonstrated a practice geared towards higher levels of application of punitive damages and the harsh adjudication of intentional infringements that give rise to serious consequences.

The courts in Jiangsu province, including the Jiangsu High Court, the Suzhou IP Tribunal and the Nanjing IP Tribunal, are also venues that are experienced in handling IP infringement cases and that are favourable to IP rights holders. In 2022, 97 cases were awarded punitive damages at the provincial level.^[5] The amount of damages increased for inventions demonstrating high levels of innovation. In 2022, for IP infringement, 278 cases were awarded damages of US\$100,000 to US\$450,000, 27 cases were awarded damages of US\$450,000 to US\$720,000, and 35 cases were awarded damages of over US\$720,000.^[6] These amounts are higher than those awarded in some other highly developed provinces, such as the Zhejiang courts, which awarded damages of US\$140,000 on average,^[7] and the Guangzhou courts, which awarded damages of US\$70,000 on average.^[8]

There are some courts that, despite being somewhat conservative about damages in previous years, demonstrate significant potential in actively applying punitive damages in high-profile cases. For example, the Tianjin IP Tribunal has awarded treble punitive damages of US\$220,000 in a toy structure invention infringement case launched by the French company Babyzen.^[9] In the Xiamen IP Tribunal, 136 cases have been awarded damages of over US\$140,000 since 2019, and the amounts of damages awarded have been increasing annually.

The Wuhan IP Tribunal is also actively applying punitive damages to increase the punishments for repetitive infringements, destruction or concealment of infringing evidence and refusal to enforce judgments. In a trade secret infringement case, the Wuhan IP Tribunal found that commercial spies had been used to steal core technology from the plaintiff, which constituted serious intentional infringement. Further, the defendant was considered to have impeded evidence production to the court by not submitting accounting books or financial materials, despite the tribunal's request for them to do so. Considering these factors, the tribunal awarded treble punitive damages of US\$1.5 million.

KEEPING A BALANCED PERSPECTIVE TOWARDS INCREASING DAMAGES

Although damages have increased in recent three years, the figures are still not as high as those in the United States; however, attorneys in China still feel encouraged by these increases, given that a report from 10 years ago showed that the average damages awarded for an invention infringement case used to be only around US\$15,000.^[10] Furthermore, whether damages are appropriate should not be assessed simply with the mindset of arriving at an impressively high number; rather, in-depth and detailed factors from various perspectives should be considered without bias when considering the elements involved in awarding damages.

One relevant factor is that in over 60 per cent of IP infringement cases, the defendants are small companies or start-ups.^[11] This means that the accused infringing products do not have large sales figures, and given that those figures form the basis for calculating damages, the damages awarded are low; however, in cases where the sales figures are robustly proved

to be large, high damages awards of over US\$500,000 are not difficult to obtain, especially in patent infringement cases between two big brand companies.

Another relevant factor to consider is the quality of the patent as a basis for litigation. Recent years have seen an improvement in the quality of patent drafting; even just five years ago, quantity was seen as more important than quality, which resulted in several 'junk' patents, especially utility model patents, which are not subject to substantive examination. In some unusual patents, the claims are almost the same as the embodiments in the description, and the whole patent document may only be four to five pages. This makes 'design around' very easy, and the presence of technical concepts in those patents are not welcome surprises but rather uncreative clichés. In this regard, it is difficult to envision how judges can arrive at a determination of high damages when faced with low-quality, uninspired patents, and given that they are often overwhelmed with a workload of around 200 cases annually.^[12]

Consequently, it is not possible for all cases to be awarded high damages. A reasonable approach towards damages should correspond to solid sales evidence. This principle also applies to punitive damages, which should be supported by evidence on subjective intent and the seriousness of the infringement.

PRACTICAL MEASURES TO INCREASE DAMAGES

Increases in damages can be practically achieved under the judicial system by taking advantage of evidence rule enhancement, accurate calculation methods and punitive damages, among other measures.

Evidence rule enhancement is the foremost element since ensuring an accurate calculation method should be based on data supported by evidence (eg, sales figures, prices and the profit rates of infringing products). In the Chinese judicial system, the burden of proof is on the plaintiff when filing an infringement lawsuit; however, in practice, sales figures and profit rates are in the hands of the defendant and cannot be obtained by the plaintiff. Evidence rule enhancement provides a solution whereby if the plaintiff can provide preliminary evidence obtained through public channels about the sales figures and profit rates, the court will order the burden of proof to be shifted to the defendant. If the defendant still refuses to submit related evidence upon request, the evidence collected by the plaintiff, which is highly likely to be unfavourable to the defendant, would be used to calculate the damages. This Chinese style of discovery may act as a leverage to force the defendant to submit evidence about damages. In the absence of sales figures, an economic analytical report would also be accepted by the courts as a basis for awarding high damages.

The judicial trend is that more and more courts are actively using accurate calculation methods to avoid criticism regarding discretion and low damages. When detailed numbers about sales figures and profit rate are obtained, it is possible for courts to calculate damages in a relatively accurate manner by multiplying together the sales figures, the price and the profit rate. For more objective purposes, the patent contribution rate may sometimes be used as a multiplier to adjust the damages in accordance with the extent to which the patent contributed to the profits.

The licensing fee constitutes the next component in calculating damages; however, relatively few patents in China are licensed and performed, so use of licensing fee in calculating damages is rare.

If none of the above can be relied on, and no solid evidence is presented, the last resort is statutory damages, which range from US\$4,500 to US\$715,000 and are completely at the court's discretion; however, if the case entails statutory damages, the figures awarded will not be high because a high damages amount cannot be established without robust justification. This is why use of an accurate calculation method is currently being promoted; if an accurate calculation method is used, the damages awarded can be practically increased.

Incorporation of punitive damages is another approach that can increase damages. As publicised by the Supreme Court in 2021, punitive damages have been awarded in 895 IP cases.^[13] The legal standard for punitive damages is strict, with consideration of the following two elements being required: subjective intent and seriousness of the infringement.

- Regarding subjective intent, a couple of factors may be considered comprehensively, including the type of patent, the validity of the IP rights, the reputation of the infringing products and the relations between the plaintiff, the defendant or the interested party.
- Regarding seriousness, factors such as the manner, the number of occurrences, the duration, the regional coverage, the scale and results of the infringement and the behaviour of the infringer during the lawsuit may be involved.

The multiplication factor for the damages is established based on subjective intent and seriousness and can range between one and five.

RECENT PATENT CASES WITH HIGH DAMAGES

The past two years have seen an increase in representative patent infringement cases with high damages.

Spin Master V Guangzhou Lingdong

In Spin Master v Guangzhou Lingdong,^[14] an invention patent for a transformable toy was claimed to be infringed. The toy can be transformed from a first form to a second form, and a magnetic force acts between the various components of the toy during deformation. The infringing products were sold in large quantities through online platforms such as JD.com, Tmall and Yihaodian. Spin Master, the plaintiff, claimed damages of 15 million yuan, which were fully supported by the Supreme People's Court.

The key point in this case is the proof of the sales profits; the Court actively applied the enhanced evidence rule to obtain the actual sales profits. First, to obtain data regarding the sales figures, the Court ordered an inquiry to collect the sales figures for 2017 to 2018 from 16 stores on JD.com and 22 stores on Tmall. The sales figures from Yihaodian for 2017 to 2018 were obtained based on the number of online post-sale comments for four stores on the Yihaodian platform.

Further, the 2018 and 2019 industry development White Papers released by the China Toy and Juvenile Products Association (recognised by the State Council to officially represent the toy industry in China) were accepted to show online and offline sales ratios in 2017 and 2018.^[15] The Guangzhou Guangzheng Hang Seng Securities Research Institute Co, Ltd, another third-party platform, also released online sales ratios similar to the above data.

The defendant's publicity materials and nationwide offline store numbers were generally consistent with the data above; therefore, according to the collected online sales figures and the proportion of online and offline sales, the overall online and offline sales figures were

estimated to be 131 million yuan. That number is also consistent with the infringer's publicity materials about product sales exceeding 100 million yuan.

Regarding profit rate, the plaintiff chose the lowest profit rate (12.28 per cent) from the profit rates released by six publicly listed companies in the toy industry. This was confirmed by the Court to be authentic and reasonable.

In view of the above, the Court calculated the total profits of infringer for 2017 to 2018 to be 16 million yuan. Since Spin Master's damages claim was 15 million yuan, the Court decided to support this claim in its entirety based on the following determinations:

- the defendant impeded the evidence collection procedure by refusing to provide evidence, such as accounting books or financial materials, of its profits obtained through infringement without justifiable reason, despite the court's clear request for it;
- the defendant's subjective intention was obvious, and the nature of the infringement severe, as it manufactured and sold 20 accused infringing toys on a large scale, and the infringement lasted several years; and
- as the defendant was the manufacturer of all the infringing products and was the source of the infringement, it should bear the full liability for the economic losses caused by the patent infringement.

Jin Minhai V Baijia Hardware Electromechanical

In *Jin Minhai v Baijia Hardware Electromechanical*,^[16] punitive damages were applied and confirmed by the Supreme People's Court on a reverse floor planer patent. The patentee had once sued the defendant, and the two parties had reached a settlement, and the defendant had compensated the patentee 30,000 yuan. Two months later, the patentee found that the defendant was still selling the infringing products, so he filed a new patent infringement lawsuit against the defendant.

The Court held that after the previous lawsuit, the defendant already knew that the allegedly infringing product he sold was infringing, yet he continued to sell the infringing product in the two months after making a commitment to cease infringement and paying compensation in the previous case. The defendant, therefore, had the intention to infringe and committed repeat infringement. As punishment, it was determined that he should pay damages. Considering that the duration of the infringement was relatively short, the profits obtained from the infringement were limited, and the patent involved in the case was soon to expire, the amount of damages stipulated in the settlement agreement in the previous case was used as the basis for calculating damages. Consequently, punitive damages of twice that amount were determined, which amounted to 60,000 yuan.

Shenzhen Shenglida V Shenzhen Jingsheng

Shenzhen Shenglida v Shenzhen Jingsheng^[17] is another punitive damages case decided by the Supreme People's Court. In this case, a multiplication factor of two was applied to award final damages of 6 million yuan. The infringing product was related to a machine that was used to polish mobile phone screens.

Regarding subjective intent, the Court believed that after the patentee sent a warning letter to the defendant, the defendant continued to sell the allegedly infringing product until the litigation, meaning that the defendant had an obvious intent to infringe.

Regarding seriousness, the large sales volume and the wide range of sales of the infringing machine were considered, with the number of infringing machines obtained in Henan, Anhui, Guangdong, Jiangxi and Fujian, among other provinces and cities, totalling 148. Based on an average price of 200,000 yuan, the sales figure was calculated to be in excess of 30 million yuan. The infringement profits were, therefore, considered to be large, resulting in the infringement reaching a serious level.

Babyzen V Hebei New Speed

In *Babyzen v Hebei New Speed*,^[18] the customs seizure approach was incorporated to obtain the sales figures of the infringing product (a foldable baby carriage). There is a relatively long history between the patentee and the infringer: the patentee had sued the infringer in Shanghai in 2017 and won the lawsuit. In 2019, Tianjin Customs seized 1,930 infringing baby carriages. A patent infringement lawsuit was subsequently filed in Tianjin based on those infringing carriages. Infringement was found to be established, and treble punitive damages of 1.5 million yuan were awarded.

The damages were calculated by multiplying the number of seized infringing products by the price and profit rate, as well as a patent contribution rate. The profit rate was partly taken from the 2017 Shanghai judgment, in which the profit rate of similar products in the annual reports of peer companies was found to be 20 per cent. Considering that the profit rate of peer companies in 2018 to 2019 exceeded 40 per cent, the Court decided the profit rate in the 2019 case to be 30 per cent. The patent contribution rate was decided to be at least 30 per cent since the solution protected by the patent substantially contributed to the purpose of the product, and the defendant's infringing product was exactly the same as that described in the patent.

Regarding subjective intent, the Court held that in the Shanghai case, the defendant should have known that the baby carriages as manufactured and sold were infringing products. Since the defendant did not cease infringement and continued to manufacture and sell the infringing products, intentional infringement was deemed to be obvious.

Regarding seriousness, the Court found that (1) the scale of the manufacture and sale of the infringing products was large, (2) the single transaction volume was nearly 2,000 units, and (3) the sales coverage was wide, with online and offline sales channels, and the market being all over China and abroad.

Ningbo Lubao V Hebei Jitong

In a standard-essential patent (SEP) infringement case between Ningbo Lubao and Hebei Jitong,^[19] the patentee's licensing rate of 20 per cent was accepted because multiple licensing contracts were provided by the plaintiff, and the court believed that those licensing contracts were robust in their objectivity. The court applied double punitive damages because despite knowing the patent was a SEP, the defendant did not actively seek to obtain a patent licence, instead directly implementing the product covered by the SEP in the Pingzan Expressway project without permission and refusing to pay the licensing fee. This was deemed to be an obvious subjective fault.

SUMMARY

Damages are always a hot topic in patent infringement litigation. With regard to attorneys, increasing the amount obtained in damages is not wishful thinking; rather, it is a goal

grounded in reality and consistent with social, economic and technical developments. Increases in damages can reasonably be supported by the judicial system. A bright future of strong IP protection can certainly be expected in China in the coming years.

Endnotes



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Specialist Chapter: How to Build an Effective Assertion-Based SEP Licensing Programme in China

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IN SUMMARY

For a licensing programme, the assertion of patent rights means much more than seeking a final remedy; the licensing programme can be concluded in a much more effective manner based on a premeditated assertion-based licensing strategy. This article discusses how to build an effective assertion-based SEP licensing programme in China to secure a successful licensing deal.

DISCUSSION POINTS

- Advantages of using an assertion in a SEP licensing programme
 - When to initiate a SEP assertion
 - Popular courts for filing SEP cases in China
 - Types of patents that can be asserted
 - Participants in the assertion
-

REFERENCED IN THIS ARTICLE

- *Unwired Planet v Huawei*
- *VoiceAge v HMD*
- *OPPO v Sharp*
- *Huawei v Samsung*
- *OPPO v Nokia*
- *Huawei v Conversant*
- *Qualcomm v Apple*
- CNIPA 2022 Annual Report

INTRODUCTION

The patent licensing negotiation practice has been reshaped in past decades, especially for standard-essential patents (SEPs). In the past, both sides of a negotiation were equal as bilateral licensing was primarily undertaken by companies that not only own patent portfolios but also implement the technologies; however, with the enormous success of the standardisation of cellular technologies, such as 4G and 5G by the Third Generation Partnership Project, the licensing ecosystem has become much more complex and has witnessed the emergence of diverse players, including smartphone manufacturers, chipset vendors, infrastructure vendors and innovation institutions.

With the emergence of non-practising entities of which the business activity is focused on licensing patents to obtain the best possible return on investment, there is an imbalance in the positions of licensing parties: non-practising entities actively seek royalty payments without obtaining cross-licences from implementers, while implementers are disadvantageously involved in negotiations for cross-licences that non-practising entities do not need. Licensees have less motivation to obtain licences, as the initial offer from the

licensor is often regarded by the licensee as intolerably high. As a result, patent owners tend to initiate legal actions after the bilateral negotiations collapse.

ASSERTIONS

In the context of active licensing, an assertion can be regarded as a pragmatic tool rather than a last resort. First, an assertion helps to keep both parties engaged. Bilateral licensing negotiations between patent holders and implementers have become drawn out because of neglect, delay tactics and other acts of gamesmanship by the implementers. Assertions act as warning to implementers. An implementer will take the licensing offer more seriously, and will therefore respond promptly, if the risk of litigation is no longer a remote possibility. It will also be motivated to seek bilateral negotiation to resolve the dispute if there is an imminent risk of suffering losses in the market should an injunction be granted during the litigation.

Second, an assertion is an acknowledged approach to verifying the value of a patent portfolio. When obtaining a licence, whether the implementer has implemented the patent and how valuable the patent portfolio are often the key debates. The negotiations often get stuck at the technical discussions before the business dialogue is even started. As the infringement and the validity of the patents are discussed and determined during the court trials, the interactions during the court trials and the judge's decisions can be referred to as solid verifications of the value of the patent portfolio. Obtaining a clearer understanding of the value of the patent portfolio makes it relatively easier for the parties to manage their expectations and make reasonable decisions, therefore leading to a better chance of a settlement between the patent holder and the implementer.

In addition to adjudicating disputes, the judicial system can serve as a positive factor in encouraging parties to agree on a licence. For example, in the *Unwired Planet v Huawei* case, the English court held that it would be improper 'to grant a final injunction unless the court is satisfied that the patent is valid and infringed, and it has determined a FRAND rate'.^[1] This implies that the court intended to take a neutral position with regard to a FRAND licence: the court's FRAND injunction encourages the two parties to agree on the FRAND terms it ushered in and enter into a FRAND licence, rather than resolving the dispute in whatever effective manner other jurisdictions may employ (eg, imposing a large risk of injunctive action against the implementer before a final judgment is made regarding the validity and infringement of the SEP); in other words, the judicial system can encourage the two parties to reach a FRAND deal by using the legal toolkits available to them rather than simply settling the dispute in a manner that favours one party over the other.

Chinese courts also prefer seeing the parties settle the dispute during the litigation. The judge is usually willing to arrange mediation between the plaintiff and the defendant to settle the case. The judge may also consider the parties' actions during the mediation when deciding on the FRAND issue. For example, in the case of *Huawei v Samsung*, the Shenzhen Intermediate Court twice held a meeting for mediation and required the parties to provide counteroffers. Whereas Huawei sent its offer, Samsung did not, and the mediation eventually failed. This was a key factor for the judge in deciding that Samsung was not in compliance with the FRAND obligation and that it delayed the negotiation, given its behaviour before and during the litigation.^[2] In light of the precedents in several jurisdictions, the courtroom can be considered an effective tool for encouraging SEP holders and implementers to agree on settlements.

Finally, even if the parties cannot settle during the litigation process, the court decision is instructive and guides future licensing negotiation behaviours. The guidelines made by the Court of Justice of the European Union (CJEU) in *Huawei v ZTE*^[3] are one example: in this case, the CJEU attempted to establish rules and procedures for granting injunctive relief in light of the willingness shown by the parties in negotiations.

Given the benefits of assertion discussed above, for a licensing programme, the assertion of patent rights means much more than seeking a final remedy; the licensing programme can be concluded more effectively based on a premeditated, assertion-based licensing strategy. Below, we discuss some takeaways for building an effective assertion-based SEP licensing programme in China to secure an effective and successful licensing deal.

WHEN TO MAKE AN ASSERTION

A SEP holder can assert its patent rights either before or after the parties engage in a substantial negotiation.

Before The Parties Engage In A Substantial Negotiation

Under the Patent Law, the patent holder is entitled to enforce its patent rights when an infringement is identified.^[4] Theoretically, the patent holder can file a lawsuit at any time once there is a valid patent and an infringement is discovered. The patent holder may seek damages or injunctive relief.

However, for SEP-based assertions, if the litigation is filed before a substantial negotiation, and the plaintiff requests an injunction, the injunction is unlikely to be granted as the element of willingness under FRAND obligations, which is determined by the behaviours of the parties during the negotiation, is a critical factor that the Chinese courts investigate and consider.^[5]

A tricky situation arises if the SEP holder filed a lawsuit before a substantial negotiation but claimed injunctive relief after the negotiation. In the *VoiceAge v HMD* case,^[6] the SEP holder, VoiceAge, filed a lawsuit against HMD after twice sending the latter a licensing offer and receiving no response. VoiceAge requested only damages upon the filing of the lawsuit. It later requested an injunction when negotiations failed during the litigation process. The German court held that HMD was unwilling to accept the licence after VoiceAge sued before it filed for injunctive relief and that it purposely delayed the negotiation. The court, therefore, issued an injunction against HMD because VoiceAge had fully fulfilled its FRAND obligations while HMD did not meet FRAND requirements. This case shows that the German court believes that the determination of FRAND behaviour is directly related to the parties' actions prior to and during litigation.

Whether the Chinese courts agree with the German courts remains to be seen. Nevertheless, the stance that violation of the FRAND obligation is considered as a factor for issuing an injunction is consistent with the judicial interpretation issued by the Supreme People's Court^[7] and the case trial regulations issued by the Beijing and Guangdong higher people's courts.^[8] When the rights holder files a request to stop the implementation of SEP (ie, a request for an injunction), judges will consider the subjective fault of the behaviour of both parties in respect of the FRAND obligation and relevant commercial practices.

After The Parties Engage In A Substantial Negotiation

A typical licensing negotiation process starts with a response from the implementer after the patent holder has sent the notification letter. The parties then discuss and execute a

non-disclosure agreement (NDA), followed by technical and commercial discussions. Ideally, the parties will engage constructively and at a regular cadence.

In practice, the negotiations are often carried out alongside various delay tactics by the implementer. For example, implementers may ignore notifications and other communications for months or years,^[9] refuse or delay signing an NDA,^[10] direct the SEP holders to suppliers for licences^[11] and provide unreasonable and unacceptable counteroffers to the SEP holders,^[12] among other things. These are typical holdout strategies used by implementers.

Although licensing negotiation is a *pas de deux*, considering the impact of the financial situations of SEP holders, patent holders cannot dance indefinitely with implementers, especially knowing that the implementers are deliberately dallying. Under those circumstances, it can be concluded that those implementers are unwilling licensees, and the patent holder can consider initiating lawsuits after a substantial negotiation if the implementers keep stalling.

POPULAR COURTS FOR FILING SEP CASES IN CHINA

Chinese courts have become among the most popular global SEP dispute resolution battlefields. A handful of people's courts in China have seasoned IP judges with experience in hearing SEP cases.

Before filing a case with these courts, the SEP holder should find out the extent of the backlog at the courts, which will significantly influence the timeline and cost of the legal proceedings and impact the effectiveness of filing the lawsuit, to increase its leverage in concluding a licence deal.

Excluding several popular Chinese courts that are experienced in handling SEP cases, such as the Shenzhen Intermediate People's Court,^[13] the Wuhan Intermediate People's Court,^[14] the Chongqing Intermediate People's Court^[15] and the Nanjing Intermediate People's Court,^[16] as well as the three IP specialised courts, there are three courts in Fujian province that have received attention for being pro-patentee: the Fuzhou Intermediate People's Court, the Xiamen Intermediate People's Court and the Quanzhou Intermediate People's Court.

In the prominent patent infringement case of Qualcomm v Apple,^[17] the Fuzhou court issued a preliminary injunction order against Apple. A German IP licensing company secured a deal with Apple by availing itself of the Fuzhou Intermediate People's Court.^[18] In addition, there are a dozen ongoing audio codec SEP cases at the Xiamen court in which complicated technological, standard and legal issues are involved.^[19] These three courts in Fujian province are, therefore, considered equivalent to the US District Court for the Eastern District of Texas, and they are becoming more and more popular for both foreign and domestic patent owners as venues to initiate lawsuits based on both non-SEPs and SEPs.

TYPES OF PATENTS THAT CAN BE ASSERTED

According to the China National Intellectual Property Administrations 2022 Annual Report, about 28 per cent of invention patents do not survive validity challenges,^[20] therefore, making assertions based on more than one patent is advisable. To balance the effectiveness and cost of carrying out lawsuits, it is recommended to assert three to six patents.^[21]

Making assertions based on a non-SEP would be an advantage if the implementer's product also falls under the scope of the patent. This is a helpful strategy considering the fact that

obtaining an injunction order for a SEP case is relatively tricky because complicated FRAND issues would be involved and a full spectrum of products that meet the standard would be banned. In contrast, when asserting a non-SEP, an automatic injunction can be granted as soon as the infringement is established, which is relatively easy to decide compared with asserting a SEP.

For example, in the global dispute between Huawei and Samsung, the parties sued each other based on both SEPs and non-SEPs. In a non-SEP infringement case before the Quanzhou Intermediate People's Court, the court found in favour of Huawei, with Huawei obtaining an injunction order and damages of 80 million yuan.^[22] Huawei took advantage of this for its licence negotiation with Samsung and obtained a favourable outcome.

ENGAGING EXPERIENCED FIRMS AND EXPERTS

SEP disputes are far more complicated than non-SEP disputes and usually require the involvement of multiple third parties, including technical appraisal institutions, experts on the standards, economists and market intelligence providers.

An experienced law firm in both licensing and litigation will oversee the involved parties and help steer the licensing procedure forwards in parallel with the litigation. It is important that the communications between the firms engaged for invalidation and infringement are coordinated. Since China has a bifurcated system, with patent validity decided separately from patent infringement, parties should be careful to ensure that any amendments to the claims in the invalidation procedure do not affect the infringement proceedings.

Further, if the budget allows, it is highly recommended to engage technical appraisal institutions, experts on the standards and economists:

- Technical appraisal institutions can provide a report to prove the patent's correspondence to the specific standard against which it is being reviewed, which helps the judge to understand the technical solutions and industrial practice.
- Experts on the standards can explain the complex technologies and the development of the relevant standards.
- Economists can serve as a strong backup for elaborating on the extent and amount of the damages claimed in the assertion.

The involvement of experts on the standards and economists not only serves as solid support that can facilitate the judge's decision-making but also allows a more explicit picture to be formed with regard to establishment of the infringement, the FRAND extent and the damages. This, in turn, helps parties to manage their expectations of the settlements through litigation or negotiation. Taking advantage of the multiple resources available in the assertion is, therefore, a critical link in achieving the final goal of reaching a licensing agreement.

CONCLUSION

Efficiency matters in an active SEP licensing campaign. Including a well-planned assertion strategy as part of the integrated licensing strategy is recommended to secure an effective and successful licensing agreement. A SEP holder can initiate an assertion after or before a substantial negotiation, but the claims in the assertion should comply with the purpose of the assertion.

Although there are several conventional Chinese courts that are popular in SEP dispute resolutions in China, the courts in Fujian province are also exceptional dynamic courts that are worth considering. It is recommended to assert three to six patents to balance costs and efficiency, with the assertion of a non-SEP being an advantage.

Finally, engaging an experienced law firm that possesses an exceptional understanding and intuition of licensing and that is capable of coordinating between multiple parties, such as technical appraisal institutions, experts on the standards and economists, is important in ensuring the success of a licensing campaign.

Endnotes



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Specialist Chapter: Much-Needed Clarity on Software Patentability Boosts Protection and Enforcement in India

Manisha Singh and Swati Mittal

LexOrbis

Summary

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IN SUMMARY

The IP protection and enforcement standards of software lack universally accepted provisions and practices. Software or computer programs are per se not patentable in India as they are excluded under section 3(k) of the Patent Act; however, Indian courts have proactively comprehended the need to change how software patents are examined. This has led to clarity on the patentability of those inventions and changes in the examination guidelines. With measures in place for the successful protection of software patents, successful enforcement is now expected to be at pace with other countries.

DISCUSSION POINTS

- Patentability of software or computer-related inventions in India
 - Evolution of the patentability criteria for software
 - Judicial approach for the protection and enforcement of software patents
 - Key points to consider for successful enforcement
-

REFERENCED IN THIS ARTICLE

- 2013, 2016 and 2017 CRI Guidelines
- Indian Patent Act 1970
- Delhi High Court
- Intellectual Property Appellate Board

INTRODUCTION

Every few years, the global digital landscape undergoes a makeover, and the industry is overhauled with improved hardware and software upgrades. With the advent of the metaverse and the rise in artificial intelligence (AI), machine learning, internet of things (IoT), blockchain and cognitive computing blockchain technology, the importance of protection and enforcement of software and computer-related inventions (CRI) has grown significantly; however, universally accepted provisions and practices to establish the IP protection and enforcement standard in relation to software is still lacking.

Software programs are protected as copyright subject matter and governed under the Berne Convention 1971 and article 10 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which protect source code and object code as literary work. In India, software programs are protected under the Indian Copyright Act 1957. While copyright protects the code, it does not protect any idea or functionality of the software.

Patent law provides wider protection to software, particularly its technical process or functional aspects. Article 27 of the TRIPS Agreement does not differentiate between different fields of technology and lays down standard patentability requirements, including novelty, inventive step and industrial capability; however, there are different eligibility criteria for software or CRI as subject matters of patents under various jurisdictions.

STATUTORY PROTECTION OF SOFTWARE IN INDIA

Under section 2(1)(j) of the Indian Patents Act 1970 (the Patent Act), “invention” means a new product or process involving an inventive step and capable of industrial application; therefore, products or processes, including computer-related inventions, that meet these requirements are considered patentable. Software or computer programs, however, are per se not patentable in India as they are excluded under section 3(k) of the Patent Act, which specifies that ‘a mathematical or business method or a computer programme per se or algorithms’ are not innovations and, therefore, not patentable.

The use of the term ‘per se’ was elucidated in the December 2001 Joint Committee Report, when the Patent (Amendment) Act 2002 was introduced. The Report stated ‘[t]his change has been proposed because sometimes the computer programme may include certain other things, ancillary thereto or developed thereon’. The legislative intent was not to deny patents in relation to all software or CRI but to only computer programs as such.

Inventive step is an important determinant for software or CRI patentability because even though inventions may be novel and have industrial applicability, the inventive step or non-obviousness criteria act as a barrier to their qualification. The Patent (Amendment) Act 2005 changed section 2(1)(ja), resulting in a new definition of ‘inventive step’. Under the new definition, any non-obvious invention is considered to pass an inventive step test if it has any technical advancement over the previous art or has economic significance, or both; therefore, the scope of CRI or software inventions is considered to have an inventive step if there is a technical effect or economic significance in addition to non-obviousness.

To clarify this position, several versions of the ‘Guidelines for Examination of Computer Related Inventions’ (the CRI Guidelines) have been published, such as those released in 2013, 2016 and 2017. The Guidelines defined major terms and focused on technical effect and technical advancement.

The 2016 CRI Guidelines allow a patent to be granted for software as long as it is ‘claimed in conjunction with a novel hardware’. They also provide the following test to examine a software patent application: the examiner interprets the claim and its true contribution. If:

- the contribution of the claim is towards a mathematical method, business method or algorithm, the claim is denied; and
- the claim is directed towards a computer program, it must be examined considering the interplay between software and novel hardware and assessed against other patentability criteria.

The 2016 CRI Guidelines also provide a non-exhaustive list of examples to assess technical effects, including high speed, efficient data search, improved reception and reduced hard-disk access time.

The 2017 CRI Guidelines set aside all these tests, providing that the examiner must judge a claim on the substance and not the form of the invention, along with examples of patentable and non-patentable claims; however, although the Guidelines do not provide tests or determinants for CRI patentability, it must be established that the claim involves a technical advancement or a significant economic advantage, or both, compared to the prior art. Further, a claim must be taken as a whole, clearing it from exclusions under the Patent Act and CRI guidelines and rendering the invention patentable. Accordingly, if the software is related to an invention or constitutes its component, it can be patentable subject

to its outcome. To overcome the objection under section 3(k) of the Patent Act, it must be demonstrated that the hardware, along with software or a computer program, is an integral aspect of the invention.

The 2017 CRI guidelines, the Manual of Patent Office Practice and Procedure and recent judicial precedents provide clear guidelines on the examination of CRIs; however, in practice, there is a lack of uniformity between controllers and patent offices. There is also inconsistency in the types of claims allowed in CRI-based patent applications: there are contradictory cases where controllers have preferred system claims over method claims, and vice versa. In some cases, the applicants have been asked to delete the system-dependent claims and amend the system-independent claim to depend on the method-independent claim.

Further, for CRI-based patent applications, the persuasive value of claims allowed in other major jurisdictions, except Europe, is also relatively low.

Despite the CRI Guidelines, the controllers at the Indian Patent Office (IPO) still sometimes expect there to be novel hardware to allow system claims. In the case of *Microsoft Technology Licensing v Assistant Controller of Patents and Designs*,^[1] the Delhi High Court addressed the objection received from the IPO on lack of novel hardware in the invention, clarifying it to be a misinterpretation of section 3(k) and emphasising the importance of the term 'per se' that follows 'computer program' in article 3(k).

Another objection often raised on non-patentability under section 3(m) records that the claims are a mere method of business or scheme and do not disclose apparatus or structural components carrying out the steps enlisted in the invention. This is more common when the patent claims lack mention of structural limitations in method claims.

Finally, the sufficiency and enablement requirements of an invention are universally standardised and can be a ground for objection if the patent application does not disclose sufficiently 'what the invention is' and 'how to perform it'. For instance, an invention will be considered sufficient if it relates to a software–hardware combination, and drawings are used to show the integration of hardware with software, pointing out every feature. If an invention relates to a method, the sequence of steps can be represented in a flowchart that shows the interoperability of different components of software and hardware.

While drafting the patent specification, the functionality must be clearly described through the best embodiment and alternatives, if any. If these crucial determinants are handled, the software and the CRI are considered patentable.

Considering that the IPO has been proactive in improving the overall IP framework in the past few years, it would be reasonable to expect the IPO to consider recent judgments to project predictability and a uniform approach in the examination process.

JUDICIAL APPROACH FOR PROTECTING AND ENFORCING SOFTWARE PATENTS

Indian courts have proactively comprehended the need for change to how software patents are examined in India, leading to clarity on the patentability of those inventions. There have been numerous instances in which patent applications have been initially refused owing to non-patentability and, after appeal, they were remanded back, and the IPO granted the patent after being satisfied that the invention had a technical effect or contribution and was not merely an algorithm. In most cases, when the applicants emphasise how the invention

provides a technical solution to a technical problem and has a technical advancement over the prior art, the IPO has granted the invention.

In *Ferid Allani v Union of India and Ors*,^[2] the Delhi High Court observed that most modern technologies, such as automobiles, washing machines and refrigerators, depend on computer programs in some manner, and if a computer program is rejected only because section 3(k) prohibits patentability, current inventions will lose their protection. It observed that the patentability bar only applies to 'computer programs per se' and not all inventions based on computer programs. It further held that if computer programs are considered non-patentable, it would be a regressive perspective, and inventions based on AI, blockchain and other digital products would also not be patentable. The Court held that 'an invention is patentable if it displays a technological effect or contribution, even if it is based on a computer programme'.

In *Enercon India v Aloys Wobben*,^[3] a similar order was passed by the erstwhile Intellectual Property Appellate Board (IPAB) in line with the landmark *VICOM* decision^[4] by the Board of Appeal of the European Patent Office. The tribunal held that even if a patent claim merely contains some process steps to carry out a technical process or achieve a technical effect, it would not be amenable to objection under section 3(k) of the Patent Act.

In *Accenture v Assistant Controller of Patents*,^[5] the invention claimed was a data document design system and design tools that addressed technical challenges faced by database systems. It was initially objected to on the grounds that the technical effect of data mapping cannot be recognised as a novel feature of an invention comprising a program without any special hardware adoption or modification. When the applicant appealed to the IPAB, the matter was remanded for reconsideration. The IPO then granted the patent, considering it not to be a stand-alone computer program; therefore, it became a rule of law that software patents do not require a special adaptation of existing hardware or any modification of such hardware.

In *Yahoo! v Controller of Patents and Rediff.com*,^[6] it was held that where technical advances are only a manifestation of a core business method, the advances will not lead to a patent being granted. Consequently, software tools that are purely business methods will not be granted patents.

Nevertheless, India has witnessed an increase in software patents in the past five to six years, with Google obtaining a patent for 'phrase identification in an information retrieval system' and Apple for a 'method for browsing data items with respect to a display screen associated with a computing device and an electronic device'. The Delhi High Court in *Telefonaktiebolaget LM Ericsson v Lava International*,^[7] clarified that if a combination of hardware and software satisfies the patentability requirements and achieves a further technical effect while solving a technical problem, the invention is patentable. It held that section 3(k) of the Patent Act would be applicable when a patent application for an abstract formula, such as an algorithm that is theoretical, is made. Mere mention of an algorithm in a patent specification cannot be a ground to infer that the invention is only an algorithm.

In accordance with the 2017 CRI Guidelines, a patent application for software as a method must be judged on substance (ie, on the underlying substance of the invention, not the form in which it is claimed); therefore, greater importance must be placed on the novelty, industrial use and inventive step used in creating the software rather than on it being a computer program or algorithm. Similarly, in *Telefonaktiebolaget LM Ericsson v Intex Technologies*,^[8]

it was held that an invention showcasing a technical effect or giving a technical contribution is not merely a computer program per se and, therefore, is patentable.

In *Microsoft Technology Licensing v Assistant Controller of Patents and Designs*,^[9] the Delhi High Court held that if a computer program was used in conjunction with hardware or resulted in a technical effect or solved a technical problem, it may be eligible for patent protection. It observed that the approach of the controller was misguided as the reason for refusal – that ‘claims were implemented on a computer and were computer-executable instructions/algorithms performed on a general-purpose computing device’ – was not correct.

Finally, in *Open TV v Controller of Patents and Designs and Anr*,^[10] the Delhi High Court dismissed an appeal filed by a patent applicant whose application was rejected under section 3(k) of the Patent Act. It observed that the invention falls under the category of business method as it is purely a method of giving media as a gift, which is nothing but a method of selling media for gift purposes; however, the Court also noted that the Report 161 of the ‘Review of the Intellectual Property Rights Regime in India’^[11] provides that the provisions of both the Copyright Act and the Patents Act need to be reviewed to protect AI-generated works and AI-related inventions. The Report further recommended that the IPO should adopt a similar approach as that in the United States and the European Union, where the mathematical methods or algorithms linked to a tangible technical device, or a practical application are held patentable. The Delhi High Court expressed its concerns that:

a large number of inventions in emerging technologies including by SMEs, start-ups and educational institutions could be in the field of business methods or application of computing and digital technologies. There is a need to have a re-look at the exclusions in Section 3(k) of the Patents Act, 1970, in view of the growing innovations in this space. As the Parliamentary Committee Report . . . recommends, the need to consider the march of technology in the digital space, is an urgent one, so that patent law is not outpaced and patenting itself does not become irrelevant in the years to come.-

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KEY CONSIDERATIONS FOR SUCCESSFUL ENFORCEMENT

While appeals can be filed under section 117A of the Patent Act before the Delhi, Bombay, Calcutta and Madras high courts, infringement suits can also be filed before commercial district courts. Recently, the Delhi and Madras high courts have inaugurated IP divisions to hear IP matters, and the Calcutta and Bombay high courts are also likely to set up their own IP divisions.

The purpose of patents becomes moot if they are not commercialised and enforced as they give exclusive rights to prevent third parties from making, using, offering for sale, selling or importing the patented product or process without consent. Software is easily reproducible at low costs and in unlimited quantities; therefore, it poses a risk to the patent holders and makes enforcement crucial as an early intervention, especially since the life cycle of software is shorter and the creation of software and CRIs incurs high research and development costs and time.

Owing to an increase in filings and grants of software patents, it is likely that the enforcement of software patents will increase. For successful enforcement, the preparation starts long before filing a patent – with a patentability search to assess the prior art. The strength

of a patent comes from the claims drafted, which in turn depend on the prior art search conducted to clearly distinguish the subject invention from the prior art. It is because although patents undergo substantive examination, the validity of a patent can always be challenged through opposition or invalidity proceedings. Invalidation is the key defence taken by infringers, which makes the prior art search pivotal to ensure the strength of the patent.

Essential considerations for patent enforcement include:

- a prior cease and desist notice and claim chart analysis;
- the time taken by the court to give decision;
- the likelihood of obtaining a preliminary injunction;
- the court's technical experience in software inventions; and
- the possibility of invalidity counteraction and the likelihood of the court to stay the proceedings to confirm the validity of the asserted patent.

As a first step, a patent can be successfully enforced at the pre-litigation stage by sending a cease and desist notice to the infringer. If the infringer decides to settle, the litigation costs and time can be saved; a final court decision may take over four to five years, and if an injunction is not granted within the first few weeks, the matter may stretch further and not reap the desired results. Even at the commercial courts, where cases are heard promptly under a case management schedule, the matter may take more than the anticipated time owing to the backlog of cases.

Successful obtention of a preliminary injunction requires clear claim mapping with feature analysis and establishment that there is a prima facie case. Further, there is always a risk of counteraction of invalidity, which may halt the proceedings as courts are likely to decide on patent validity. Presently, Indian courts have limited software patent infringement jurisprudence, which is expected to change with the establishment of specialised IP courts.

CONCLUSION

With India emerging as one of the world's largest economies and moving towards fulfilling its goals of becoming a US\$1 trillion digital economy by 2026, patent protection and enforcement of software and CRIs have gained tremendous importance. India envisions becoming a significant trusted player in the global value chains for digital products, devices, platforms and solutions. The progress is evident as India has become one of the fastest growing digital economies in the world, with the adaptation of novel software technologies, such as the Unified Payments Interface (UPI) for payments from any digital wallet or bank through a single UPI ID, CoWIN for covid-19 vaccination bookings and digit certificates, DigiYatra for entry to airports by face authentication and e-passports for paperless travel.

In conclusion, the trend of patent filings and grants in AI, software and CRIs in the fields of healthcare, image processing, transportation, edtech, IoT automation and fintech shows that the golden age for innovators in this space has arrived. With successful protection, successful enforcement is the next stop as courts have now embraced a pro-patentee and IP-friendly approach.

Endnotes



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Australia: Three Superior Court Decisions Look Set to Have Serious Patent Implications

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[Spruson & Ferguson](#)

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IN SUMMARY

This article discusses three leading patent cases delivered by Australia’s superior courts during the past 12 months, each of which has important implications for Australian patent law, practice and policy.

DISCUSSION POINTS

- The High Court’s missed opportunity to provide clarity on Australia’s requirements for the patent eligibility of computer-implemented inventions
- The Full Federal Court’s confirmation that the Commonwealth Government could not recover damages for higher prices paid to an innovator pharmaceutical company during the period of enforcement of an interlocutory injunction restraining the launch of a generic product
- The High Court’s affirmation of the Full Federal Court’s decision that only human inventors (and not artificial intelligence platforms) are entitled to apply for patents

REFERENCED IN THIS ARTICLE

- *Aristocrat Technologies Australia Pty Ltd v Commissioner of Patents* [2022] HCA 29
- *Commonwealth of Australia v Sanofi (formerly Sanofi-Aventis)* [2023] FCAFC 97
- *Commissioner of Patents v Thaler* [2022] FCAFC 62
- Patents Act 1990 (Cth)

Injunctions At A Glance

<p>Preliminary injunctions – are they available, how can they be obtained?</p>	<p>The court can order an interlocutory injunction (similar to a US preliminary injunction) early in a proceeding. It considers (1) whether the applicant has established a prima facie case of infringement and (2) the balance of convenience.</p>
<p>Permanent injunctions – are they available, how can they be obtained?</p>	<p>A permanent injunction will usually be granted if infringement is found of a valid claim at trial. Although the court does not generally consider the balance of convenience, the granting of a permanent injunction is subject to the court’s discretion.</p>
<p>Is payment of a security/deposit necessary to secure an injunction?</p>	<p>An applicant seeking an interlocutory injunction must agree to compensate any party adversely affected by the interlocutory injunction if it is later determined that no valid claim of a patent has been infringed. This undertaking may need to be secured by a payment to</p>

	the court. No undertaking or security is required for a permanent injunction.
What border measures are available to back up injunctions?	Australia does not have any customs or other border protection mechanisms for enforcing injunctions or detecting infringements of patent rights. Australia does have a customs notification and seizure regime for registered trademarks and copyright works.

SPLIT DECISION REGARDING COMPUTER-IMPLEMENTED INVENTIONS

On 17 August 2022, the High Court of Australia issued a split decision in *Aristocrat v Commissioner of Patents*.^[1] This case related to the patentability of computer-implemented inventions – in particular, to a system and method for an electronic gaming machine (EGM). With six justices presiding over the appeal (after the seventh fell ill on the day of the hearing) the High Court was divided three-to-three on whether Aristocrat's application concerned patentable subject matter. The split decision means that the appeal was dismissed, and the decision of the Full Federal Court, rejecting Aristocrat's patent application, was upheld.

While the High Court's decision has not provided the clarity that patent owners and IP professionals were hoping for regarding the patentability of computer-implemented inventions in Australia, it leaves the door open for further development of Australian law in this area. It also offers some key takeaways for patentees, confirming that an advance in computer technology is not essential for patent eligibility, and that characterisation of the invention remains as important as ever.

The case has been remitted to the Federal Court for further consideration and is ongoing. Further clarity from the case, therefore, may be obtained in the coming months or years.

Summary Of The Decision

The issue for determination by the High Court was whether Aristocrat's invention, relating to a system and method for a feature game on an EGM, was patentable subject matter under Australian law. All members of the Court agreed that an invention must be more than a mere scheme or abstract idea to be patentable,^[2] in line with well-established principles; however, the justices were divided as to the proper characterisation of Aristocrat's invention.

Chief Justice Kiefel, together with Justices Gageler and Keane (the Kiefel decision), characterised the invention as nothing more than a new system or method of gaming that was merely an abstract idea without any variation of generic computer technology. It followed from that characterisation that the invention was not patentable subject matter.^[3]

By contrast, Justices Gordon, Edelman and Steward (the Gordon decision) characterised the invention as an EGM that was altered by implementation of the feature game. Their honours were satisfied that there was inventiveness and ingenuity in the incorporation of the game into the EGM, and concluded that the invention constituted patentable subject matter.^[4]

Key Takeaways

It was hoped that the High Court's decision would clarify the patentability of computer-implemented inventions under Australian law. Although the decision has not resolved this issue, it does present some key takeaways.

Advancement In Computer Technology Not Required

An important issue for consideration by the High Court was whether the Full Federal Court adopted a correct approach to assessing the patent eligibility of computer-implemented inventions. A plurality in the Full Court adopted a two-part test that involved asking whether the claimed invention involved an advance in computer technology.^[5] As argued by Aristocrat before the High Court, that approach presents the risk that a computer-implemented invention may be held to lack patent-eligible subject matter, notwithstanding that it involves an advance or technical contribution in another field of technology.

Both the Kiefel and Gordon decisions rejected the Full Court's approach. On their face, these decisions seem to indicate that computer-implemented inventions that result in an improvement in another field of technology may constitute patentable subject matter.^[6]

This provides some reassurance for patentees whose inventions may not involve an advance in computer technology but nevertheless deliver technical advantages in other fields.

Characterisation Remains Crucial For Determining Patentability

The split between members of the High Court in this case ultimately hinged on the correct characterisation of Aristocrat's invention, demonstrating how significant this step is for determining patentability.

The Kiefel decision emphasised the lack of 'adjustment to generic computer technology' or the lack of a component that is 'physically affected' by Aristocrat's invention,^[7] quoting *Grant v Commissioner of Patents*,^[8] while the Gordon decision emphasised the game controller of the invention providing an 'altered' EGM.^[9] While establishing no binding precedent, these comments highlight the importance, under current Australian law, of ensuring that a computer-implemented invention is described in sufficient detail to enable it to be clearly distinguished over generic or standard computer technology.

Future Implications

Unfortunately, the High Court's decision does not resolve the questions that surround the patent eligibility of computer-implemented inventions in Australia. Being a split decision, it does not provide a binding precedent on which lower courts or administrators can rely. As such, it is unlikely that the decision will impact the current examination practice at IP Australia. In individual cases, arguments for or against patentability may be developed from the principles explained in the Kiefel and Gordon decisions.

The uncertainty surrounding the patent eligibility of computer inventions under Australian law remains for now. Nevertheless, the split decision leaves the door open for the High Court to further consider the patentability of computer-implemented inventions in the future, including in this same case, should it continue and move back up through the levels of appeal again after being remitted to the Federal Court.

NO PAY DAY FOR COMMONWEALTH IN SANOFI DAMAGES CLAIM

On 26 June 2023, the Full Court of the Federal Court of Australia delivered its keenly awaited judgment in *Australia v Sanofi*.^[10] It upheld the trial judge's decision that the Commonwealth Government (the Government) is not entitled to damages arising from the grant of a 2007 interlocutory injunction preventing Apotex from launching generic clopidogrel products, on the basis of a patent that was later found to be invalid.^[11]

In the 2008 financial year, Sanofi's Plavix clopidogrel products (also sold in Australia as Iscover by Bristol Myers Squibb), a medication inhibiting the formation of blood clots, was the third most heavily Government-subsidised prescribed drug in Australia. The Government's costs for that year extended to approximately A\$170 million.

In August 2007, Apotex commenced legal action to revoke Sanofi's Australian Patent No. 597784 covering the product and was quickly met with an interlocutory injunction application. The injunction was granted and remained in force until the patent was ultimately found wholly invalid by the Full Court and special leave for appeal to the High Court was refused. Apotex's clopidogrel products were launched on 1 May 2010.

On grant of the interlocutory injunction, Sanofi was required to give the 'usual undertaking as to damages', by which it undertook to compensate any person adversely affected by the operation of the injunction.^[12] After the patent was revoked, both Apotex and the Government brought claims pursuant to the undertaking, seeking damages for their losses resulting from the delayed launch of Apotex's products. Apotex's claim was settled, whereas the Government continued with its claim: the Government's claim was based on its lost opportunity for pricing decreases for clopidogrel products, which would have been triggered by a first generic entry, including (1) an immediate mandatory price reduction and (2) further price disclosure-related price reductions, which would have occurred in the years following. The Government's claim on this basis exceeded A\$325 million plus interest.

Key Findings And Implications

The Full Court upheld the decision of the trial judge that the Government did not succeed in making out its case.^[13] Ultimately, this finding arises from a failure to make out the counterfactual that Apotex would have launched in the circumstances at play at the relevant time, had Sanofi not obtained an interlocutory injunction.

The appeal decision highlights the complexities in establishing that counterfactual to the required standard. In addition, the Full Court did not consider the trial judge's finding that it was more likely than not that the Government would have been prepared to reverse statutory reductions in the reimbursed price for Sanofi's products triggered by the generic listing on the Government's Pharmaceutical Benefits Scheme (PBS), if sale of the generic product was subsequently restrained by a permanent injunction.^[14] Both of these matters are likely to continue to be raised in interlocutory injunction hearings as factors requiring a re-evaluation of the delicate balance between the interests of both parties in such a scenario.

The decision also highlights the need for compelling evidence, supported by contemporaneous documents, from the ultimate decision makers at the generic party and the Government to convince the Court that, but for the grant of the interlocutory injunction, the generic product would have been launched and listed on the PBS in the face of the significant damages risk if patent infringement was later made out.

Finally, in overturning the judge's conclusion that the Government's losses were not a direct consequence of the interlocutory injunction (because it did not restrain PBS listing), the Full Court has alleviated some pressure on the need to explicitly include a restraint in that regard in interlocutory injunction orders.

First-instance Decision Against The Government

The first-instance decision delivered in May 2020 was the first case dealing with a claim by the Government for damages in these circumstances. The Government had previously

settled claims for compensation against Wyeth relating to extended release formulations of the antidepressant venlafaxine (Effexor XR) and against AstraZeneca relating to the rosuvastatin (Crestor). The judgment also followed the late 2018 Federal Court decision relating to venlafaxine, in which the generic party claims were upheld, including third-party generic companies who were not party to the proceedings.^[15]

At first instance, Justice Nicholas confirmed that, in principle, a claim by the Government on an undertaking regarding damages in these circumstances could be made out; however, the Government failed in its case in several respects:

- The Court found that the Government's losses were not a direct consequence of the interlocutory injunction granted. In this case, the injunction prohibited commercial activities such as manufacture and sale, but did not explicitly restrain listing by Apotex of its products on the PBS. There had been some debate at the original interlocutory injunction hearing regarding whether PBS listing would be a patent infringing act and, therefore, whether the Court should restrain that act by injunction; however, Apotex, in any event, gave a separate undertaking to refrain from PBS listing its products, given that practically it would not have been able to meet the guarantee of supply requirements of PBS listing in the face of an injunction on supply. Crucially, the Court found that Apotex's undertaking was not supported by any undertaking regarding damages from Sanofi. Accordingly, it found that the loss was directly caused by Apotex's decision not to list on the PBS, not by the interlocutory injunction itself.^[16]
- Despite Apotex's Australian managing director giving evidence that Apotex would 'almost certainly' have launched 'at risk',^[17] Justice Nicholas was not satisfied that Apotex's CEO and ultimate decision maker, who did not give evidence, would have authorised a launch if no interlocutory injunction had been granted.^[18]
- The Court found that it was more likely than not that the Government would have been prepared to reverse statutory reductions in the reimbursed price for Sanofi's products triggered by the generic listing on the PBS, if sale of the generic product was subsequently restrained by a permanent injunction.^[19]

Full Court Upholds Decision Against Government

On appeal, the Full Court focused on two key issues – whether the trial judge erred in finding that:

- Apotex would not have sought to PBS list its clopidogrel products even if it had not been restrained by the interlocutory injunction (Apotex launch and listing issue); and
- the loss claimed by the Government did not flow directly from the interlocutory injunction (directness issue).^[20]

The Court noted that other issues in the appeal all related to 'further hypothetical causative obstacles sequentially secreted within each other',^[21] all within the overarching hypothetical scenario where Apotex did list and launch its products in 2008; however, these issues did not arise if one of the two key issues above was decided against the Government. That proved to be the case.

On the Apotex launch and listing issue, the Court reviewed a significant body of both documentary and testimonial evidence relied on at trial, including a substantial number of emails. Among other asserted errors, the Government argued that the trial judge had failed

to have regard to various parts of this material and submissions made at trial, and that he had erred in drawing a Jones v Dunkel inference against the Commonwealth for failing to call Dr Sherman (ie, an inference that evidence from Dr Sherman, the ultimate Apotex decision-maker, would not have assisted the Government).^[22] Notably, the Government also claimed that by reason of his delay in giving judgment (31 months from hearing), the trial judge had lost the advantage usually afforded to a trial judge with regard to the assessment of credit of witnesses.

The Full Court rejected all these arguments, affirming the trial judge's approach to the evidence. On the question of delay, it found that the trial judge had clearly set out his reasons, showing that he was very much aware of the detail of the evidence and its significance. The judge's reasons were described as 'a most thorough and searching excavation of the very complicated factual questions which the case generated'.^[23]

The Government, therefore, failed to show that, had the injunction not been granted, Apotex would have launched its products. Its failure in this crucial respect was determinative of the case.^[24]

The Court also considered the directness issue, on which it found that the trial judge had erred in applying such a strict causative test.^[25] Notwithstanding an intermediate causative step (Apotex's undertaking not to PBS list) between the grant of the interlocutory injunction and the loss suffered by the Commonwealth, the loss did flow directly from the injunction.

Further Implications

It remains to be seen whether the Government will seek special leave to appeal to the High Court – an appeal that might be considered ambitious in light of the Full Court's strong endorsement of the trial judge's approach to the evidence in the case. Regardless, it is likely that the implications of this case will be felt not only in future damages cases, but also at the interlocutory injunction stage.

PATENT LAW DOES NOT RECOGNISE AI AS ELIGIBLE INVENTOR

In November 2022, the High Court refused an application for special leave to appeal made by Stephen L Thaler from the April 2022 decision of the Full Federal Court of Australia^[26] that his 'device for the autonomous bootstrapping of unified sentience' (DABUS) artificial intelligence (AI) platform was not entitled to apply for an Australian patent because it was not human.

Background

Dr Thaler filed Australian Patent Application No. 2019363177 on 17 September 2019, which relates to a container with a wall including a fractal profile with corresponding convex and concave fractal elements on the interior and exterior surfaces. Those features were said to enable multiple containers to be coupled together via 'inter-engagement' while also improving grip and heat transfer. Dr Thaler has pursued patents for this invention, naming DABUS as the inventor, in high-profile cases worldwide, including in the United Kingdom^[27] and the United States.^[28]

Refusal By The Commissioner Of Patents

In a decision delivered on 9 February 2021, the Deputy Commissioner of Patents (the Deputy Commissioner) concluded that only a person (natural or legal) can be granted a patent and that, in the absence of devolution of title from the inventor, the inventor will be the applicant.^[29] Although an applicant can be entitled to have the application assigned to them, it was

generally understood that a machine cannot own property and, therefore, cannot assign something it does not own.

Successful Appeal By Thaler To The Federal Court

The Deputy Commissioner's decision was, surprisingly, overturned on appeal to a single judge of the Federal Court, Justice Beach, in a decision delivered on 30 July 2021.^[30] Justice Beach reasoned that the word 'inventor' in the Patents Act 1990 (Cth) (the Patents Act) should be interpreted flexibly to account for unforeseen technological advances,^[31] and that it is a noun that can be a person or a thing.^[32]

Successful Appeal By The Commissioner Of Patents To The Full Court

In a decision delivered on 13 April 2022,^[33] the Full Court of the Federal Court of Australia (Chief Justice Allsop and Justices Nicholas, Yates, Moshinsky and Burley) overturned the decision of Justice Beach and found that only a human can be an inventor. They noted, in particular, that section 15(1)(a) of the Patents Act provides that 'a patent for an invention may only be granted to a person who is the inventor' and that the ordinary English meaning of 'inventor' is the person responsible for making the invention, that being 'the person who makes or devises the process or product'.^[34]

High Court Did Not Wish To Hear The Issue

The High Court's November 2022 refusal of Dr Thaler's application for special leave makes clear that the Patent Act, as it stands, provides only for the grant of patents to human inventors and their successors in title. Any change to that position must arise from legislative change rather than case law.

There is significant and active debate throughout the Australian legal and patent professions, industry and Government about what Australia's policy position and law, including in relation to patents and copyright, should be with respect to AI-generated works. It will be especially interesting to follow these developments, in Australia and internationally, over the coming months and years.

Endnotes

- 1 Aristocrat Technologies Australia Pty Ltd v Commissioner of Patents [2022] HCA 29. [^ Back to section](#)
- 2 *ibid* at [22] and [116]. [^ Back to section](#)
- 3 *ibid* at [73]. [^ Back to section](#)
- 4 *ibid* at [154]. [^ Back to section](#)
- 5 Commissioner of Patents v Aristocrat Technologies Australia Pty Ltd [2021] FCAFC 202 at [26]. [^ Back to section](#)
- 6 Aristocrat [2022] HCA 29 at [46], [78], [87] and [122]. [^ Back to section](#)
- 7 *ibid* at [73] to [74]. [^ Back to section](#)

- 8** Grant v Commissioner of Patents [2006] FCAFC 120 at [70]. [^ Back to section](#)
- 9** Aristocrat [2022] HCA 29 at [154]. [^ Back to section](#)
- 10** Commonwealth of Australia v Sanofi (formerly Sanofi-Aventis) [2023] FCAFC 97 (Sanofi FCAFC). [^ Back to section](#)
- 11** *ibid* at [391]. [^ Back to section](#)
- 12** *ibid* at [7]. [^ Back to section](#)
- 13** *ibid* at [391]. [^ Back to section](#)
- 14** Commonwealth of Australia v Sanofi (formerly Sanofi-Aventis) (No. 5) [2020] FCA 543 (first-instance decision) (Sanofi No. 5) at [528]. [^ Back to section](#)
- 15** Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth [2018] FCA 1556. [^ Back to section](#)
- 16** Sanofi No. 5 at [451]. [^ Back to section](#)
- 17** *ibid* at [283]. [^ Back to section](#)
- 18** *ibid* at [351]. [^ Back to section](#)
- 19** *ibid* at [528]. [^ Back to section](#)
- 20** Sanofi FCAFC at [10(a)] and [10(b)]. [^ Back to section](#)
- 21** *ibid* at [11]. [^ Back to section](#)
- 22** *ibid* at [85]. [^ Back to section](#)
- 23** *ibid* at [387]. [^ Back to section](#)
- 24** *ibid* at [390]. [^ Back to section](#)
- 25** *ibid* at [82]–[83]. [^ Back to section](#)
- 26** Commissioner of Patents v Thaler [2022] FCAFC 62. [^ Back to section](#)
- 27** Thaler v Comptroller-General of Patents, Designs and Trademarks [2021] EWCA Civ 137. [^ Back to section](#)
- 28** Thaler v Vidal, No. 2021-2347 (Fed. Cir. 2022). [^ Back to section](#)
- 29** Stephen L Thaler [2021] APO 5 at [20]. [^ Back to section](#)

- 30** Thaler v Commissioner of Patents [2021] FCA 879. [^ Back to section](#)
- 31** *ibid* at [124]. [^ Back to section](#)
- 32** *ibid* at [120]. [^ Back to section](#)
- 33** Thaler [2022] FCAFC 62. [^ Back to section](#)
- 34** *ibid* at [100]. [^ Back to section](#)

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India: Key SEP and Antitrust Challenges Demonstrate Judicial Desire to Strengthen Patent Regime

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[Anand and Anand](#)

Summary

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IN SUMMARY

In this article, we briefly cover legislative changes, decisions in the two dominant fields of Indian patent litigation, India's first decision on antitrust and patent law and orders that have refined patent jurisprudence.

DISCUSSION POINTS

- Legislative restructuring
 - SEPs
 - Life sciences
 - Antitrust and patents
 - Growing jurisprudence on patent law
-

REFERENCED IN THIS ARTICLE

- Delhi High Court Intellectual Property Division Annual Report 2022–23
- *Intex v Ericsson*
- *Nokia v Oppo*
- *Novartis v Natco*
- *Boehringer Ingelheim v Vee Excel Drugs*
- *Consolidated case of Ericsson v CCI*
- *In re Swapan Dey and Vifor*
- Patents Act 1970

Over the past two decades, the patent regime in India has been on a steady climb towards a place among the world's strongest patent jurisdictions. The judiciary has been steering this drive and has shifted gears in recent years, resulting in the past year witnessing the start of India's moment in the global patent jurisprudence spotlight.

The Indian judiciary has delivered very strong decisions in the past 12 months. It is also in the process of authorising some others, which are expected to refine nuanced yet important aspects of the Indian patent law.

In this article, we briefly cover legislative changes, decisions in the two dominant fields of Indian patent litigation (ie, standard-essential patents (SEPs) and life sciences), India's first decision on antitrust and patent law and orders that have refined patent jurisprudence.

LEGISLATIVE RESTRUCTURING

Abolishment Of The IPAB And Creation Of The IPD

In early 2021, Parliament announced its plans to abolish the appellate tribunal body in India, the Intellectual Property Appellate Board (IPAB), and transfer its cases to various high courts – a plan that, at the time, was regarded with uncertainty by patent litigators and prosecutors.

In 2022, the Delhi High Court answered the legislature's call and became the first high court in the country to set up an IP division (the Delhi IPD). The Delhi IPD comprises three separate benches of single judges, and an appeal bench that presides over them, dedicated to hearing only IP cases.

Although it inherited over 3000 cases from the IPAB, the Delhi IPD's first annual report card is impressive: in just one year, decisions were made in 45 per cent of all appeals from the Indian Patent Office (IPO), 66 per cent of all original patent invalidation petitions and 50 per cent of IP lawsuits filed before it.

The arrival of the Delhi IPD has already raised the standard of intellectual property in India: the IPO's slow pace of decision-making and its notoriety for passing poorly reasoned orders have been deprecated by the Delhi High Court to the extent that the Assistant Controller General of Patents was made to undergo a course on passing judicial orders at the Delhi Judicial Academy after a trend was noticed whereby instead of providing the reasons behind the rejection of a patent application, the IPO had started simply to copy and paste the statutory provisions without delineating how they were applicable to the patent in question.^[1]

Following the success of the Delhi IPD, in April 2023, the Madras High Court in Chennai set up its own IPD, and other high courts are expected to follow suit.

India's vision for the next decade of IP law is captured in the Delhi IPD's Annual Report 2022–23. Some of the Delhi IPD's aims in the coming years are as follows:

- establishment of IPDs in at least 10 to 15 high courts across India;
- creation of a robust panel of scientific advisers to assist the courts;
- acceleration of the patent litigation process;
- cultivation of a damages culture in IP cases;
- strengthening of the Indian judiciary by appointing specialist IP lawyers as judges;
- promotion of women inventors, single inventors and small businesses both at the IPO and in the courts; and
- development of India into a hub for high-quality patent drafting by promoting interdisciplinary education at the school and college level.^[2]

Procedural Rules To Fine Tune And Speed Up Patent Litigation

The success attained by the Delhi High Court can be attributed to the speed, depth and maturity of its IPD judges' adjudication. Each case is viewed not through a traditional lens but rather as an opportunity to refine the direction that Indian patent law and policy must take.

The Court is aided in its endeavour through the newly enacted Delhi High Court Rules Governing Patent Suits 2022, which address new aspects, including:

- tests for proving infringement of SEPs (claim-chart mapping);
- the creation of a scientific panel of advisers to assist the court from a neutral position in highly technical litigation; and
- confidentiality clubs and the need to exclude non-licensing personnel, especially in the SEP context.

The Commercial Courts Act 2015 had already laid the foundation of speedy litigation through summary judgments, case management hearings and flexible trials, among other things. These new patent rules refine some aspects of traditional patent litigation and address new fields and concepts in patent law, which did not exist when the Patents Act 1970 was enacted.

SEPS

Intex V Ericsson

The most recent decision that tackled core SEP issues in India from a jurisprudential standpoint was Philips v Bhagirathi Electronics.^[3] Delivered in 2018, it remains India's only judgment on SEPs, delivered after a full trial.

Between 2018 and 2022, some implementers started to declare that India's stance has shifted, and interim relief is no longer available in SEP disputes. The Delhi High Court emphatically rejected this line of thought in March 2023 by upholding an interim order in Ericsson's favour against the Indian mobile manufacturer Intex, which was refusing to license its SEPs.^[4] It also rejected Intex's argument that India should follow the UK model and not grant an injunction until the full trial on validity and fair, reasonable and non-discriminatory (FRAND) terms is complete.^[5]

The Court noted that the judge–population ratio is low in India, which prolongs the time needed by the courts to pass decisions; however, this is the reason that India must grant interim injunctions, lest a domino effect arise by which the denial of interim relief discourages innovator companies from conducting further research and development directed at India.^[6]

More important than the outcome of the decision are the principles that the Court laid down for deciding future SEP disputes. Some of those principles are as follows:

- implementers do not need access to the SEP holder's licensing agreements to make a counteroffer;
- an injunction, and not damages, is the answer to solving hold-out by an unwilling licensee;^[7]
- recent decisions in the United Kingdom such as InterDigital v Lenovo^[8] do not apply in the Indian context;^[9]
- injunctions and interim payments for the entire SEP portfolio can be decided even if just one patent in the suit is asserted (the silver bullet rule);^[10]
- even before interim relief, courts can direct the implementer to make ad hoc royalty payments (pro tem payments);^[11] and
- at the interim stage, the alleged infringer must do a lot more to avoid an injunction than simply claiming the invalidity of the SEPs; the challenge should be strong.^[12]

The decision has laid a strong foundation for SEP holders to litigate in India: it has positioned India as possibly the only jurisdiction in the world that not only grants interim relief to SEP holders but also recognises their right to receive pro tem royalties as security, at the beginning of a lawsuit, even before the court addresses the questions of infringement, FRAND compliance and validity.

Nokia V Oppo

Pro tem security orders are equitable orders passed by the court to balance the rights and interests of both parties until the case is finally decided. These orders present a unique facet of Indian litigation that enables parties to secure monetary relief even before the case is heard on merits of interim injunction etc. These orders have ranged from accepting bank guarantees by implementers to ordering an implementer to park away real estate and keep it free from third-party claims.

However, the latest decision by the Delhi High Court in *Nokia v Oppo*^[13] marked a milestone and has introduced the untested concept of pro tem security. After a 2018 cross-licence agreement between Nokia and Oppo expired, and the parties could not reach an agreement on renewing the licence, Nokia brought a suit against Oppo in India (among other jurisdictions). Nokia invoked a rather obscure provision of law^[14] to claim its right to receive pro tem security, before the Court heard the parties on merits, based on admissions made by Oppo regarding its liability to pay royalties to Nokia.^[15]

The court noted that a SEP holder (in this case, Nokia) is at a disadvantage relative to an implementer (in this case, Oppo) as it cannot seek an injunction without protracted FRAND negotiations;^[16] therefore, an implementer is duty-bound under Indian law to deposit ad hoc royalties with the court until the full suit is decided or the parties execute a licensing agreement. It held that Nokia had already established a prima facie case of infringement because Oppo had:

- been an ex-licensee of Nokia for three years starting from 2018;
- continued to negotiate with Nokia for renewal of the licensing agreement;
- made counteroffers to Nokia;
- offered to make interim payments to Nokia; and
- approached the China court seeking determination of FRAND rates, which meant that the patents in question were SEPs.^[17]

LIFE SCIENCES

Pharmaceutical patent litigation continues its turbulent path, with *Novartis v Natco* constituting an extremely progressive decision^[18] and *Boehringer Ingelheim v Vee Excel Drugs*^[19] constituting a setback to patentees. These decisions have seen conflicting views from separate judges on selection inventions (ie, the genus versus species debate).

Novartis V Natco

This decision alleviated some of the deep wounds delivered to pharma patent owners by previous decisions in 2021 that seemed to close the door on the concept of co-pendency of species and genus patents. While granting an injunction to Novartis, it arrived at the following findings:

- disclosure in a patent specification and coverage of its claims are distinct concepts;^[20]
- mere coverage of a compound in the claims of the genus patent is not sufficient to invalidate a later species patent – disclosure for lack of novelty is required;^[21]
- selection patents, although not mentioned specifically in statute, are valid and enforceable in India; and
-

US Orange Book listings or patent term extensions that state that a drug is covered by both the genus and the species patent do not mean that the invention of the two patents is the same cannot be used against a patentee in response to an infringement claim.^[22]

Boehringer Ingelheim V Vee Excel Drugs

Two months after the Novartis v Natco decision, another bench of the Delhi High Court passed a diametrically opposite decision, which denied an injunction to Boehringer against entities that were marketing its patented drug linagliptin. Some of the Court's reasons were as follows:

- if the compound claimed in the species patent was also covered in the earlier genus patent, the Court is likely to presume that it was also disclosed in the earlier genus patent,^[23]
- there is not much difference between the concepts of covered, encompassed and disclosed, apart from semantics;^[24]
- working statements (Form 27) or US Food and Drug Administration Orange Book listings, which show that one drug is covered by the genus and the species patent, suggest that the invention of both patents is the same,^[25] and
- selection patents may be granted in India, provided they terminate at the same time as the earlier genus patent.

The Court noted that Boehringer had made a previous statement to the IPO several years ago that linagliptin was disclosed in the earlier genus patent; therefore, the Court did not allow it to change course and later claim that it was disclosed only in the species patent. Further, the international search report on the species patent had also suggested that the species patent was not novel or inventive in respect of the earlier genus patent.^[26]

Some elements of this decision seem to contrast with the Novartis v Natco decision. While an initial glance may suggest that both decisions are completely contrary, on closer inspection, it becomes clearer that Boehringer was denied an injunction because there were some serious obstacles to the novelty of its patent not on principles of law, but on facts specific to that patent.

ANTITRUST AND PATENTS

Consolidated Case Of Ericsson V CCI

A 2016 decision in a case concerning allegations made against Ericsson for alleged non-FRAND practices with prospective Indian licensees and a 2020 decision in a case concerning allegations against Monsanto's practices of allegedly charging high royalties, imposing one-sided terms on sublicensors for its patents over traits of Bt cotton, saw the Delhi High Court hold that claims of antitrust and abuse of dominance on the basis of alleged misuse of monopolistic patent rights (either denying entry to market or charging high royalties for a licence) were solely the domain of India's competition regulator: the Competition Commission of India (CCI).^[27]

The 2023 decision has reversed this position and has held that the Patents Act is a specialised legislation that entrusts the Controller General of Patents to ensure that:

- patents are used in India;
- patented inventions are made available to persons at reasonably affordable prices and in sufficient quantity;
- patent licences are free of restrictive or unfair trade conditions; and
- compulsory licences are granted to interested applicants on reasonable terms if the patentee fails to use the patent in India or meet the public's requirements.^[28]

The Court gave an interesting explanation to section 3(5) of the Competition Act 2002 that exempted the reasonable exercise of IP rights from being categorised as anticompetitive practices. The Court held that the reason for the legislature to make this exception was to exclude patent licensing agreements from the scope of examination under the Competition Act and relegate this issue to the domain of the Controller General of Patents.^[29] As a result, the CCI proceedings against Ericsson and Monsanto have been quashed.^[30]

Whether this decision reflects the final position that India takes on this issue as a matter of law and policy remains to be seen. The CCI has the option of appealing the decision and having the final question be decided by the Supreme Court.

In Re Swapan Dey And Vifor

October 2022 saw India's first decision by the CCI on a claim of abuse of dominance and anticompetitive conduct against a pharmaceutical patent holder.^[31]

The claim against Vifor was that it prevented fair play in the market by granting licences only to two entities and by denying the claimant a licence for its patented drug ferric carboxymaltose for the treatment of anaemia.^[32] There was also a secondary claim that Vifor was supplying the drug to government institutions at much cheaper rates than market costs.^[33]

The complaint was dismissed at the outset, and the claimant's request for investigating Vifor for anticompetitive conduct was rejected. Its reasons were as follows:

- Vifor entered into short-term patent licensing agreements (three years), with the possibility of extensions. The agreements were not restrictive or one-sided and were not anticompetitive.^[34]
- Vifor, as a patentee, has the freedom to choose who it wishes to license its patents to; third parties do not have a right to license its patent.^[35]
- The patent was expiring in October 2023, after which all players will be free to enter the market.^[36]
- Vifor's decision to price its drug at a cheaper rate for government institutions than the price on the open market was not anticompetitive. Pricing under government programmes is not comparable with the open market.^[37]

The decision is encouraging for patent holders and supports the fact that the competition regulator in India will decide complaints in the most objective, neutral and case-specific manner.

GROWING JURISPRUDENCE ON PATENT LAW

Section 3(k): No Blanket Bar To Software Or Business Method Patents

Section 3(k) of the Patent Act is pitted against every patent based on software and artificial intelligence (AI). The IPO has rejected several patents simply on the grounds that they relate to software. Without examining whether the inventions had technical effect, there was a valid concern that serial rejections of those patents would disincentivise the growth of AI technology in India.

In May 2023, the Delhi High Court clarified^[38] that software inventions are patentable if used in conjunction with hardware or if they contain a technical effect. It further held that a technical effect can be gleaned if the invention solves a technical problem, enhances a technical process or has some other technical benefit.^[39] It also cautioned that technical effect is an ever changing phenomenon that is entwined with technological growth and that the parameters of its definition must be continuously revised.^[40]

In *OpenTV v Controller of Patents*,^[41] the Court expressed concern at the rejection of business method inventions under archaic definition of section 3(k). Citing the 161st report by the Parliamentary Standing Committee on Commerce, the decision acknowledged that a large number of inventions concerning emerging technologies will be in the field of software, and, therefore, a relook at the strict implementation of section 3(k) was required.^[42]

New Twists In The Doctrine Of Equivalence

Two decisions of the Delhi High Court have brought the doctrine of equivalence to the forefront of infringement disputes.

The first case is that of *Sotefin v Indraprastha Cancer Society* concerning infringement of a patent for smart dollies.^[43] The Court discussed the well-established principle of the doctrine of equivalents but in the context of deciding whether the difference in the impugned product from the patent claims relates to an essential or non-essential element.

The Court laid down the 'all-essential elements' rule: a patent is infringed when all the essential elements of the claim are carried out by the alleged infringer.^[44] The absence of non-essential elements in the alleged infringer's product will not establish non-infringement.^[45]

Whether an element is an essential element of a claim is determined based on the following factors:

- the common general knowledge of a person of ordinary skill in the art (POSA) on the date of publication of the patent;
- whether the POSA would have considered it obvious that a variant of an element of the claim would be irrelevant to the way the invention works; and
- the intent of the inventor, either express or implied from the claims, that a particular element is essential, disregarding any other evidence of the inventor's intent that is external to the patent claims.^[46]

This decision has put a spanner in the works of many defendants, who have sought to confuse the courts by insisting that a patent is infringed only if all elements (and not all essential elements) of a claim are implemented by it.

The decision of *FMC Corporation and Ors v Natco Pharma Limited*^[47] by the Appellate Bench of the Delhi High Court saw the Court refine the features of the doctrine of equivalence in the context of process patents. The traditional elements (ie, substantially the same function

being performed, in substantially the same way, to achieve the same result)^[48] were modified to involve:

- identification of the essential elements of the two processes;
- identification of the necessary steps of the two processes; and
- examination of the interaction of the key elements at each step.^[49]

Only if there is substantial similarity in all three factors above, and the differences between the two processes are trivial, can a process patent be deemed infringed under the doctrine of equivalence.

Divisional Patent Applications

In *Boehringer Ingelheim v Controller of Patents*,^[50] the Delhi High Court declared that only the claims must be considered when assessing whether there is unity of invention or plurality of inventions. A divisional application is not maintainable if plurality resides in the specification and not in the claims.^[51]

The same principle was further reinforced in *Novartis v Controller of Patents*.^[52]

Amendment Of Patent Applications

Nippon A&L Inc v Controller of Patents,^[53] the Delhi High Court held that applications to amend a patent before it is granted will be treated with leniency compared to those filed post-grant. With this test, the Court observed that the desire to amend the patent from a product-by-process patent to a process patent was admissible as the scope of the patent application was being narrowed and not expanded.^[54]

However, the decision in *Nestlé v Controller of Patents* clarified that there is no bar to an application to amend the patent after its grant.^[55]

Allergan v Controller of Patents cautioned against 'hypertechnical' reasons for rejecting an application for amendment^[56] and that the right of a patent applicant to amend the claims (in relation to the originally filed foreign Patent Cooperation Treaty (PCT) application) is not foreclosed as there is no occasion provided to the applicant to amend the claims at the time of the PCT application entering the India national phase.^[57]

In this case, the originally filed application in the United States contained method claims of the kind that were not patentable in India. The IPO's rejection of the application to amend the Indian patent to include product claims on the ground that the national phase application did not conceive product claims. The Court's reason was that there was no occasion for patent applicants to amend the claims as originally filed in the United States.

Simplicity Is No Bar To A Patent

The Delhi High Court went back to basics in *Avery Denisson v Controller of Patents* and held that simplicity of the invention is not to be confused with obviousness.^[58] It also gave a rule of thumb for patent examiners, that if the prior art cited against the patent is quite old, it suggests the existence of an inventive step.^[59]

Pending Challenges To Patent Validity Do Not Prevent Enforceability

In *AstraZeneca AB v West Coast*, the Delhi High Court shot down a misinterpretation by generic companies of a statement of the Supreme Court in *Alloys Wobben v Yogesh Mehra*

that rights in a patent are not crystallised until a post-grant opposition pending against it is decided in favour of the patentee.^[60]

The Court applied the inversion test to determine that this statement was not the ratio decidendi of the Supreme Court's decision, and clearly was not the test to decide whether a patent is enforceable against an infringer. The decision held that the grant of a patent entitles the patentee to file an infringement suit, irrespective of whether a challenge to its validity is pending.

CONCLUSION

The past year has seen continued advancements to maturing the status of Indian patent litigation. The establishment of the Delhi IPD marks a milestone in India's judicial history that will pivot India to a truly modern patent system – a system that not only stands toe-to-toe with most modern jurisdictions but also follows its own unique path.

The true beauty of India's IP regime lies in the fact that the very spirit and ethos of the Indian culture lies in ensuring balance and driving progress while maintaining an altruistic spirit and placing the greater good at the centre of efforts to innovate.

Endnotes



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Japan: Unexpected Shift Sees Courts Become Increasingly Pro-Patentee

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Summary

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Q | &NBSP; ARE THERE FORUMS OUTSIDE THE COURT SYSTEM IN WHICH IT IS POSSIBLE TO ASSERT PATENTS IN YOUR JURISDICTION? IF SO, UNDER WHAT CIRCUMSTANCES MIGHT IT BE APPROPRIATE TO USE THEM?

Q | &NBSP; IN WHAT CIRCUMSTANCES DO COURTS IN YOUR JURISDICTION ACCOMMODATE REMOTE HEARINGS, FOR EXAMPLE, DURING PANDEMIC-RELATED LOCKDOWNS?

Q | &NBSP; ARE THERE ANY OTHER NOTABLE ISSUES RELATING TO THE ENFORCEMENT SYSTEM IN YOUR JURISDICTION?

Q | HOW CAN PATENT OWNERS BEST ENFORCE THEIR RIGHTS IN YOUR JURISDICTION?

Patent infringement litigation is the most common and effective measure in many circumstances. A patent owner may seek a permanent injunction or damages in litigation.

In some circumstances, strategically combining a preliminary injunction with litigation is a great option to expedite a case.

Q | ARE MEDIATION AND ARBITRATION REALISTIC ALTERNATIVES TO LITIGATION?

Mediation and arbitration are not commonly used in Japan. Many patent owners choose litigation over mediation or arbitration, trusting formal court procedures.

Recently, the Tokyo and Osaka district courts started providing arbitration services for IP-related disputes. The services are intended for simple cases and are not suitable for complex patent infringement disputes.

Q | WHO HEARS PATENT CASES?

A panel of three judges hears a case. One main judge reviews the case, and an experienced chief judge supervises him or her. A court-appointed technical expert may support judges to help them understand the technical aspects of the case as most judges do not have technical backgrounds.

Q | WHAT LEVEL OF EXPERTISE CAN LITIGANTS EXPECT FROM COURTS?

Japanese courts have highly specialised divisions dedicated to IP-related cases. In particular, the chief judge of each division has extensive experience in patent infringement lawsuits.

Q | ARE VALIDITY AND INFRINGEMENT DEALT WITH TOGETHER IN PROCEEDINGS?

Japanese courts decide infringement and validity issues together. Parties are expected to raise both infringement and validity arguments at an early stage; however, parties are often allowed to raise an invalidity defence later as the prior art search takes time.

Q | WHO MAY REPRESENT PARTIES ENGAGED IN A DISPUTE?

Attorneys-at-law (bengoshi) may represent a party in an infringement lawsuit. A patent attorney (benrishi) who holds a specific certification that is relevant for an infringement lawsuit may represent a party, but only together with an attorney-at-law.

Q | TO WHAT EXTENT IS FORUM SELECTION POSSIBLE IN YOUR JURISDICTION?

There is little room for forum selection in Japan. The Tokyo and Osaka district courts have exclusive jurisdiction over first-instance patent-related cases. In some circumstances, patent owners may have the option to choose between those two courts.

The Intellectual Property High Court is the only appellate court for patent-related lawsuits.

Q | TO WHAT EXTENT IS PRETRIAL DISCOVERY PERMITTED?

Japan does not have discovery proceedings. In some circumstances, a court may grant a document production order; however, this is not always available owing to strict requirements. It is difficult to obtain evidence from an opposing party.

Japan has an inspection procedure that allows a court-appointed expert to inspect the manufacturing plant of an accused infringer; however, a patent owner must first show a certain level of probability of infringement to use this procedure, and this requirement is difficult to meet. The availability of this procedure is limited.

Q | TO WHAT EXTENT IS EVIDENCE WRITTEN AND ORAL AT PROCEEDINGS?

Japanese patent litigation particularly focuses on written evidence. Witness testimony is extremely rare in patent infringement cases. Parties are generally expected to submit written declarations instead of witness testimony.

Q | WHAT ROLE, IF ANY, CAN EXPERT WITNESSES PLAY?

In many cases, the parties will retain their own technical expert and submit a written expert declaration. Having an expert helps the parties to persuade the judges regarding technical issues; however, technical arguments that are too detailed are often not helpful. It is important to choose an expert who appears trustworthy to Japanese judges.

Q | IS THE DOCTRINE OF EQUIVALENTS APPLIED BY COURTS IN YOUR JURISDICTION AND, IF SO, WHAT FORM DOES IT TAKE?

Five requirements must be satisfied for the doctrine or equivalents to apply:

- the difference between the claim and the accused product does not constitute an essential part of the patented invention;
- the invention can achieve the same purpose and function, even if the distinguishing element is replaced by the technology used in the accused's product or method;
- a person who is ordinarily skilled in the art could have easily conceived of the accused's product or method at the time of manufacture of the product;
- the configuration of the patented product was neither publicly known nor easily conceived at the time of the patent application; and
- no special circumstances exist, such as prosecution estoppel.

Q | ARE THERE PROBLEMS IN ENFORCING CERTAIN TYPES OF PATENT RELATING TO, FOR EXAMPLE, BIOTECHNOLOGY, BUSINESS METHODS OR SOFTWARE?

The field to which the patent relates does not affect patent enforcement. The patent eligibility requirements in Japan are less strict than those in the United States and the European Union. The only exceptions are SEPs: it is difficult to obtain injunctions based on SEPs, and the damages awarded in cases concerning SEP infringements are also very low.

Q | TO WHAT EXTENT ARE COURTS OBLIGED TO CONSIDER PREVIOUS CASES THAT HAVE COVERED ISSUES SIMILAR TO THOSE PERTAINING TO A DISPUTE?

Japan is not a common law country; however, lower courts usually follow the previous decisions of higher courts. Arguments based on the previous decisions of higher courts are often very persuasive to Japanese judges.

Q | TO WHAT EXTENT ARE COURTS WILLING TO CONSIDER THE WAY IN WHICH THE SAME OR SIMILAR CASES HAVE BEEN DEALT WITH IN OTHER JURISDICTIONS? ARE DECISIONS FROM SOME JURISDICTIONS MORE PERSUASIVE THAN THOSE FROM OTHERS?

Decisions from the US or European courts on the same dispute may affect the outcome; however, their influence is limited.

Q | WHAT REALISTIC OPTIONS ARE AVAILABLE TO DEFENDANTS SEEKING TO DELAY A CASE? HOW MIGHT A PLAINTIFF COUNTER THESE?

The strategy depends on the judges handling the case. A defendant may delay the litigation by filing a patent validity claim before the Japan Patent Office (JPO). Some judges will wait for the JPO's decisions, but others will not.

Judges usually allow time extensions owing to the need to translate documents for foreign parties.

If a plaintiff seeks damages together with a permanent injunction, an extra six months is required. A plaintiff in strong need of an early injunction may only seek a permanent injunction first and later file another lawsuit to recover damages.

Q | UNDER WHAT CIRCUMSTANCES, IF ANY, WILL A COURT CONSIDER GRANTING A PRELIMINARY INJUNCTION? HOW OFTEN DOES THIS HAPPEN?

Obtaining a preliminary injunction is a separate procedure from that for obtaining a permanent injunction, but the procedures are very similar. As judges carefully review both infringement and validity, preliminary injunction proceedings often take more than 10 months. A preliminary injunction should be granted if an accused infringer causes substantial harm to a patent owner by infringing a valid patent.

Q | WHAT IS THE REALISTIC TIME FRAME TO GET A DECISION AT FIRST INSTANCE FROM THE INITIATION OF PROCEEDINGS?

If a patent owner seeks both a permanent injunction and damages, the proceedings will usually take around 18 months. If a patent owner seeks only a permanent injunction, the proceedings will take approximately 12 months. If a defendant is a non-Japanese entity, an extra six months will be required owing to service of complaint.

Q | HOW MUCH SHOULD A LITIGANT BUDGET TO TAKE A CASE THROUGH TO A DECISION AT FIRST INSTANCE?

This varies depending on the case and the law firm. Usually, the total budget will be US\$80,000 to US\$200,000.

Q | TO WHAT EXTENT ARE THE WINNING PARTY'S COSTS RECOVERABLE FROM THE LOSING PARTY?

If a plaintiff wins a case, a court may award reasonable attorneys' fees as damages. A defendant will not recover its attorneys' fees even if it wins a case. The court costs paid by the winning party are recoverable from the losing party; however, those costs are often foregone as they are small.

Q | WHAT REMEDIES ARE AVAILABLE TO A SUCCESSFUL PLAINTIFF?

A permanent injunction and damages are available.

Q | HOW ARE DAMAGES AWARDS CALCULATED?

Damages are presumed based on:

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the marginal profit of the plaintiff's product multiplied by the quantity of the infringing products sold by the defendant;

- the marginal profit of the defendant's product multiplied by the quantity sold by the defendant; or
- reasonable royalties.

The marginal profit of the whole product is presumed as damages even if the technical significance of the patent relates to only part of the product. The defendant may rebut the presumption by proving relevant facts, such as the market difference, the existence of other competing products, its marketing efforts or the existence of other features of the product that the invention does not have.

Q | UNDER WHAT CIRCUMSTANCES WILL COURTS GRANT PERMANENT INJUNCTIONS?

A court will grant a permanent injunction as long as it finds that an accused infringer is infringing a valid patent.

Q | DOES THE LOSING PARTY AT FIRST INSTANCE HAVE AN AUTOMATIC RIGHT OF APPEAL?

The losing party always has the option to appeal before the Intellectual Property High Court.

Q | HOW LONG DOES IT TYPICALLY TAKE FOR THE APPELLATE DECISION TO BE HANDED DOWN?

It takes around six months.

Q | IS IT POSSIBLE TO TAKE CASES BEYOND THE SECOND INSTANCE?

A losing party may appeal the appellate court's decision, although it is rare for the Supreme Court to hear a patent infringement case. The success rate is as low as 1 per cent.

Q | TO WHAT EXTENT DO THE COURTS IN YOUR JURISDICTION HAVE A REPUTATION FOR BEING PRO-PATENTEE?

In recent years, the Japanese courts have been very pro-patentee. Japan used to be recognised as an anti-patentee jurisdiction, but official statistics indicate that the success rate for patentees has doubled in the past five years.

Q | ARE THERE FORUMS OUTSIDE THE COURT SYSTEM IN WHICH IT IS POSSIBLE TO ASSERT PATENTS IN YOUR JURISDICTION? IF SO, UNDER WHAT CIRCUMSTANCES MIGHT IT BE APPROPRIATE TO USE THEM?

A customs suspension to prevent the import of infringing products is available. A panel appointed by customs reviews the case. However, the panel often waits for a court decision, especially in a complex case; therefore, the effectiveness of the customs suspension is often limited for patent owners.

Q | IN WHAT CIRCUMSTANCES DO COURTS IN YOUR JURISDICTION ACCOMMODATE REMOTE HEARINGS, FOR EXAMPLE, DURING PANDEMIC-RELATED LOCKDOWNS?

Most hearings can be held remotely as long as the court finds it adequate and both parties agree; however, the final oral hearing should be held in person.

Q | ARE THERE ANY OTHER NOTABLE ISSUES RELATING TO THE ENFORCEMENT SYSTEM IN YOUR JURISDICTION?

Japanese courts have been very pro-patentee in the past few years, which makes Japan an attractive jurisdiction in which to file infringement lawsuits. At the same time, the patent infringement risks are larger, and companies are strongly advised to conduct a thorough risk evaluation when providing their products or services in Japan.



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Philippines: Low Numbers of Filings Expose Key Challenges in Pursuing Litigation

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Summary

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IN SUMMARY

In the past decade, only a handful of patent litigation cases have been filed in the Philippines despite the increasing number of patent applications. Patent cancellation cases only account for 1 per cent of inter partes cases filed with the Intellectual Property Office of the Philippines while the number of patent infringement cases is less than half of those involving trademarks. In this article, we give an overview of patent litigation in the Philippines and identify the considerations and challenges faced by patent rights holder.

DISCUSSION POINTS

- Patent applications have been steadily increasing, although this increasing trend is not observed in relation to patent litigation cases
- The limited number of patent litigation cases filed annually reflects the challenges faced by rights holders in pursuing patent actions in the Philippines

REFERENCED IN THIS ARTICLE

- IPOPHL
- IP Code
- Office of the Prosecutor
- Court of Appeals
- Supreme Court
- Bureau of Customs

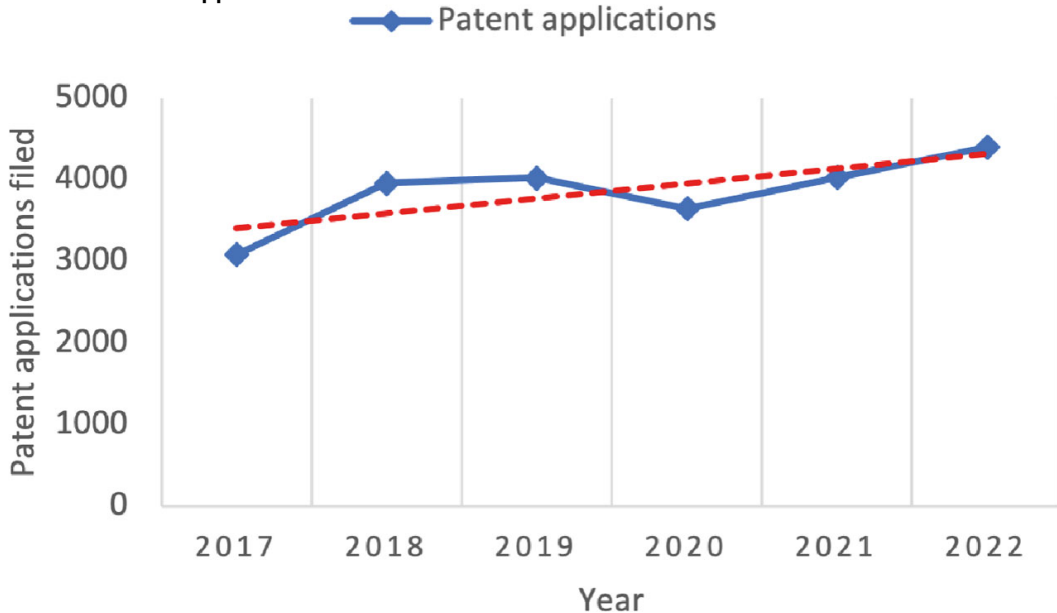
Injunctions At A Glance

Preliminary injunctions – are they available, how can they be obtained?	The patent rights holder must show that (1) it is entitled to the injunction, (2) it would be severely harmed by commission, continuance or non - performance of the act in question if it were to continue or (3) a person is actively, or is threatening or attempting, to commit acts violating the rights in question.
Permanent injunctions – are they available, how can they be obtained?	During trial, the patent rights holder must establish that it is entitled to have the acts in question permanently enjoined.
Is payment of a security/deposit necessary to secure an injunction?	Unless exempted, the patent rights holder must execute a bond in the amount to be fixed by the judge or hearing officer.
What border measures are available to back up injunctions?	The patent rights holder may request the Bureau of Customs to monitor and inspect, on its own initiative, suspected imports and to issue an alert or hold order against

any imports that are suspected to contain infringing goods.

Patent applications in the Philippines have been steadily increasing over the years. Although the outbreak of the covid-19 pandemic in 2020 triggered a drop in patent filings, the growth trajectory has since recovered (see Chart 1);^[1] for 2021 and 2022, the Intellectual Property Office of the Philippines (IPOPHL) has reported year-on-year growth in patent filings of 10 per cent and 9.3 per cent, respectively.^[2]

Chart 1: Patent Applications Filed From 2017 To 2022



A similar growth trajectory is present in trademark applications (see Chart 2), which reflects the IPOPHL's active promotion of IP rights in the Philippines.

Chart 2: Trademark Applications Filed From 2017 To 2022



This increasing trend, however, is not observed in relation to the number of IP cases filed with the IPOPHL. Despite rising awareness of the necessity of protecting IP rights through

registration, filing of litigation cases, which is reflective of the propensity to protect and enforce IP rights, remains limited. In the past decade, patent cancellation and infringement cases filed with the IPOPHL have only numbered around seven and six cases per year, respectively.^[3]

In this article, we will discuss the considerations and challenges facing patent rights holders in pursuing patent litigation in the Philippines.

OVERVIEW OF PATENT LITIGATION IN THE PHILIPPINES

In the Philippines, patent litigation includes inter partes cases (ie, cancellation cases) and IPR violation cases (infringement cases).

Patent cancellation cases are filed with the IPOPHL, specifically its Bureau of Legal Affairs (BLA). A patent, or any of its claims or parts of a claim, may be cancelled on any of the following grounds:

- the subject invention is not new or patentable;
- the patent disclosure is not sufficiently clear and complete for it to be carried out by a person skilled in the art; and
- the patent is contrary to public order or morality.

On receipt of a petition for cancellation, the BLA requires the respondent-patentee to file its answer. The case is then referred to a mediation proceeding for the parties to explore the possibility of amicable settlement. If no settlement is reached, the case undergoes a preliminary conference for clarification and simplification of the issues, stipulation of facts, and submission or presentation of documents and other evidence. The parties then submit their respective position papers, and the case is deemed submitted for decision.

Patent infringement cases may be filed with the IPOPHL as an administrative complaint or with the commercial courts as a civil action. The commencement of an administrative complaint with the IPOPHL is independent of and without prejudice to the filing of a civil action with a commercial court; however, resort to both options may amount to forum shopping, which is a ground for dismissal of the case.

The IPOPHL has exclusive original jurisdiction to an administrative complaint for patent infringement, provided that the total damages claimed is not less than 200,000 Philippines pesos. Once the complaint is filed, a summons is issued requiring the respondent to file its answer. The case then undergoes a pretrial conference in which the parties simplify the issues, stipulate the facts and explore the possibility of amicable settlement. The case proceeds to trial, where each party is given eight months to present and offer their witnesses and evidence, and an additional period of two months for their rebuttal and surrebuttal evidence. The parties then submit their respective memoranda, and the case is deemed submitted for decision.

A civil action for patent infringement is filed with the regional trial court designated as a special commercial court (SCC). Similar to the procedures in an administrative complaint, a summons is issued directing the respondent to file its answer. The case undergoes a pretrial conference and mandatory court-annexed mediation. If no settlement is reached, the case proceeds to trial. In some instances, the judge may submit the case immediately for decision upon termination of the pretrial conference or may require clarificatory hearings if necessary.

On termination of the pretrial conference, clarificatory hearing or trial, the judge issues a decision on the case.

In a patent infringement case, whether an administrative complaint or civil action, the patent rights holder may recover damages, attorneys' fees and other litigation expenses and secure a permanent injunction and destruction order. The IPOPHL may impose a fine of 5,000 to 150,000 Philippines pesos in an administrative complaint.

Although unlikely, a criminal action for patent infringement may be pursued if infringement is repeated after a court has found the defendant guilty of a previous infringement. A criminal action is commenced by filing a complaint affidavit with the Office of the Prosecutor for a preliminary investigation. If the prosecutor finds probable cause, an 'information' is filed with the court, which then conducts the trial and renders judgment. If found guilty, a penalty of imprisonment from six months to three years and a fine of 100,000 to 300,000 Philippine pesos may be imposed on the defendant.

The decision in a patent cancellation or infringement case rendered by a hearing or adjudication officer of the BLA is appealable to the BLA director, whose decision is further appealable to the director general of the IPOPHL. In turn, the decision of the director general of the IPOPHL, as well as the decision of a commercial court in a civil action for patent infringement, can be appealed to the Court of Appeals and finally to the Supreme Court. In the Philippines, it is quite common for cases to be escalated to the Supreme Court.

While filing the patent infringement action (whether with the IPOPHL or the commercial court), or anytime during the pendency of the case, the patent rights holder may apply for the issuance of a preliminary injunction. To obtain a preliminary injunction, the patent rights holder must establish that:

- it is entitled to the injunction, and the whole or part of the injunction comprises restraining the commission or continuance of the act or acts complained of, or requiring the performance of an act or acts, either for a limited period or perpetually;
- the commission, continuance or non-performance of the act or acts complained of during the litigation is likely to result in injustice to the patent rights holder; or
- a party or any person is doing, threatening, is attempting to do or is procuring the commission of an act or acts that infringe the rights that are the subject of the action or proceeding, rendering the judgment ineffective.

Prior to the resolution of the application for a preliminary injunction, a summons is issued requiring the respondent to file its comment. If granted, the resolution sets the amount of the cash bond to be executed by the applicant. If it is later shown that the applicant is not entitled to a preliminary injunction, the bond will be used to pay for the damages sustained as a result of issuing the injunction.

In matters of urgency, the patent rights holder may apply for a temporary restraining order, which is effective for only 20 days. In matters of extreme urgency, the patent rights holder may apply for a temporary restraining order that is effective only for 72 hours. A certification from the patent holder, the expert or the competent authority that the products are infringing, and if it is determined that continuing access to the products by the public poses a danger and risk to life, health and public safety, may be considered a matter of extreme urgency, with the potential to result in great injustice to the patent rights holder.

In addition to obtaining an injunction order, the patent rights holder may request the Bureau of Customs to monitor and inspect, on its own initiative, suspected imports and to issue an alert or hold order against any imports that are suspected to contain infringing goods.

STATISTICS OF PATENT CASES FILED WITH THE IPOPHL

Only an average of seven patent cancellation cases have been filed annually with the IPOPHL in the past decade. As shown in Table 1, they account for only 1 per cent of inter partes cases filed with the IPOPHL.

Table 1: Inter Partes Cases Filed With The IPOPHL In 2012 To 2022

Year	Trademarks ^{[[4]]}	Patents
Average	632	7
2012	603	7
2013	483	8
2014	554	4
2015	602	15
2016	776	14
2017	661	8
2018	709	6
2019	719	3
2020	546	3
2021	748	4
2022	548	6

The average number of patent infringement cases filed with the IPOPHL for the same period is even lower at around six cases per year. In contrast, trademark infringement cases account for more than double this value (see Table 2).

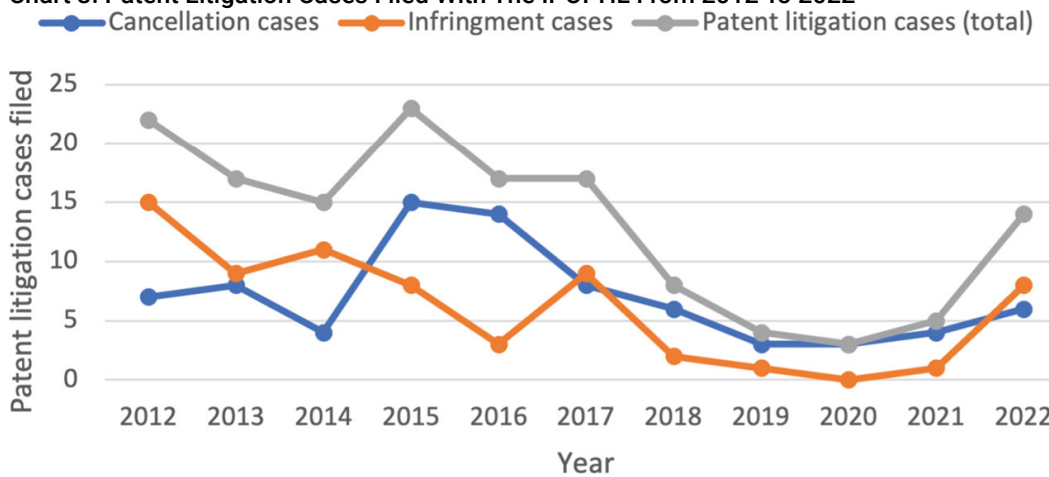
Table 2: Infringement Cases Filed With The IPOPHL In 2012 To 2022

Year	Trademarks	Patents
Average	14	6
2012	9	15
2013	20	9
2014	23	11
2015	17	8
2016	15	3
2017	12	9

2018	28	2
2019	5	1
2020	7	0
2021	13	1
2022	8	8

While these data do not include patent infringement cases filed with commercial courts,^[5] it is reflective of the rarity of patent infringement actions in the Philippines. In total, the average number of patent litigation cases (cancellation and infringement cases) filed with the IPOPHL is only around 13 cases per year. The average from 2018 to 2022 is even lower at around 6.8 cases per year. Unlike the increasing trend in patent applications, the number of patent litigation cases has dropped (see Chart 3). Even if the effect of the covid-19 pandemic is taken onto account, the number of cases for the preceding years are still low.

Chart 3: Patent Litigation Cases Filed With The IPOPHL From 2012 To 2022



CONSIDERATIONS AND CHALLENGES IN PATENT LITIGATION

The limited number of patent litigation cases filed annually reflects the challenges faced by rights holders in pursuing patent actions in the Philippines. The cost, length and venue of litigation, as well as the evidence and expertise required, in relation to the profitability of the invention and the remaining term of patent protection are some of the considerations that are taken into account. Quite often, these considerations are seen as deterrents disincentivising rights holders from instituting patent litigation cases in the Philippines.

Cost Of Litigation Versus Profitability Of Invention

One of the primary considerations in deciding whether to pursue a patent litigation case is the costs involved. Litigating in the Philippines can be quite expensive owing to the various proceedings the case must undergo, the evidence and witnesses that must be presented, and the time taken for a decision to be reached.

The attorneys’ fees involved in prosecuting a patent cancellation case may cost over US\$10,000, and even over US\$20,000 for a patent infringement case. These are conservative estimates, and the costs may go up to as much as twice these values depending on several factors, such as the complexity of the invention; the extent of evidence and the number of

witnesses, including experts, that will have to be presented; and the number of respondents. The costs may further increase if the decision, or any order or resolution, is appealed or subjected to a review. As discussed above, there are several stages of appeal, and litigation cases are often elevated to as high as the Supreme Court.

In this regard, prior to instituting a patent litigation case, the patent rights holder usually assesses the profitability of its invention in relation to the cost of litigation. This assessment takes into consideration the profitability of the invention not only at the time of infringement but also by the time a final decision is likely to be made. Although the patent rights holder may eventually win the litigation, by the time a final decision is issued, a new generation of products may have been introduced in the market, thereby diluting the impact of a favourable decision.

Depending on the field of technology to which the invention belongs, the marketability of an invention may rapidly decline over the years. Some fields have witnessed rapid advancements in technology, such as telecommunications, in which new products with better features are constantly introduced in the market; therefore, the profitability of the invention and the costs of litigation are taken inconsideration in instituting a patent action.

Length Of Litigation Versus Term Of Protection

The patent rights holder must also consider the length of litigation. A case normally undergoes various stages of proceedings: from the preparation and filing of the complaint to the preliminary, mediation and pretrial conferences, and to the trial and judgment. Generally, it takes at least two years for a decision to be rendered in a cancellation case, and three years in an infringement case. Since the decision and the orders and resolutions issued during the proceedings are subject to multiple stages of appeal or review, obtaining a final and executory decision may take a considerable length of time. It is quite common for a patent to have already expired before a decision is rendered or becomes final.

Under the IP Code, invention patents have a non-renewable term of 20 years.^[6] If the patent sought to be cancelled has already expired, the cancellation case will likely be dismissed on the ground of mootness since there is no patent to be cancelled or upheld. In that event, the merits of the case will no longer be delved into, the issue on the validity of the patent remains unresolved, and the rights appertaining to it remain unclear.

In contrast, patent infringement cases can survive the expiration of the patent. The IP Code allows the patent rights holder to collect damages within four years of the time the cause of action arose. As long as the patent infringement case is filed within the four-year period, the expiration of the patent should have no effect.

The remaining term of protection and the projected length of litigation are also considered by patent rights holders when deciding whether to pursue a patent litigation case.

Evidence And Expertise Required

Unlike trademark litigation cases, patent litigation cases require technical evidence and expertise. Whether in a patent cancellation or an infringement case, this technical requirement entails more time and cost.

In trademarks, it is usually sufficient to visually and aurally compare the competing marks to determine confusing similarity. In contrast, mere visual inspection of a product or the claims of a patent is inadequate. Further analysis and testing must be done by an expert person

skilled in the art. Accordingly, litigating patent cases necessitates employing technical analysis and expert witnesses. Moreover, because of the technical nature of the evidence, more hours are spent in the preparation and presentation of evidence, which results in further costs.

The technical evidence and expertise required in patent cases means that obtaining a preliminary injunction against a patent-infringing product is not a straightforward matter. In those cases, the judge or hearing officer can be expected to wait for a full trial before deciding whether to issue an injunction.

Venue Of Litigation

Patent cancellation cases are instituted with the IPOPHL while patent infringement cases may be filed as an administrative complaint with the IPOPHL or as a civil action with commercial courts; however, filing an administrative complaint for patent infringement case with the IPOPHL has certain advantages.

Commercial courts hear and try numerous cases with different causes of action, not limited to IP matters. Often, this results in a full docket and affects the speed at which cases are heard and decided. On the other hand, the IPOPHL has a significantly lower docket because of its limited and highly specialised jurisdiction; therefore, it is expected to render decisions faster than commercial courts.

Second, patent cases require comprehension of technical matters. Since the hearing officers of the IPOPHL are routinely deciding on technical matters, they have more experience in understanding, analysing and deciding patent infringement cases compared to commercial court judges; therefore, it is usually easier to present evidence and prove infringement before the IPOPHL.

Lastly, the standard of proof required for administrative cases filed with the IPOPHL is substantial evidence, or relevant evidence that a reasonable mind might accept as adequate to support or justify a conclusion. In contrast, civil cases heard by commercial courts involve more technical and strict evidential rules. In civil cases, the standard of proof required is preponderance of the evidence, which means that the evidence as a whole adduced by one side is superior to that of the other. Considering the lower standard of proof required, establishing infringement is easier in administrative cases.

CONCLUSION

While patent applications with the IPOPHL have witnessed an upwards trend over the years, the same cannot be said for patent litigation. Compared to trademarks, patent cancellation and infringement cases account for only a handful of filings every year.

This is symptomatic of the challenges faced by patent rights holders in pursuing patent litigation actions in the Philippines. The cost, length and venue of litigation; the resources, evidence and expertise required; the profitability of the invention; the impact of the decision on the business; and the remaining term of patent protection are some of the considerations that must be considered to incentivise patent rights holders to be more active in enforcing their rights in the Philippines. By overcoming these challenges, the Philippine patent litigation landscape will become more dynamic and encourage more innovation.

Endnotes



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South Korea: Recent Legislative Reforms and Judicial Efforts Expected to Improve Patent Enforcement Environment

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[Kim & Chang](#)

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IN SUMMARY

Recent patent law developments have substantially improved the patent enforcement environment in Korea. Patent litigation in Korea often involves simultaneously handling an infringement action before the district court and an invalidation action before the IPTAB, and a number of changes have been made to streamline those parallel proceedings. With little or no 'home-court advantage' in Korean courts and the establishment of international panels, Korea is becoming a more attractive venue for foreign parties.

DISCUSSION POINTS

- Key aspects of the Korean patent litigation system
- Benefits of recent patent law developments to patentees
- Impact of recent court decisions on the pharmaceutical industry
- Korea as an attractive patent litigation venue for foreign parties

REFERENCED IN THIS ARTICLE

- Patent Act and the 2016, 2019, 2020 and 2021 amendments to the Act
- Supreme Court, Case No. 2019Hu10609, 8 April 2021
- Supreme Court, Case No. 2022Hu10210, 2 February 2023
- IP High Court Case No. 2020Huh5832, 17 February 2022

Injunctions At A Glance

Preliminary injunctions – are they available, how can they be obtained?	Preliminary injunctions are available. A preliminary injunction action can be filed at the district court and may take four to eight months.
Permanent injunctions – are they available, how can they be obtained?	Permanent injunctions are available as injunctive relief in infringement actions filed at the district court. An infringement action generally takes 10 to 20 months to be resolved at the district court.
Is payment of a security/deposit necessary to secure an injunction?	Courts may issue a preliminary injunction order without requesting a security deposit, but they generally require the plaintiff to post a security bond before enforcing the order. A permanent injunction order is not enforceable until the decision that issued the order becomes final and conclusive; however, if a court issues a provisional enforcement order with the permanent injunction order, the plaintiff can enforce the injunction immediately.
What border measures are available to back up injunctions?	An action before the Korea Trade Commission (KTC) is available, and an

order against importation or exportation of infringing goods can be obtained from the KTC. A customs action before the Korea Customs Service (KCS) is available, and a suspension request can be filed against infringing imports with the KCS.

INTRODUCTION

In recent years, numerous changes in the patent law (eg, expanded discovery and higher damages) have substantially improved the patent enforcement environment in Korea. The Korean Intellectual Property Office (KIPO) has been taking steps to improve the quality of examinations and reduce the invalidation rates of issued patents^[1]. The judiciary has also been making efforts to make Korea a more attractive venue for foreign companies to litigate. This article will first discuss a few key aspects of patent litigation in Korea that practitioners in other jurisdictions may not be familiar with and then highlight some of these recent changes in the Korean patent litigation landscape.

KEY ASPECTS OF PATENT LITIGATION IN KOREA

Bifurcated System

Korea has a bifurcated system in which patent infringement and validity are decided in separate proceedings in different forums: infringement actions are initially handled at first instance by the district courts, and invalidation actions are initially handled by the Intellectual Property Trial and Appeal Board (IPTAB) within KIPO. Although patent validity can be challenged as a defence in an infringement action in court (a court may review validity and dismiss the infringement case if it finds that the patent is clearly invalid), a patent can only be formally invalidated through an invalidation action before the IPTAB.

Parallel Proceedings In District Courts And The IPTAB

Patent litigation in Korea often involves parallel proceedings in the relevant district court and the IPTAB. A court may stay an infringement action pending the conclusion of an invalidation action, and whether the court stays the case depends on a number of factors, such as the tendencies of the judges in the court panel, the docket load and the number of patents asserted. Accused infringers often file an invalidation action after a patent infringement suit is filed, and courts often stay the infringement action pending the outcome of the invalidation action.

While an infringement action generally takes 10 to 20 months to be resolved in a district court (assuming that one patent is asserted), an invalidation action may take four to 14 months to be resolved at the IPTAB. An invalidation action may be expedited by the IPTAB (taking as little as four to six months) if there is a pending infringement action involving the same patent, but an invalidation action may take longer if the patentee files a correction petition to amend the claims during the invalidation action.

Invalidation actions and infringement actions can be appealed to the IP High Court,^[2] which is a specialised court that hears IP matters with nationwide jurisdiction, and final appeals are handled by the Supreme Court. Inter partes cases are heard de novo by the IP High Court; the IP High Court can consider new evidence (eg, a new prior art reference) and arguments in the appeal even if they were not asserted at the lower level.

The system for patentees to file corrections is flexible albeit complicated at times. In response to an invalidation action, a patentee may file a correction petition to narrow the claims, correct typos or clarify ambiguous language. Corrections can be made multiple times as the patentee can file a correction petition whenever the petitioner submits a new argument or new evidence. The IPTAB reviews the petition to decide whether to accept it, and if it is accepted, it will render a decision on the invalidation action based on the corrected claims.

Since the correction petition is submitted during the invalidation action, the petition (and, therefore, the corrected claims) becomes final only when the IPTAB's invalidation action decision validating the patent becomes final after the appeal proceedings, if any. Further, even if the IPTAB's invalidation action decision is unfavourable to the patentee, the patentee may file a separate correction action at the IPTAB for further or different corrections of the claims in view of the IPTAB's decision in the invalidation action.

Corrections can significantly complicate and prolong the litigation process, and recent Supreme Court decisions have placed limits on the correction practice to streamline litigation proceedings.^[3]

In connection with streamlining litigation proceedings, the Patent Act was amended in 2021 to include a new provision requiring timely submission of arguments and evidence in IPTAB proceedings. In practice, parties can submit new arguments or evidence virtually at any point in an IPTAB proceeding (eg, an invalidation action) as long as the proceeding is not closed. IPTAB trial examiners may set a deadline for the submission of arguments or evidence, but parties can submit a brief with little substantive content to meet the deadline and then later submit additional briefs or evidence to supplement the earlier brief. This practice often leads to delays and prolongs litigation.

It remains to be seen how this new 'timely submission' requirement is being implemented to change this practice; nevertheless, it may help streamline litigation in the future.

Permanent And Preliminary Injunctions

A patentee has a choice of filing an infringement action at the district court to obtain a permanent injunction and damages, or filing a preliminary injunction action at the district court to obtain a preliminary injunction only.

A patentee who prevails in an infringement action is entitled to a permanent injunction as a matter of right; however, a permanent injunction order is not enforceable until the decision issuing the order becomes final and conclusive. If a court issues a provisional enforcement order (which is commonly granted) together with the permanent injunction order, the patentee can enforce the order immediately. The alleged infringer is likely to appeal the decision and request a stay of the provisional enforcement, which is often granted by the court, provided that the defendant pays a security deposit. Since an infringement action generally takes 10 to 20 months to be resolved at the district court, and the appeal process could take up to a few years, an enforceable permanent injunction is not quickly obtainable.

On the other hand, while a preliminary injunction action may take only four to eight months at the district court, and a preliminary injunction is immediately enforceable, a preliminary injunction is generally more difficult to obtain. A patentee can seek one if there is an imminent risk of irreparable harm to the it. The patentee must show prima facie infringement and the need for provisional relief.

In determining whether there is a need for provisional relief, the irreparable harm to the patentee owing to infringement is generally balanced against the economic harm to the alleged infringer if an injunction is granted. Courts may issue a preliminary injunction order with or without requesting a security deposit, but they generally require the plaintiff to post a security bond before proceeding to enforce the preliminary injunction in case the order is later reversed or revoked on appeal. A preliminary injunction is enforceable while the appeal is pending.

RECENT PATENT LAW DEVELOPMENTS FAVOUR PATENTEES

Significant changes in the patent law in the past few years have improved the patent enforcement environment for patentees in Korea.

Expanded discovery

While discovery is limited in Korea,^[4] amendments to the Patent Act in 2016 have made it easier for patentees to obtain documents from defendants to prove infringement and damages. The scope of document production orders has been expanded to allow evidence of infringement to be subject to production. Further, accused infringers may no longer refuse to respond to a document production order by claiming that the requested materials contain trade secrets, as had often been the case in the past, if those materials are necessary to prove infringement or damages. The courts also have the discretion to presume that 'the facts that the requesting party intended to prove based on the requested materials' are true if the requested materials are not produced and it would clearly be difficult for the requesting party to prove those facts without the requested materials.

On the other hand, accused infringers may request the court to limit the scope of access to information, such as by limiting access to certain portions of the materials or limiting who may have access to the materials. The courts can also review documents in camera to determine whether the materials contain trade secrets and can implement protective orders to restrict access.

These changes to discovery have been particularly helpful for patentees that need to obtain evidence to prove infringement of method patents but that have no access to the accused infringer's premises.

Actual Product Or Process Must Be Described To Deny Infringement

An amendment to the Patent Act in 2019 has made it more difficult for an accused infringer to deny infringement when the patentee has made a prima facie showing of infringement: an accused infringer must now provide details about the product or process that it is actually using. If the accused infringer refuses to provide those details without reasonable justification, the court may assume that the accused infringer has actually committed the infringing activity as claimed by the patentee.

Treble Damages For Wilful Infringement

A new provision was added in the 2019 amendments to the Patent Act to provide courts with the discretion to award damages of up to three times the amount of actual damages as a punitive measure in cases of wilful infringement. Courts take into consideration the following factors to determine the amount of punitive damages:

- whether the infringer is in a dominant position;

- the infringer's wilfulness or the degree to which the infringer perceived a risk of harm to the patentee;
- the scale of the harm suffered by the patentee because of the infringement;
- the economic benefits to the infringer from the infringement;
- how frequently and how long the infringing activity was committed;
- the criminal penalty for the infringing activity;
- the infringer's financial status; and
- the efforts that have been made by the infringer to remedy or reduce the harm to the patentee.

Reasonable Royalties For Excess Infringing Sales

In addition to lost profits for infringing sales up to the patentee's production capacity, an amendment to the Patent Act in 2020 now allows patentees to claim a reasonable royalty for the infringer's sales in excess of the patentee's production capacity. The amendment aims to protect patentees that are small or medium-sized companies with smaller production capacities.

Software Patents

An amendment was made to the Patent Act in 2020 that broadened the scope of method patents. Patentees are now more incentivised to enforce their software patents against online transmissions of a program. Software inventions are patentable subject matter if the claims concern certain statutory categories (eg, methods, apparatuses, computer-readable mediums (having a computer program or data recorded thereon) and computer programs stored on storage mediums). Before the amendment, online transmission of a program did not constitute practising a method.

The amendment expanded the meaning of 'practising' a patented invention to include the act of offering a process for use; in other words, practising a process invention means 'an act of using the process or an act of offering the process for use'.

Another amendment to the Patent Act added a subjective 'knowledge' requirement to an act of offering a process for use; therefore, to enforce a patent against online transmission of a program, the patentee must show that the alleged infringer knew that the use of the process would infringe the patent. To do so, patentees should consider sending cease-and-desist letters to potential infringers.

SIGNIFICANT COURT DECISIONS INVOLVING PHARMACEUTICAL PATENTS

In recent years, there have been a number of Korean court decisions that have had a positive impact on the patentability of pharmaceutical inventions. Two key cases are highlighted as examples.

Supreme Court Relaxes Patentability Standard Of Selection Inventions

The Supreme Court issued a landmark decision in 2021 that redefined the patentability standard of selection inventions.^[5] A selection invention is an invention where all or part of the constitutional elements of the invention are species of a genus in the prior art.

Before this decision, the inventiveness of a selection invention was based on its remarkable effects over the prior art, while the difficulty of deriving the features of the selection invention was ignored. The criteria of selection inventions was, therefore, criticised as being unduly strict.

In this decision, the Supreme Court upheld the validity of a selection invention patent and held that selection inventions should be reviewed under the same general inventiveness criteria as all other inventions by first taking into consideration the difficulty of deriving the features of the invention; therefore, the difficulty of deriving the features of the invention and remarkable effects should be considered.

The Supreme Court upheld the validity of a patent covering apixaban by:

- determining that the prior art disclosed a very broad general formula covering apixaban but did not disclose or suggest a motivation to develop its core structure or substituents, and that a person skilled in the art would have had to experiment with numerous combinations of selections to arrive at the subject invention; and
- finding that subject invention exhibited remarkable effects over the prior art.

Pharmaceutical Compound Patent Covers Generic Prodrugs

In a significant decision^[6] that substantially enhances the protection of innovative drug patents in Korea, the IP High Court and the Supreme Court confirmed that AstraZeneca's patent on the active ingredient in Forxiga (dapagliflozin) covered a generic product using a prodrug ester form of the active ingredient under the doctrine of equivalents during its patent term extension (PTE), even though the patent did not expressly claim the prodrug ester form because the term 'prodrug ester' was deleted from the patent claims during prosecution. The IP High Court determined that the deletion addressed a formality issue in response to the rejection from the KIPO rather than a substantive issue and that it would not have been difficult to conceive or develop the generic's prodrug over the claimed compound. The Supreme Court upheld the IP High Court's decision.

A PTE in Korea is limited to covering the original drug approval on which the PTE is based, and, in the past, generic pharmaceutical companies have tried to avoid or design around originator patents using different salt forms of the original approved active ingredient. These efforts of generic pharmaceutical companies were rejected by the Korean courts, which clarified that other salt forms are still within the scope of the patent as long as they involve the same pharmacological mechanism of action and would not have been difficult to conceive from the original approved salt form.

Dong-A ST tried a different strategy by developing a drug using a prodrug ester form of dapagliflozin with an added ester moiety. After the patient ingests the drug, that moiety would detach from dapagliflozin in the body instead of developing a different salt form. Although the prodrug did not provide a real advantage compared to Forxiga, Dong-A ST argued that the prodrug compound had a different chemical structure outside the literal scope of the dapagliflozin patent, and that the prodrug was not equivalent because AstraZeneca had deleted the term 'prodrug ester' from the claims during prosecution. The IPTAB agreed with Dong-A ST, and AstraZeneca appealed to the IP High Court.

The IP High Court overturned the IPTAB's decision, finding that the prodrug was an equivalent because it used essentially the same compound (dapagliflozin) to achieve its effect, and that

it would not have been difficult to conceive nor was it unexpectedly advantageous. Further, the court ruled that the deletion of 'prodrug ester' during prosecution did not clearly indicate AstraZeneca's intention to exclude prodrug esters from the patent scope, because the KIPO's general practice at the time was to reject any use of the term 'prodrug' in patent claims on formality grounds; deleting the term was, therefore, intended to quickly resolve the rejection, not to reduce the scope of the patent. The Supreme Court upheld the IP High Court's decision.

A MORE ATTRACTIVE VENUE FOR FOREIGN PARTIES

There is little or no 'home-court advantage' in Korean courts, so there is no need for foreign parties to be concerned about bias against foreign companies. For example, one study found that foreign patentees' success rates in patent cases with respect to damages claims were higher than Korean patentees' success rates.^[7]

The Korean judiciary has also been aiming to make Korea a global hub for patent litigation by making a number of changes, including allowing international panels in courts. International panels are panels of judges that allow the parties to submit evidence and present arguments in a foreign language, such as English, and issue a decision in the foreign language. If both parties in a patent litigation case agree, the case can proceed as an international case, to be heard by an international panel; therefore, for example, counsels may argue in English, or Korean with simultaneous English translation, and evidence can be submitted in English without a translation. International panels should make litigation more convenient and efficient for foreign parties.

CONCLUSION

This article has highlighted a number of recent changes that have substantially improved the patent enforcement environment in Korea, and it will be interesting to see their continuing impact in the coming years. With semiconductor, display and battery industries continuing to grow as key industries in Korea, and an increasing number of patent applications being filed in Korea for artificial intelligence, blockchain and metaverse-related inventions, there may be an increase in patent litigation in these technological fields in the future.

Endnotes

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Specialist Chapter: New Challenges in Proving Patent Infringement Damages in the United States

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Summary

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TYING FACTS OF THE CASE TO THE DAMAGES ANALYSIS

COMPARABILITY OF LICENCES

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IN SUMMARY

Over the past decade, the degree of scrutiny under which courts in the United States evaluate a party's damages calculations, and particularly the methodology employed by the damages expert in determining reasonable royalties, has changed. Parties file complex pre-trial Daubert motions attacking the admissibility of damages experts' testimony. The cases over the past year suggest that US courts now exercise more flexibility in what they find to be admissible.

DISCUSSION POINTS

- Tying facts of the case to the damages analysis
 - Comparability of licences
 - Temporal considerations
 - Apportionment
-

REFERENCED IN THIS ARTICLE

- *Daubert*

Over the past decade, the degree of scrutiny under which courts in the United States evaluate a party's damages calculations, and particularly the methodology employed by the damages expert in determining reasonable royalties, has changed. Parties file complex pre-trial Daubert^[1] motions attacking the admissibility of damages experts' testimony.^[2] For challenges addressing reasonable royalty damages, US courts apply a discerning eye to three main items:

- Has the expert tied the specific facts of the case to the methodology used to reach its opinion?
- Has the expert relied on sufficiently comparable licence agreements?
- Has the expert sufficiently apportioned the value of the patented technology from the unpatented aspects of the accused product?

Under Daubert, US judges do not hesitate to exclude damages opinions that fail to meet the demanding reliability requirements for admissibility.^[3] The escalation in excluding patent damages opinions under Daubert began in earnest about 10 years ago, with the courts initially being rigid in application of admissibility standards.^[4] The cases over the past year, however, suggest that US courts now exercise more flexibility in what they find to be admissible.

TYING FACTS OF THE CASE TO THE DAMAGES ANALYSIS

While US courts recognise that 'estimating a reasonable royalty is not an exact science',^[5] conclusory expert testimony on damages will not suffice in today's environment. An expert may not simply recite comments regarding the 15 Georgia-Pacific factors, and then pronounce that the patented invention deserves a certain royalty rate. Instead, the 'damages experts must not only analyze the applicable factors, but also carefully tie those factors to

the proposed royalty rate.^[6] This generally requires concrete reasons for how and why the patented invention or accused product meets or fails to meet a particular factor.^[7]

Additionally, the expert must ‘carefully tie proof of damages to the claimed invention’s footprint in the marketplace’. While sometimes overlapping with considerations of apportionment, this factor requires showing that any value that the accused product attained from infringing, which the expert relies on to support a royalty rate, must be attributed to the patented features and not to other unpatented features.^[8]

Damages opinions that a court likely would have excluded a few years ago can survive an admissibility challenge if the expert’s opinion is grounded in material relevant facts. For example, a district court recently allowed a reasonable royalty opinion that resulted in damages equalling 120 per cent of the accused infringer’s total sales revenues.^[9] The court found that the expert sufficiently tied his opinions to the facts of the case by presenting an analysis of public information showing that the likely sales price of the accused product was four times higher than the accused infringer contended.

COMPARABILITY OF LICENCES

Before an expert relies on a licence agreement as evidence of a proper reasonable royalty, the expert must show that the licence agreement addresses technologically similar subject matter under economic circumstances comparable to what the parties would face in the hypothetical negotiation (ie, the date the accused infringer first infringed).^[10]

Perfect comparability between a patent licence agreement and the hypothetical negotiation rarely exists. An agreement may provide for a lump sum payment while the expert seeks a running royalty. The agreement may address a portfolio of patents where the infringement only addresses one or two patents from that portfolio. Agreements may address variations in the technical subject matter. Experts failing to acknowledge these differences, or conclusory opining the differences do not matter, may see their opinions struck. Recent cases, however, show that experts that provide non-conclusory plausible explanations, tied to the facts of the case, for how the relevant differing aspect of the licence agreement can be adjusted to fit within the parameters of the case’s hypothetical negotiation often survive a Daubert challenge as they have established a ‘baseline comparability’.^[11]

TEMPORAL CONSIDERATIONS

For infringement cases litigated 20 years ago, the law appeared to implicitly assume that a licence agreement reached far away in time from the date of the hypothetical negotiation could not be comparable.^[12] That view no longer prevails. Recent cases show that:

damages experts are permitted to rely on license agreements entered years after [or before] the hypothetical negotiation date so long as the expert details the facts and circumstances that led the expert to conclude that the license agreement is technically and economically comparable to the hypothetical license in th[e] case.^[13]

APPORTIONMENT

Unless the patented feature in the accused product drives its sale, US law requires that ‘the ultimate reasonable royalty award must be based [only] on the incremental value that the patented invention adds to the end product.’^[14] This requirement, referred to as

apportionment, plays an important role in determining damages where the accused product has multiple components or features. Many damages opinions fall in a Daubert challenge for a failure to sufficiently apportion.

A few years ago, as one apportionment methodology, US courts began requiring that a patentee limit the royalty base to the smallest salable patent-practising unit (SSPU).^[15] However, it soon became evident that the SSPU methodology was not easy or proper to apply in many instances. In some cases, the patented feature was merely one component of the SSPU, and thus an apportionment beyond the SSPU was needed.^[16] In other instances, available licence agreements were directed only to the overall end product.

In the first steps of bringing some flexibility to apportionment, courts recognised that an economist can apportion:

in various ways—by careful selection of the royalty base to reflect the value added by the patented feature, where that differentiation is possible; by adjustment of the royalty rate so as to discount the value of a product’s non-patented features; or by a combination thereof.^[17]

For example, where an expert can provide non-conclusory testimony showing that a licence agreement is comparable to the patented invention and that the agreement has built-in apportionment relevant to the patented technology, the expert does not necessarily have to supply a quantitative apportionment.^[18] Parties may also rely on other products, even later developed products, as a ‘benchmark’ when determining a reasonable royalty where those benchmark products are shown to be technologically comparable to the asserted patents.^[19]

CONCLUSION

The foregoing shows that, while the law may now allow for greater variety of ways to support a patent-damages opinion, many pitfalls lurk in the background that can thwart the effort to successfully prove damages. Wise litigants will retain and involve a competent damages expert from the outset of the matter and work closely with that expert to make the opinion as strong as possible to withstand the inevitable Daubert challenge.

Endnotes



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Colombia: Why a Robust Patent System is Leading to Litigation Wins

Andrés Rincón and Eliana Portilla

Cavelier Abogados

Summary

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IN SUMMARY

This article presents a general approach to understanding patent litigation in Colombia, giving insight into how the jurisdiction and competence works and discussing other key aspects regarding patent enforcement, including preliminary actions allowed by the procedural code and the stages and timing of infringement actions, among other things.

DISCUSSION POINTS

- Jurisdiction and competence over infringement
 - Award of damages
 - Judicial injunctions
 - Pre-litigation evidence request
 - Stages within the patent infringement process
 - Bifurcated path between infringement and invalidity
 - Doctrine of equivalents and prosecution history estoppel
-

REFERENCED IN THIS ARTICLE

- Colombian Criminal Code
- Colombian Procedural Code
- Ericsson v Apple
- Telemetrik v Excelec

Colombia is a World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) standard country and Patent Cooperation Treaty member, with a post-grant opposition patent system and an absolute novelty standard, allowing patents in all fields of technology after a substantial examination is carried out. Granted patents within the fields of mechanics, software-implemented inventions, telecommunications and pharma, among others, are fully enforceable before Colombian criminal and civil courts, with a separate path for infringement and validity.

Colombian patents do not grant their holders the right to carry out the invention. Instead, they grant the right to prevent third parties without the holder's consent from manufacturing, offering for sale, selling, importing for any purpose, or using the patented product, process or product obtained directly through a patented process.

Therefore, any person holding Colombian patent rights has legal standing against any person infringing their right or against those performing acts that manifest the imminence of an infringement. In the case of co-ownership of a patent right, any of the co-owners may bring an action related to patent infringement without the consent of the others being necessary, unless otherwise agreed between the co-owners.

Although provisional protection rights do not exist for pending patents and the applicant does not have legal standing to initiate patent infringement actions or preliminary injunctions

in such instances, as soon as the patent is granted, any legal action taken towards infringement would allow the patent holder to claim damages as from the publication date of the patent application.

Patent infringement actions are barred after two years from the date on which the owner became aware of the infringement or five years from the date on which the infringement was last committed.

JURISDICTION AND COMPETENCE OVER INFRINGEMENT

Infringement actions might be sought before criminal or civil courts. However, criminal actions for patent infringement are rare and limited to anticounterfeiting goods, especially when it may represent a danger for human or animal health.

For civil actions, patent holders may choose between the ordinary courts of the circuit, where infringement takes place, or the ordinary circuits where the defendant is domiciled or incorporated. In addition, as of 2012, the Colombian Patent Office was given preferred national jurisdiction for infringement actions associated with industrial property rights through an independent judicial branch. In any case, regardless of the preferred jurisdiction chosen by the plaintiff, infringement procedures are essentially of oral nature in double instance procedures, and appeal remedies take place before a superior tribunal.

The Colombian Patent Office's judicial branch (CPOJB) is an independent branch of the Patent Office. While the latter takes care of patent prosecution on an administrative level, the CPOJB has public officials who are, by all means, judges who must abide by the procedural rules in the same manner as civil judges do. The difference between the CPOJB and ordinary civil judges is that the latter have residual jurisdiction, whereas the CPOJB ones only know about unfair competition actions and industrial property infringement. None of the Colombian judges, either ordinary or from the CPOJB, has a technical background, but it is fair to say that the CPOJB is the closest to a specialised jurisdiction for industrial property affairs.

The only forum shopping with respect to patent infringement actions is that allowing a choice between the CPOJB and civil circuit judges. However, it is not possible to choose a particular judge, because once an action is filed, the case is randomly distributed among the judges (in Bogotá alone, there are more than 50 civil circuit judges).

AWARD OF DAMAGES

Courts may award damages to the patent holder as monetary compensation for patent infringement. To calculate those, Colombian legislation establishes the following criteria:

- the consequential damage and the loss of profits suffered by the rights holder as the result of the infringement;
- the amount of the profits earned by the infringer as a result of the infringing acts; and
- the price that the infringer would have paid for a contractual licence, considering the market value of the rights infringed and the contractual licences that have already been granted.

However, compensation shall only proceed with respect to the subject matter covered by the granted patent and shall be calculated based on the exploitation carried out by the defendant.

Furthermore, as previously mentioned, the patent holder may request the recognition of damages for the unauthorised use of its patent during the period between the application's publication in the gazette for industrial property matters of the Colombian Patent Office and the date on which the granting resolution is issued.

JUDICIAL INJUNCTIONS

Colombian legislation and practice provide patent holders with the possibility to obtain injunctive relief. In that sense, judicial injunctions seek to prevent infringement from occurring, to avoid consequences when it has already occurred or continues to occur, to obtain or preserve evidence to further file a complaint on the merits, and to ensure the compensation of damages.

With the appropriate technical evidence, it is possible to request and obtain preliminary injunctions either *ex parte* or *inter partes*. Nevertheless, *forex parte* procedures, if the alleged infringer becomes aware of the existence of an *ex parte* process, it may request the court to switch procedures to *inter partes*, so that both parties are heard before a decision over injunction is made.

Local provisions comprise a non-exhaustive list of injunctions, including:

- the immediate halt of the acts constituting the alleged infringement;
- the removal of the products resulting from the alleged infringement, including the containers, packaging, labels, printed or advertisements or other materials, as well as the materials and means that predominantly served to commit the infringement;
- the halt of the import or export of the products, materials or means that predominantly served to commit the infringement;
- the placement of a bond by the alleged infringer; or
- the temporary closure of the defendant's or respondent's establishment when necessary to prevent the continuation or repetition of the alleged infringement.

However, the petitioner or the court may request or declare any other measure it deems appropriate.

The scope of the injunction will depend to a great extent on the way in which it is requested by the petitioner. These are usually requested in a very broad manner, so that they cover all existing and future products containing the patented product or process, and all forms of use, sale offerings, commercialisation, imports and exports, by any physical or digital means and by any natural or legal person, whether a current or future distributor or any other third party. Moreover, courts may issue an injunction as requested by the petitioner or may tailor it as appropriate.

The purpose of the injunction is to avoid the continuation of the alleged infringement of the patent, so that both the court *ex officio* or the petitioner may request the extension of its scope at any time, covering new channels or third parties identified during the execution process of the injunction order.

The *sine qua non* requirements for a court to grant an injunction are:

- the existence of an allegedly infringed right (*fumus bonis iuris*);
-

the reasonable evidence of existence of the infringement or imminence of the infringement; and

- the fact that not having the injunction may result in greater harm or damage to the patent holder (*periculum in mora*).

Additionally, courts may only order the injunction if decreeing it is necessary to avoid the occurrence of greater damage or harm generated by the time a final decision on the merits may take place and it does not cause an unfair and disproportionate affectation of rights, considering the benefit for the patent holder but also the effect it would have on other persons or the community itself.

Failure to comply with a court order (such as an injunction) is a crime under the Colombian Criminal Code that can lead to imprisonment for up to four years. Colombian criminal law applies to both nationals and foreigners who commit a crime in Colombia. Therefore, proceedings may be initiated against the legal representative of the company, the distributor and any third party performing infringing acts.

Additionally, if the preliminary injunction was executed *ex parte*, the petitioner must prove that it filed an infringement action within 10 days of the injunction's execution. Otherwise, the court will lift the measure and impose the payment of damages to the petitioner.

It is difficult to predict the length of a preliminary injunction process starting from its filing until its issuance, including any appeal. However, common practice suggests a six-month term as a reasonable period for a first instance decision and approximately four additional months to decide an appeal, as it happened in the *Ericsson v Apple* infringement case. In such proceedings, taking an average of eight months, 13 different alleged standard essential patents (SEPs) related to 4G and 5G technology were brought before 12 different courts simultaneously, including two preliminary injunction requests filed before the CPOJB, and 11 before ordinary civil courts. As of the standard of evidence required for the issuance of a preliminary injunction, only one of the civil courts decreed a preliminary injunction against Apple, but the tribunal revoked this decision when deciding the appeal, mainly due to a lack of summary evidence on the actual infringement. Some of the decisions to deny the preliminary injunction were appealed by the plaintiff and sustained by the tribunal, essentially for the same reasons. What became clear is that even for SEPs, the evidentiary benchmark is the same as for ordinary patents, meaning that evidence of an actual infringement of a claim must be provided to eventually obtain a preliminary injunction.

PRE-LITIGATION EVIDENCE REQUEST

It is the plaintiff's obligation to provide evidence proving the existence of the infringement that gave rise to the complaint. However, our internal provisions consider the possibility for the patent owner to request pre-litigation evidence to gather the necessary evidence prior to the filing of the infringement lawsuit. The evidence to be collected may consist of the interrogation of the alleged infringer, statements regarding the authorship, the scope and content of a document, the disclosure of documents and movable property, witness declarations and inspections by the court of documents, places, objects and persons. The petitioner of the pre-litigation evidence decree may file its request before the CPOJB or the civil courts.

STAGES WITHIN THE PATENT INFRINGEMENT PROCESS

Judicial proceedings are of a 'rule-bound' nature, meaning that they have stages that must follow the order and timing established by the procedural code. A stage does not begin until the previous stage has been concluded.

Infringement proceedings, as mentioned above, have two instances: the first one being before the ordinary courts of the circuit or the CPOJB, at the patentee's choice, and the second one occurring before the superior tribunal.

The first instance starts with the filing of the infringement action. If the document is filed in due form and complies with all the formalities, it is admitted by the judge between approximately one and three months after the filing. Otherwise, the judge issues an order requesting the correction of formal errors or submission of missing documents. The alleged infringer may file its response within 20 business days of the notification of the action's admission.

Once the action is admitted, the judge sets a date for the initial hearing in which the facts are settled, conciliation between the parties is promoted and all evidence is decreed and performed if possible. If all evidence is settled, the judge grants 20 minutes for each party to present their closing arguments orally. Upon request of one or both parties, the judge may grant more time. After the parties have been heard, the judge issues the ruling. When some evidence could not be presented during the initial hearing, such as technical expertise or judicial inspections, the judge will set a date for the final hearing, where the remaining evidence must be settled, the parties present their closing arguments and the judge issues a ruling orally during the hearing or in writing within 10 working days of the hearing. The first instance may not last more than one year after admission of the infringement action.

The second instance starts with the filing of an appeal, which must precisely contain and present all the arguments. If the ruling is issued during one of the hearings, the appellant must file the appeal orally immediately after hearing the decision. If the ruling is issued in writing, the appellant must file the appeal within three working days of the ruling's notification.

The appeal filed before the first instance judge must contain the arguments in a concrete and precise manner to be formally accepted, but the grounds of the remedy shall be sustained before the judge of the second instance.

In principle, the second instance process may not last more than six months (extendable for six additional months by the judge) from the time the tribunal receives the file. However, given that Colombia is a member of the Andean Community of Nations and as matters related to industrial property are governed by the norms dictated within the Community framework, the national judge cannot issue a final judgment without the existence of a prejudicial interpretation issued by the Andean Court with respect to the Andean norms involved in the matter under discussion. Therefore, the second instance process is adjourned for the time it takes to request and obtain the mandatory preliminary interpretation, which is approximately six months. The Andean Court recently decided to apply *stare decisis*, according to which national judges are not obliged to request a preliminary interpretation when the same matter has already been analysed and clarified in previous interpretations, avoiding the need to adjourn the judicial process in such cases.

BIFURCATED PATH BETWEEN INFRINGEMENT AND INVALIDITY

Patent infringement actions and patent invalidity actions are independent and need to be filed before different authorities. While infringement actions are filed against the alleged infringer before civil courts, invalidity actions are filed before administrative courts. Parties to each action are also different. Whereas civil actions happen between the patent holder and the alleged infringer, invalidity actions need to be filed against the Colombian Patent Office for having granted an alleged invalid patent, with the patent holder being an interested third party to the case. According to the above, invalidity as such would not provide a suitable defence against infringement allegations. It may, however, help as a persuasive tool against inter-party preliminary injunction procedures.

Until 25 January 2022, patent invalidity actions were single instance procedures filed before the Council of State, which is the highest judicial authority for administrative affairs. However, from that date onwards, invalidity actions are now filed before administrative tribunals at the first instance, and its decision is subject to appeal before the Council of State.

DOCTRINE OF EQUIVALENTS AND PROSECUTION HISTORY ESTOPPEL

A general rule for Colombian courts is that direct infringement is demonstrated by a literal interpretation of the claims. Infringement by equivalence is not expressly contemplated in the law, but it is not expressly excluded either, meaning that courts are free to perform their claim construction analysis according to the evidence of the case. It was not until the recent case of *Telemetrik v Excelec* that courts started to apply the doctrine of equivalents within the claim analysis in patent infringement actions. In this case, the Andean Court set the first precedent with respect to the applicability of the doctrine of equivalents in the Andean Community framework by stating that the judge may, if they so consider, make an equivalence assessment with respect to the elements of the allegedly infringing product or process. For this purpose, the Andean Court suggests applying the test of the triple substantial identity, which consists of determining whether the elements of the allegedly infringing product or process perform the same function, operate in the same way and accomplish the same technical result as the elements of the claim against which they are compared. In addition, the Andean Court of Justice also considered it is valid to analyse the prosecution history of the patent application and its narrowing amendments and limitations, as a limitation for the application of the doctrine of equivalence, providing a precedent for a file-wrapper estoppel. Based on such interpretation, the second instance judge in the *Telemetrik v Excelec* case carried out the claim construction analysis by applying the triple substantial identity test to conclude that there was no literal infringement or infringement by equivalence. Moreover, the tribunal also established that even if the result of the test would have shown equivalence, the prosecution history of the patent would void the possibility to apply the doctrine.

What is clear under these considerations is that Colombia does not only grant robust patents in all fields of technology, but also offers in parallel an effective enforcement of such patents before courts, providing both plaintiff and defendant with due process and challenge before superior courts with reasonable timelines.

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Mexico: How Improved Preliminary Injunction Regulations are Impacting Damages Claims

[Sergio L Olivares Sr](#) and [Karla Olvera](#)

[OLIVARES](#)

Summary

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IN SUMMARY

In Mexico, the protection of intellectual property has been gradually evolving and adapting to international standards, favouring the implementation of specialised institutions and an improved consolidated system. However, until recently, the true effectiveness of the protection mechanisms provided for in the applicable laws and regulations was heavily criticised, particularly regarding the enforcement of patent rights.

DISCUSSION POINTS

- The protection mechanisms for intellectual property in Mexican law
 - The Mexican Patent and Trademark Office and infringing patents
 - Changes to injunctions and damages claims brought about by the Federal Law for the Protection of Industrial Property
-

REFERENCED IN THIS ARTICLE

- Industrial Property Law
- Federal Law for the Protection of Industrial Property

In Mexico, the protection of intellectual property has been gradually evolving and adapting to international standards, favouring the implementation of specialised institutions and an improved consolidated system. However, until recently, the true effectiveness of the protection mechanisms provided for in the applicable laws and regulations was heavily criticised, particularly regarding the enforcement of patent rights.

These criticisms derive from the fact that, although the holder of a patent has the possibility of submitting a request for an administrative declaration of an infringement with the Mexican Patent and Trademark Office (IMPI) and, when applicable, of requesting the implementation of preliminary injunctions that allow the infringing product to be withdrawn from the market, among other precautionary measures, IMPI's criteria have allowed it to be very common to encounter cases where the alleged infringers can request and obtain in just a couple of days the lifting of those injunctions, as long as they posted the required counterbond.

These loopholes in the provisions regulating the lifting of preliminary injunctions allowed infringers to implement strategies where the objective was to obtain the lifting of the injunctions and continue with their infringing activity during the entire duration of the administrative procedure with IMPI and further appeal stages, in which case, despite obtaining a decision favourable to their interests, the holders of the patent rights will not be able to obtain due compensation for the damage suffered during the time in which the infringing product continued in the market, regardless of the applicable administrative sanctions.

The foregoing is due to the fact that in accordance with the now abrogated the Industrial Property Law (the IP Law) (in force until 4 November 2020), for the holders of an exclusivity right to be able to obtain compensation for damage suffered as a result of an infringing

conduct, first they had to obtain a final decision from IMPI declaring the infringement, and subsequently, they could go to the civil courts to file a special claim for damages.

However, it is well known that, in practice, the processing of a request for an administrative declaration of infringement with IMPI can take several years. To this, we must add the time invested in subsequent challenges eventually filed by any of the parties before the courts, which means that obtaining a final decision of infringement by IMPI may take six, eight or even more years, and this is just the first step to be able to later file a claim for damages with an independent jurisdictional authority.

These circumstances had the consequence that, despite managing to obtain a favourable decision on the infringement action with IMPI, patent holders basically lost the motivation to initiate an independent claim for damages, as this new civil claim is also prone to multiple challenges and stages that will lead to an additional judicial process of several years. In addition, they reached this stage with a considerable financial burden that in many cases no longer allowed them or simply made it impractical to engage in a new judicial procedure.

The above was resolved in jurisprudence 13/2014, where the Supreme Court determined that to claim damages with the civil courts, a prior declaration of infringement by IMPI is an essential requirement, on the grounds that said authority is the only one empowered to resolve disputes related to industrial property rights, and the civil courts' expertise is limited to evaluating the damage caused by the infringement.

The Supreme Court later decided a landmark case, in which it was established as a basic requirement to claim damages derived from an administrative declaration of infringement in accordance with the IP Law, the existence of a prior final decision by IMPI and to properly evidence the causal nexus between the infringement and the damages – namely, to demonstrate that the actual damage originated as a direct consequence of the infringing conduct previously sanctioned by IMPI.

In accordance with this ruling, it is not sufficient to have a previous declaration of infringement by IMPI, and it is required to accurately evidence the cause-and-effect relationship (immediate and direct) between the infringement and the alleged damage, which by the way, is the general rule set forth in Mexico civil law in connection with damages.

Due to the above, to date in our country, there are very few cases where decisions have been issued ordering the payment of damages derived from a declaration of a patent infringement prosecuted by IMPI.

However, as a result of the obligations imposed on the Mexican government due to the entry into force of the United States–Mexico–Canada Agreement, which replaced the well-known North American Free Trade Agreement, on 1 July 2020, the new Federal Law for the Protection of Industrial Property was approved, which entered into force on 5 November 2020, and in which, among other positive amendments, radical changes were introduced in connection to injunctions and damages claims, with which it is sought to provide the holders of exclusive rights with different mechanisms that facilitate their processing and make it possible to obtain a timely resolution.

In the past, injunctions were also granted almost automatically; that is, to obtain a decision granting and ordering the implementation of injunctions by IMPI, it was sufficient to file a petition with IMPI formally alleging a violation of a patent right and posting a bond

to compensate for any damage possibly caused to the defendant when obtaining an unfavourable resolution.

However, the new Federal Law for the Protection of Industrial Property clearly states that to decide on the approval or denial of preliminary injunctions, IMPI must now carry out a weighted analysis of the particularities of the case, mainly, the appearance of a prima facie case, the non-violation of public order provisions and that general interest is not affected.

In addition, IMPI must take into consideration the seriousness of the infringement and the nature of the requested injunction, for which it will require the petitioner to evidence the existence of an infringement of its right and the existence of the possibility of suffering irreparable damage, in addition to posting a sufficient bond to compensate for the damage that could be caused to the entity against whom the injunction was requested. In this regard, the law provides that to fix the amount of the bond, IMPI will take into consideration the elements provided by the petitioner, as well as those that arise from the records in the file.

Likewise, under the new IP Law, IMPI is now empowered to require the petitioner to increase the amount of the initial bond when after the implementation of the injunctions it is clear that the bond initially posted is insufficient to guarantee the damage that could be caused to the alleged infringer.

In practice, the petitioner generally provides in advance, together with its brief requesting the implementation of injunctions, a bond for an amount determined in accordance with the evidence means demonstrating the alleged infringement and the damage that it is suffering or expects to suffer in the short term. Subsequently, IMPI analyses this information and determines whether or not it is sufficient.

As mentioned before, in accordance with the provisions of the now abrogated IP Law, to obtain the lifting of injunctions it was sufficient for the defendant to post a counterbond for the amount of the bond exhibited by the plaintiff plus an additional 40 per cent.

Relevant modifications were made to the new Federal Law for the Protection of Industrial Property in this regard, as although the defendant is still entitled to request the lifting of the injunctions, it is now expressly stated that to decide on their lifting, IMPI must analyse whether the damage suffered by the person on whom the injunctions were imposed is greater than that which may be caused to the petitioner, and taking into consideration the appearance of a prima facie case, assess whether its lifting affects the public order or the general interest.

As for damages, the new IP Law considers two different paths. On the one hand, the patent holder is now allowed to file in parallel with the infringement action a separate civil claim with the ordinary courts directly claiming the payment of damages from the infringer, meaning that it is no longer necessary to wait for the issuance of a final infringement decision by IMPI.

And on the other, it introduces an incidental damages claim, according to which the holder of the rights may claim the damages generated as a consequence of the declaration of infringement directly with IMPI, which will now be empowered to quantify these damages and order the infringer to pay them, once IMPI has issued an administrative declaration of infringement, and this decision is enforceable.

Accordingly, the new law now expressly provides that to determine the amount of compensation, the date on which the infringement was evidenced must be taken into account, and that the compensation in no case may be less than 40 per cent of the legitimate

value indicator presented by the affected holder, such as the value of the infringed products or services calculated by the market price, or the profits that the holder would have ceased to receive as a result of the infringement, to name a few.

Although these changes are intended to considerably reduce the resolution times applicable to the current regime for claiming damages for the benefit of patent holders, there are certain peculiarities in these procedures that still cast doubt on their full effectiveness, because if they opt for a civil claim, the courts will have to suspend the trial process when the infringer challenges the validity of the related patent through a request for an administrative declaration of invalidity with IMPI.

The process also cannot be resumed until the correlative resolution is issued, which would again leave us in a scenario similar to the previous one. This is in addition to the fact that the experience of civil courts in matters related to industrial property rights is limited and work should be done jointly with IMPI for the correct implementation of the new mechanisms provided by law.

The correct implementation of this new system for claiming damages will bring many challenges, both for individuals and for the authorities. It is precisely for this reason that, according to the provisions of the transitory articles of the law in question, these amendments will not come into force until the corresponding modifications have been made to the organic structure of IMPI and it has the required financial, human and material resources for this purpose.

Finally, it should be pointed out that the current Federal Law for the Protection of Industrial Property entered into force on 5 November 2020 and clearly states that administrative declarations of infringement that were already in process at the entry into force of said law will continue to be processed and will be resolved in accordance with the provisions contained in the now abrogated IP Law.



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Specialist Chapter: Navigating High Stakes Patent Injunction Abuse

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Summary

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IN SUMMARY

This article emphasises the importance of prioritising valid and infringed patents for all stakeholders, including individual parties, courts, multi-jurisdictional bodies such as the Unified Patent Court, and regulatory agencies. Additionally, it provides relevant background information to better comprehend the European Commission's objectives in its draft policy to address standard essential patents. Further, this article demonstrates how unjust injunctions can disrupt fair competition, hinder market entry and lead to overpayments that stifle innovation and economic growth. We begin by discussing historic high-stakes examples, modern disputes and assessing industry performance over time. We analyse lessons learned and conclude with summarised findings.

DISCUSSION POINTS

- High-stakes examples and recent disputes
 - Patent performance in litigation
 - Lessons learned
-

REFERENCED IN THIS ARTICLE

- *Nokia v OPPO*
 - *Nokia v Daimler*
 - *eBay Inc v MercExchange, LLC*
 - *NTP, Inc v Research in Motion, Ltd*
 - *Unwired Planet v Huawei*
 - *InterDigital v Lenovo*
 - *Microsoft Corp v Motorola, Inc*
-

Negotiating licences under the looming shadow of injunction threats can be as daunting as Dorothy's encounter with the Wizard of Oz. Yet, much like Dorothy discovered, a closer examination often reveals these threats to be more smoke and mirrors than genuine power.

This article emphasises the importance of prioritising valid and infringed patents for all stakeholders, including individual parties, courts, multi-jurisdictional bodies such as the Unified Patent Court, and regulatory agencies. Additionally, it provides relevant background information to better comprehend the European Commission's objectives in its draft policy to address standard essential patents.^[1]

Prioritising legitimacy preserves system integrity, ensures fairness in dispute resolution, promotes efficiency and instils confidence in the patent system. Further, this article demonstrates how unjust injunctions can disrupt fair competition, hinder market entry and lead to overpayments that stifle innovation and economic growth.

We begin by discussing historic high-stakes examples, modern disputes such as OPPO and Daimler, and assessing industry performance over time. We analyse lessons learned and conclude with summarised findings.

HISTORIC HIGH-STAKES EXAMPLE

In 2001, NTP Inc sued Research in Motion (RIM),^[2] the maker of BlackBerry smartphones, to get better terms in patent negotiations. RIM made costly concessions under the threat of injunction. Ironically, the United States Patent and Trademark Office (USPTO) later found that all but one of the critical patents NTP relied on were invalid (see below).

Background

During the NTP lawsuit, BlackBerry devices and email services were widely used by international businesses, the US/Canadian governments and foreign government personnel. RIM could have settled early but believed the patents wouldn't survive a challenge. The US Supreme Court had yet to set limitations on injunctions in the eBay v Merc Exchange case.^[3] The US district court thus ordered an injunction barring the sales of all BlackBerry devices and services. Faced with market exclusion, RIM settled with NTP for a staggering US\$612 million. Later USPTO and appeal court decisions found four of the five asserted patents invalid.

Timeline

- In 2001, NTP Inc sued RIM for patent infringement, alleging that RIM's BlackBerry devices violated five of NTP's wireless email patents.
- In November 2002, the jury ruled in favour of NTP.^[4] The jury's decision was upheld on appeal on 2 August 2005, and an injunction was set for 24 March 2006.
- On 4 March 2006, RIM and NTP reached a settlement, where RIM agreed to make a (non-refundable) payment of US\$612 million.^[5]
- As of 2009, three patents were removed from the case and the USPTO found the two remaining NTP patents invalid.
- In 2011, the US Court of Appeals for the Federal Circuit, affirmed one of the invalidation decisions and remanded the other back to the USPTO.^[6]

OPPO AND DAIMLER CASES

In recent events, Nokia filed lawsuits against OPPO in multiple jurisdictions^[7] to gain leverage in licensing negotiations. However, an unexpected twist occurred when the European Patent Office (EPO) Board of Appeals invalidated Nokia's patents.^[8] Interestingly, Nokia had previously used the same patents against Daimler in Munich just a couple of years before, coercing them into an undeserved settlement.

Regrettably, the EPO decision came too late for Daimler, as they had already made substantial payments and agreed to unfavourable terms to avoid the potentially massive damage that an (unjust) injunction would have caused.

Timeline Of The Daimler Case

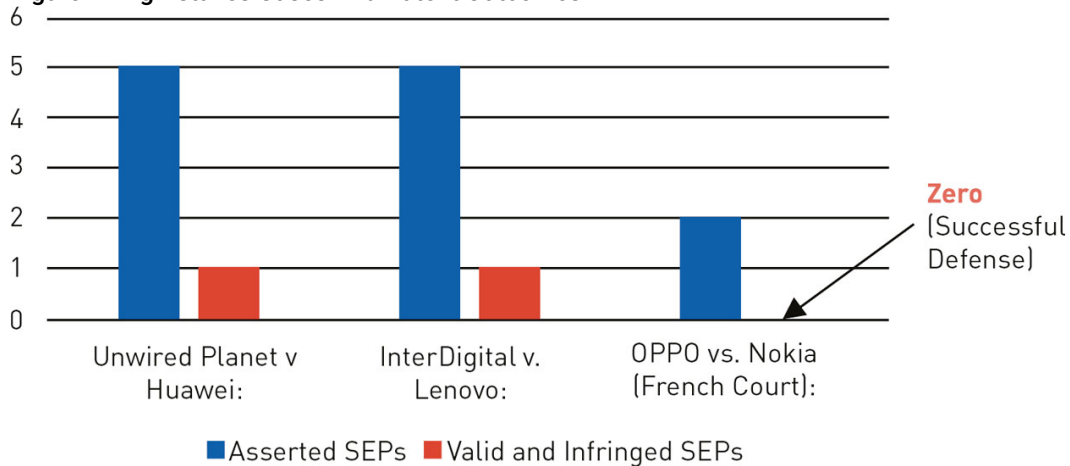
- In August 2020, the Mannheim District Court issued an injunction order against Daimler.^[9]

- In January 2021, the European Patent Office upheld the patents asserted against Daimler. As a result, the infringement case against Daimler proceeded without delay, and the associated injunction remained in effect.
- On 1 July 2021, the parties settled.^[10] Until then, they had significant differences in the terms of a bilateral licence. The settlement prevented the injunction from going into effect.
- However, in May 2023, OPPO was able to invalidate two patents of Nokia^[11] that had been asserted against Daimler.

PATENT PERFORMANCE IN LITIGATION

In many licensing negotiations, disputes are resolved without going to court. However, in high-stakes cases, the patents initially claimed to be infringed often ultimately fail scrutiny in litigation. For example, in the UK Unwired Planet v Huawei case,^[12] the court found only two out of five asserted patents valid and infringed. Similarly, in the UK case of InterDigital v Lenovo,^[13] only one out of five claimed patents were deemed valid and infringed.^[14] In July 2023, OPPO successfully defended against two Nokia lawsuits in a French Court.^[15] This case raised concerns for cases in Germany where Nokia could face accusations of wrongfully enforcing injunctions.^[16] See Figure 1 for a summary of these outcomes.

Figure 1: High-stakes Cases And Patent Outcomes

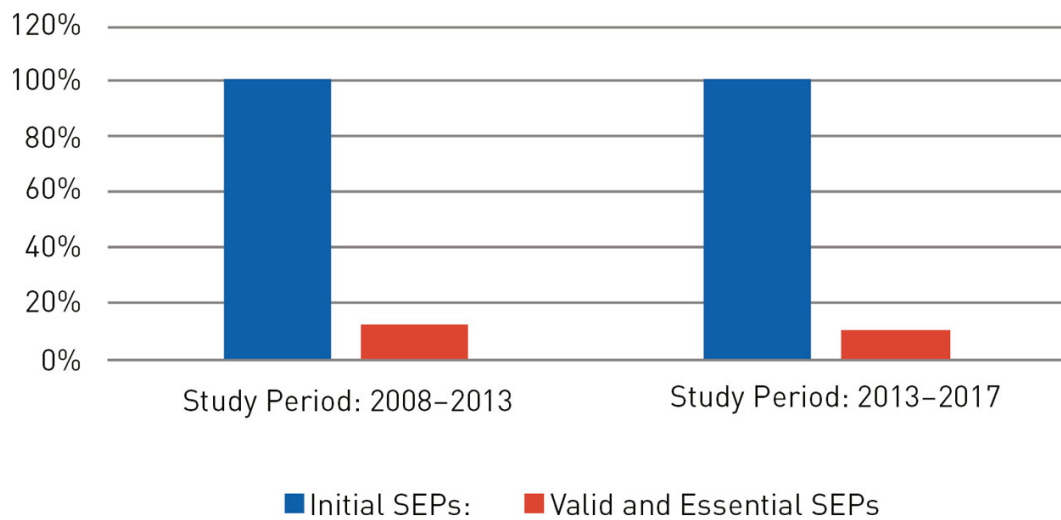


More Injunction Performance Data On SEPs

Few asserted patents survive to the end of the litigation process. A study conducted in 2013 by John (Jay) Jurata and David Smith^[17] analysed 85 adjudicated SEPs asserted by highly litigious companies over five years. The findings revealed that the courts recognised only one out of eight asserted SEPs as valid and essential, amounting to just 12.5 per cent of the initially claimed SEPs.

A subsequent study covering the period from 2013 to 2017 examined 71 asserted SEPs. The courts determined that only eight patents were valid and infringed, accounting for a meagre 11 per cent of the initially claimed SEPs.^[18] In many of these cases, courts found none of the asserted patents valid and infringed.

Figure 2: Percentage Of Valid And Essential SEPs Recognised By The Courts



The data from the study highlights that only a tiny fraction of initially claimed (presumably best) SEPs prove to be valid and essential or infringed.

SEP Injunctions Drastically Impact Negotiation Prices

With injunctions in play, the threatening prospect of market exclusion holds significant leverage in any patent negotiation, potentially leading to extortionate tactics. Eliminating non-infringed and invalid patents, if feasible, would shrink the negotiation scope and should reduce the amount of royalties due. In the study examples above, the 12 per cent survival means a staggering reduction in infringed patents. Also note that eight of the 13 cases studied resulted in zero patents surviving,^[19] meaning no compensation.

Exaggerated Patent Valuations Also Succumb To Scrutiny At Trial

In *Microsoft v Motorola*,^[20] all patents survived, but Judge Robart described Motorola's 2.25 per cent per unit offer as a 'naked royalty' that is 'unreasonable and unfair'. His final determination was 3.471 cents and 0.55 cents per unit for the respective patents. His findings were much lower than the initial demand: about US\$4.48 per unit.^[21] In *Optis Cellular v Apple* (UK decision, May 2023), the court set the royalty determination at 0.5 per cent, which was one-quarter of the 2 per cent initial Optis demand leaked to the press. In *Interdigital v Lenovo* (UK decision in March 2023), Interdigital sought a global FRAND rate of US\$0.489 per unit. However, the court found that InterDigital had not provided sufficient evidence to support its damages claim. The court set the global FRAND rate at US\$0.175 per unit, 36 per cent of InterDigital's original demand.^[22]

This section delved into injunction-inspired cases where the excessive number of patents claimed to be valid and infringed and the overstated royalty demands did not stand up to scrutiny. Examples such as RIM and Daimler (worth hundreds of millions of dollars) demonstrate that initial court decisions may be insufficient. Issuing an injunction before court and patent office processes are complete frequently results in inequitable and irreversible consequences. The enormous legal costs, the lost management time and the reputational impact, regardless of the outcome, were also staggering. Many similar cases exist beyond what's covered here. Additionally, the fear of market exclusion has forced other companies to accept detrimental terms to avoid litigation, leading to overpayments that hamper research and development, payroll and capital expansion. Significant improvements are needed to address this major economic impact of a flaw in the overall system.

LESSONS LEARNED

The essence of a patent system is to incentivise innovation and drive economic growth. Courts must not facilitate abusive licensing schemes centred around dubious patents that should never have been granted. While refining patent validation processes and enhancing patent quality are crucial, they merit distinct attention and won't be covered here. The emphasis here lies on the need for courts to maintain the integrity of the patent system by discerning and handling questionable patents.

Easily Obtained Unjust Injunctions Reward The Wrong Behaviour

Easily obtained unjust injunctions undermine the patent system's purpose of fostering innovation and economic growth. Courts must avoid inadvertently supporting abusive negotiations that divert resources from crucial areas like production, research, payroll and employment. Affected companies may fall behind on significant innovations of their own (consider medical devices as just one example). In addition, the companies that supply supporting infrastructure to enjoined companies (eg, suppliers, retailers, restaurants and food stores) also suffer.

Other companies will accept unfair terms to avoid litigation. The cost impact can easily affect economic growth. Critical nascent industries, such as the Internet of Things, may be especially vulnerable to excessive and unpredictable hardware costs.^[23]

Additionally, unjust injunctions disrupt a patentee's commitment to accepting monetary compensation for infringements, impeding the beneficial adoption of standards.

Equitable Solutions Provide A Way Forward

Courts have many tools to ensure fairness and equity. In the United States, the eBay decision established important guidelines for granting injunctions. Many jurisdictions worldwide also value equitable solutions. However, in some jurisdictions, courts focus on infringement without considering patent validity. Ignoring validity while enforcing injunctions worsens negotiation imbalances.

Prudent Injunction Use Is Vital; Fair Solutions Can Offer Just Compensation

Misusing injunctive relief can obstruct settlements.^[24] Treating the patent as a right to enjoin the use of a product that is many orders of magnitude more complex than the patent claims is neither good law nor economics. Properly assessing patent rights would boost innovation and growth.

Timely Patent Validity Decisions Are Crucial

An early resolution before exclusion orders take effect can be a key tool to ensure a fair and just outcome for legitimately challenged validity. The US Patent Trial and Appeal Board (PTAB) provides for fair and efficient proceedings. By allowing only 'reasonably likely' challenges, the PTAB filters out unwarranted challenges and maintains a streamlined process, with an average resolution time of just 10.5 months.

A Constructive And Thorough Examination Of Equitable Solutions Does Not Hinder Innovation

Some argue an economy will grow faster with more patents of any quality extracting high royalties. Their argument allows undeserving patent holders to profit from the efforts of genuine inventors. Diverting funds from true innovators and hardworking, productive companies would stifle their investment in research and development, payroll and capital

expenditures. A thorough examination of equitable solutions is essential for innovation to grow productivity.

Patent Systems May Advantage Foreign Entities Outside Of The Domestic Economy

According to the USPTO,^[25] in 2022, 56 per cent of all utility patents granted in the United States were owned by foreigners. The European Patent Office^[26] numbers for 2022 show 49.2 per cent held outside the European Union. There is a valid concern that some foreign entities, especially those funded by large banks and investment funds, will repatriate their profits from litigation, taking funds away from the respective economies.

Courts Have Resources To Deal With Bad Actors

For patent holders monetising their patents, seeking deterrents against uncooperative licensees is reasonable. Striking a balance and exploring equitable alternatives is crucial. Courts often use timely remedies such as stays, escrow, interest payments and punitive actions. Jurisdictions lacking appropriate remedies may wish to consider legislative actions. Courts can ensure fair compensation by implementing suitable measures and recognising the potential for patent invalidity while minimising the need for injunction enforcement reserved for exceptional cases.

CONCLUSION

This article highlighted the pitfalls of injunction threats in patent licensing negotiations. While many negotiations culminate amicably, the shadow of aggressive injunction threats can paradoxically stifle the innovation they're meant to protect. It's crucial for stakeholders – innovators, businesses, policymakers and judicial authorities – to adopt a balanced approach, emphasising equitable solutions and fair compensation. It's time for all involved to take proactive steps: engage in transparent discussions, support reforms prioritising patent validity and quality, and collaboratively develop frameworks that deter patent abuse. By actively addressing the misuse of injunctions, we safeguard genuine innovation and pave the way for a more collaborative and constructive patent landscape.

Endnotes



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Specialist Chapter: Trends and Strategies in Global Pharma and Biotech Patent Litigation

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IN SUMMARY

International patent protection is now part-and-parcel for any significant drug or therapeutic, and, as a result, disputes over patent ownership and infringement now regularly implicate a myriad of related laws across international venues. In this article, we analyse a handful of recent global patent disputes in pharma and discuss how differing local laws can affect litigants and substantive outcomes, and how parties can leverage international patent disputes.

DISCUSSION POINTS

- Leveraging local patent laws for disparate results
 - Leveraging litigation to drive favourable settlement
-

REFERENCED IN THIS ARTICLE

- CRISPR-Cas9
- Amgen v Sanofi & Regeneron cases
- Ultomiris litigation
- Biktarvy litigation

INTRODUCTION

Because biotechnology and pharmaceutical companies market their products worldwide, patent protection – which operates on national level – must be sought globally. This approach requires an appreciation of the subtle, but often important differences between countries about what inventions can be protected by patents. Companies often seek patent protection for blockbuster therapies or drugs, in a wide range of markets. As a consequence of worldwide patent protection and product markets, patent litigation has increasingly gone international. One has to act locally to secure patent protection, but companies must think globally about litigation and how it can be used strategically in an offensive and defensive fashion.

In this article, we review several recent biotechnology and pharmaceutical patent disputes about how parties have approached global patent litigation.

LEVERAGING LOCAL PATENT LAWS FOR DISPARATE RESULTS

Because of differences in local patent and procedural laws, the same set of facts may lead to dramatically different outcomes across jurisdictions. Although international agreements have harmonised many aspects of patent law,^[1] there remain substantive variations. These differences present not only opportunities to leverage local laws to obtain an outcome that would have been out of reach elsewhere, but also dangers, as compliance with one country's laws does not mean compliance with another's. Moreover, many of the nuances of a given jurisdiction's laws will not become evident until well into litigation, and thus parties should think carefully even in early patent prosecution.

CRISPR-Cas9

The CRISPR-Cas9 dispute, which has raged in the United States and Europe, illustrates how differing patent prosecution rules can lead to different substantive outcomes in the control of patent rights.

For nearly a decade there has been an ongoing international disagreement over who has priority rights for the patents related to CRISPR-Cas9 technology, a revolutionary discovery that allows for efficient and reliable gene editing.^[2] In 2012, the University of California, Berkeley^[3] and the University of Vienna^[4] (collectively CVC) filed a patent application directed to the CRISPR-Cas9 technology. Soon after their initial discovery, the Broad Institute^[5] filed a patent based on additional modifications to the CRISPR-Cas9 system that enabled the technique to work in eukaryotic cells – a classification of cells that includes all animal and human cells. Both parties filed patents covering the method that included claims using the technique in eukaryotic cells (ie, mammalian cells), and, inevitably, there was a dispute between the two parties about which one was entitled to a patent. The stakes were enormous – a Nobel prize and likely billions in licensing revenue.^[6]

Beginning in 2014, in the United States, the CVC group attempted to use interference proceedings to establish that the CVC group was the first to invent the CRISPR-Cas9 technology as applied to eukaryotes.^[7] To date, the CVC group has filed two interference proceedings. In both cases the USPTO ruled in favour of the Broad Institute – ie, that the Broad Institute's use in eukaryotic cells is a separate invention and that the CVC group was not the first to invent it.^[8] The first of these interferences was affirmed by the Federal Circuit in 2018,^[9] and the second interference resulted in a 2022 USPTO decision also in favour of the Broad Institute.^[10] While the appeal for the latter is ongoing, it appears that the Broad Institute has secured patent rights of the use of CRISPR-Cas9 in eukaryotic cells, and thus in humans and animals, in the United States.^{[11],[12]} Thus, and because the CVC group still holds foundational patents directed to the underlying basis of the technology, both the Broad Institute and the CVC group have patent rights covering the application of CRISPR-Cas9 to eukaryotic cells in the United States.

In Europe, however, the Broad Institute was less successful. There, the CVC group was able to use the differences in patent rules to drive a different outcome. Specifically, during patent prosecution, the Broad Institute relied on a claim of priority to earlier US applications that named an inventor, Luciano Marraffini, who did not appear on the European patent filing.^[13] Inventor Marraffini had transferred his right to priority to a third party, Rockefeller University. As a result of strict European rules on priority claims, the European Patent Office (EPO) ruled that the Broad Institute could not rely on its US priority date, because it did not own all of the priority rights. This loss of priority resulted in a win for the CVC group and the revocation of the Broad Institute's patents – a ruling that was later affirmed by the Board of Appeals at the EPO.^[14] Challenges to priority rights are a major issue in Europe as many US companies have discovered to their unending heartache.^[15] Despite these setbacks, the Broad Institute still holds additional patents and patent applications, and disputes regarding these are ongoing.

It is evident from the CRISPR-Cas9 example that the differences in governing law between the United States and the EPO allowed the CVC group to reach a favourable outcome in Europe that they were unable to achieve in the United States. The dramatically different outcomes illustrate that careful attention must be paid to the rules in each jurisdiction, and while your patent may be 'safe' in one jurisdiction, a slight difference in the law can completely change the result depending your 'safe' patent protection elsewhere.

Amgen V Sanofi & Regeneron, Anti-PCSK9 Abs

Amgen Inc, Sanofi, and Regeneron Pharmaceuticals Inc have fought a patent battle over anti-PCSK9 monoclonal antibodies in the United States, Europe, Japan and Australia. Amgen markets one such antibody product under the brand name Repatha, which is covered by patents directed to the antibody itself. Sanofi and Regeneron have partnered to market a competing antibody product under the brand name Praluent. As a result of the patent battle, several of Amgen's patents were invalidated, including through a recent high-profile US Supreme Court case,^[16] but invalidation of Amgen's patent rights in this case has not been universal or consistent.

In 2014, Amgen sued Sanofi and Regeneron in a US district court for infringement of patents directed to monoclonal antibodies that target PCSK9 and that are used to treat high cholesterol. The claims recited antibodies that were functionally claimed.^[17] Unsurprisingly, the parties disputed whether this functional claiming satisfied the US written description and enablement requirements.^[18] The case proceeded to trial, where a first jury found that the claims were not invalid for lack of written description and enablement. Following a reversal at the Federal Circuit because of faulty jury instructions, a second jury again found that the claims were not invalid. Despite two jury rulings, the district court ultimately ruled, via a judgment as a matter of law, that the claims were invalid as not adequately enabled. The Federal Circuit affirmed, and Amgen appealed to the US Supreme Court, leading to the recent *Amgen v Sanofi*^[19] decision wherein the US Supreme Court held that claiming all antibodies that bind to a specific target, potentially numbering in the millions, while only disclosing 26 examples, did not satisfy the enablement requirement of section 112. The decision did not purport to change the basic law of enablement and relied on century-old precedent, but it has cast a pall on the validity of broad genus claims, particularly in the pharmaceutical and biotechnology industries.^[20]

But, as noted, Amgen pursued an aggressive patent enforcement strategy internationally, including suits in Japan, Europe and Australia.

In Europe, Sanofi and Regeneron have generally won out, but local procedural rules meant that Amgen was able to temporarily block competing sales. Specifically, in an initial win for Amgen, the Regional Court at Düsseldorf found infringement and issued an injunction against infringing sales of Sanofi and Regeneron's commercial product in 2019.^[21] Unlike the United States, Germany bifurcates infringement and invalidity proceedings. Thus, Amgen was able to leverage this bifurcated procedure to block sales before a ruling on validity of the relevant European patent.^[22] A 2020 opposition proceeding before the EPO's Technical Boards of Appeal resulted in amendments to the patent that meant it no longer covered the relevant products.^[23] The parties continue to litigate various related patents, and the parties have moved to the Unified Patent Court (UPC), where they brought both infringement and revocation actions.^[24] The UPC actions are still in their infancy, but to date have resulted in the first-ever UPC Court of Appeals decision, which dealt with procedural deadlines.^[25]

In Japan, Amgen saw initial success. In 2018 the Japanese IP High Court ruled that Amgen's patent was valid in the face of a challenge by Sanofi and that Sanofi infringed.^[26] Regeneron, however, was able to bring a separate, later action that included additional evidence and experimental data, and in 2023, the Japanese IP High Court issued a decision opposite to its first.^[27] Specifically, the Japanese IP High Court invalidated Amgen's claims for reasons similar to those the US Supreme Court would later use (ie, that the patent's specification did not support claiming all antibodies that bound to a target and inhibited PCSK9 binding).

Further, the Japanese IP High Court differentiated Regeneron's case from Sanofi's because Regeneron presented new arguments and evidence.^[28] Thus, by bringing a second action and introducing new evidence, Regeneron was able to effectively take a second bite at the apple and succeed where Sanofi had not. These types of subsequent challenges may be more difficult in countries outside of Japan, such as the United States.

Amgen saw more success sustaining the validity of the PCSK9 patent in Australia. Specifically, in 2022, Amgen defeated opposition actions to several of its patent applications, even though these applications had claims that were similar to those invalidated elsewhere^[29] (ie, functionally defined claims).^[30] These applications, however, were examined under Australian law that existed before the Intellectual Property Laws Amended (Raising the Bar) Act of 2012. The Raising the Bar amendments came into effect in April 2013 and heightened disclosure requirements from a 'full description' and 'fair basis' standard^[31] to instead requiring that the scope of the claims be commensurate with the technical contribution and be enabled for their full scope. While it is an open question as to whether these applications would have survived under modern law, Amgen was nonetheless able to successfully leverage Australia's local laws to obtain claims that had been found unpatentable elsewhere.

The multinational litigation saga of PCSK9 illustrates how patent practitioners can leverage success in some jurisdictions (here Europe and Australia) to offset set-backs in others.

LEVERAGING LITIGATION TO DRIVE FAVOURABLE SETTLEMENT

In addition to leveraging the nuances of local law, litigants can also use the pressure of litigation itself, and its associated costs, to drive settlement and licensing. Below, we detail two global disputes that ultimately resulted in high-value agreements.

Ultomiris Litigation^[32]

In 2022, Roche's Chugai Pharmaceutical (Chugai) and AstraZeneca's Alexion (Alexion) settled their major global patent dispute regarding the prescription drug Ultomiris (ravulizumab) used for the treatment of adults and children with paroxysmal nocturnal hemoglobinuria (PNH), a rare blood disorder.^[33]

From 2009 to 2013, Chugai patented its invention related to methods of removing an antigen from plasma in the United States, the European Union and Japan.^[34] However, beginning in 2016, when Alexion developed Ultomiris with the alleged use of certain similar molecules and methods as Chugai's invention, Alexion challenged the validity of Chugai's patents in the European Union and Japan.

In the European Union, Alexion challenged five of Chugai's patents, four of which were revoked by the EPO. For example, on 19 December 2019, the Opposition Division of the European Patent Office revoked European Patent No. 2552955 pursuant to article 101(3)(b) EPC (based on the novelty and inventive step grounds).^[35]

In Japan, the IP High Court invalidated four Chugai's Japanese patents challenged by Alexion.^[36] In particular, on 26 June 2019, the Japanese IP High Court invalidated Chugai's patent titled 'Antigen-Binding Molecule Capable of Binding to Two or More Antigen Molecules Repeatedly,' since the Court has determined that the description of this invention does not conform to the enablement requirements of Japanese Patent Law.^[37] According to the Japanese IP High Court, the 'Detailed Description of the Invention fails to describe the constitution of the invention to the extent that allows a person ordinarily skilled in the art to

implement the case where a plurality of sites are substituted with histidines.^[38] Subsequently, the Supreme Court of Japan dismissed Chugai's appeal against this invalidity decision.^[39]

In 2018, Chugai took the offensive and initiated the patent infringement litigation in Japan and the United States.

Specifically, Chugai sued Alexion in the Tokyo District Court alleging that Alexion's product Ultomiris infringed two patents in Japan. One of the two asserted patents had already been invalidated.^[40] Therefore, Chugai filed a correction to the claims of this patent-in-suit.^[41] Alexion countered that the corrected claims are still invalid and not infringed.

Chugai also sued Alexion in the United States in November 2018 in the District Court for the District of Delaware alleging that Ultomiris infringed its US Patent No. 9,890,377.^[42] Upon issuance of the US Patent No. 10,472,623 in November 2019, Chugai filed a second lawsuit in the US, which was consolidated.^[43] Chugai asked for injunctive relief and unspecified damages.^[44] The parties litigated the case until December 2021, when after claim construction proceedings, discovery, filing requests for jury instruction and several delays with trial, the parties initiated a global settlement process.^[45]

Under the terms of the 2022 settlement agreement, Alexion agreed to pay Chugai US\$775 million in exchange for the Japanese firm withdrawing the patent infringement lawsuits it filed in various courts in Europe, Japan, and the United States.^[46] This case clearly illustrates how one company can use foreign patent invalidation proceedings to gain leverage in US and global patent infringement disputes to force a settlement on reasonable terms. Although substantive patent law varies from country to country, the factual findings and admissions in foreign invalidation decisions may be used globally. Moreover, patent vulnerabilities and strengths in commercially significant jurisdictions may provide leverage to negotiate reasonable settlements of worldwide litigations. The threat of a patent infringement ruling and the associated risk to a company's ability to market its product, however, provides a compelling justification for a substantial licence fee or upfront payment, or both, particularly for companies without diversified income streams from multiple products.

Biktarvy Litigation[47]

Biktarvy (bictegravir, emtricitabine, and tenofovir alafenamide) is a single-tablet regimen used to treat HIV-1 infection developed by Gilead Sciences, Inc (Gilead).^[48]

In February 2018, ViiV Healthcare, GSK and Shionogi (collectively ViiV) filed a lawsuit against Gilead in the US District Court of Delaware, alleging that the commercialisation of Biktarvy infringes on ViiV's US Patent No. 8,129,385 (the '385 patent) covering ViiV's dolutegravir under the doctrine of equivalents, as the bictegravir in Biktarvy was alleged to be 'not substantially structurally different' from the claimed dolutegravir.^[49]^[50] However, Gilead raised several counterarguments, including invoking the 'dedication-disclosure rule', arguing that the '385 patent described, but did not claim, the formulation used in Biktarvy, and, therefore, there could not be an infringement under the doctrine of equivalents.^[51]

In November and December 2019, ViiV filed similar patent infringement related to Biktarvy lawsuits against Gilead in France, Germany, Ireland and the United Kingdom (asserting the European Patent No. 3,045,206); in Australia (asserting Australian patent No. 2,006,239,177); in Japan (asserting Japanese patent No. 4,295,353); and in Korea (asserting Korean patents Nos. 1,848,819 and 1,363,875).

In August 2019, ViiV also filed a similar lawsuit against Gilead in the Federal Court of Canada, alleging that Gilead infringed the ViiV's Canadian patent No. 2,606,282 (compound patent covering ViiV's dolutegravir). In April 2020, the Federal Court of Canada determined that Biktarvy does not infringe on the claims of the ViiV's Canadian patent No. 2,606,282 and dismissed the case after holding a summary trial.^[52] The court found that 'bictegravir does not fall within any of the asserted claims' of the patent No. 2,606,282.^[53] On 16 June 2021, Canada's Federal Court of Appeal (FCA) upheld this decision and specifically noted that 'the Federal Court's finding that the patent, properly construed, did not cover bictegravir.'^[54]

This case was globally settled in 2022, with Gilead agreeing to make an upfront payment of US\$1.25 billion as well as a 3 per cent royalty on all future US sales of Biktarvy (about US\$6 billion in 2020) and in respect of the bictegravir component of any other future bictegravir-containing products sold in the United States.^[55] However, Gilead received a worldwide licence to relevant patents relating to dolutegravir and a covenant not to enforce any patents controlled by ViiV against Gilead in connection with any past or future claims of infringement relating to Biktarvy and any future product containing bictegravir.^[56] Considering the expiration date of the '385 patent is estimated to be in 2027, and the risks of significant damages calculated based on the revenue from Biktarvy in the US litigation, this settlement agreement could be considered favourable for Gilead.^[57]

Overall, this case illustrates how pharmaceutical and biotechnology companies use foreign proceedings to leverage favourable resolution of US and global patent disputes. In particular, certain determinations made by foreign courts, especially key factual determinations, might be helpful in negotiating a better settlement in global patent litigation. Careful consideration about breadth during prosecution of ViiV's patent was also significant to allow ViiV to obtain additional licensing revenue from a drug molecule that was structurally similar to its patented dolutegravir molecule.

TRENDS AND STRATEGIES

In recent years, there has been a trend towards more complex and high-stakes global patent disputes in the pharmaceutical industry, including parallel litigation across multiple jurisdictions. Although the United States has historically been the leading jurisdiction of patent litigation, other jurisdictions, such as the European Union, Canada, Japan and Australia, are becoming increasingly important. The above disputes highlight that differences in law across jurisdictions can result in differing substantive outcomes and that potential litigants need to prepare and account for these possibilities. Moreover, the lessons above show that these concerns are not exclusive to those actively engaged in litigation, as even during patent prosecution parties must consider the downstream consequences as they gather and produce assignments records or draft support and enablement positions, consider seeking to invalidate certain patents of third parties and use factual findings from foreign administrative proceedings and litigation in the patent disputes litigated in the United States. Accordingly, any global patent litigation strategy has to start early in a technology's lifecycle as minor – or at least what seems minor or not directly relevant at the time – issues early on can have dramatic consequences down the line.

Endnotes

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Specialist Chapter: A Primer on US Litigation When It Comes to Software Patents

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IN SUMMARY

US software patent litigation often presents unique issues. These issues can include subject-matter eligibility under 35 USC section 101 and means-plus-function construction under 35 USC section 112, questions of joint infringement for the sale of the accused software, and line-drawing between US infringement and extraterritorial activities. Over the past five years, there have been substantial developments in these areas under US law.

DISCUSSION POINTS

- Software patent limitations in functional language, and 2022 decisions of the Federal Circuit
 - Subject-matter eligibility challenges to software patents involve a now-clear 'safe harbour'
 - Whether damages are available for foreign sales of software
 - Other issues software patents present such as ITC jurisdiction, IPR estoppel and prior use invalidity
-

REFERENCED IN THIS ARTICLE

- *Dyfan, LLC v Target Corp*
- *Akamai Techs, Inc v Limelight Networks, Inc*
- *Travel Sentry v Tropp*
- *Enfish, LLC v Microsoft Corp*
- *WesternGeco LLC v ION Geophysical Corp*
- *Power Integrations, Inc v Fairchild Semiconductor Int'l, Inc*
- *In re WinGen LLC*

Reports of the demise of US software patents are somewhat exaggerated, and software-based products and services are undoubtedly key parts of our global economy. Here, we focus on US litigation issues unique to software patents and practical points to consider on either side of a case. We draw on experiences obtaining a US\$600 million judgment in a software patent case, preparing for another jury trial asserting different software patents in a case that settled for a royalty payment in excess of US\$250 million and successfully defending against a software patent through trial at the International Trade Commission (ITC).

SOFTWARE PATENTS

Software is a set of instructions to operate a computer system and execute tasks. Source code is the human-readable form of those instructions, and object code is the form readable only by computers. The purest example of a software patent is one with claims directed to a non-transitory computer-readable medium containing computer-executable instructions that cause processors to perform a task. That type of US patent claim, called a computer-readable medium (CRM) claim, often has companion system and method claims,

and what is common across each type of claim is a description of steps carried out by software to complete a task.

CLAIM CONSTRUCTION

Software claims are more likely to have limitations expressed in functional language, which makes them more susceptible to something called means-plus-function (MPF) interpretation under US law, even when the claim does not expressly use the word ‘means’ and thus presumptively is not subject to this law. This seemingly academic issue can have serious consequences. If a court construes a term as MPF, the court looks to the specification for a specific algorithm that performs the function listed as a claim element. If the court finds such an algorithm, the claim element will be limited to that algorithm plus ‘equivalents thereof’ as of the date of patent issuance; but if there is no such algorithm, the court must hold the claim invalid.

The US Federal Circuit explored this issue in the 2022 Dyfan case, which concerned software claims. The Federal Circuit held that the defendant had not shown that the claim limitations were purely functional – thus, did not invoke MPF construction – and the Court acknowledged that artisans often describe the structure of software with functional language, making such claims unique. The relevant question is whether the claim language itself provides a sufficient description that an artisan would recognise as a particular computer-executable instruction or set of instructions. ‘Code configured to cure cancer’ would fail, but ‘code configured to multiply two inputs’ likely would be okay. For present purposes, the point is that this often-ignored issue warrants special consideration in the context of software patents because it frequently can lead to early invalidation of the patent claims.

INFRINGEMENT

If a software patent has a CRM claim, the company that sells the software typically will be the direct infringer (ie, the single entity that satisfies each claim limitation). When it comes to other claim types, litigants should familiarise themselves with joint infringement under the Federal Circuit’s Akamai and Travel Sentry decisions. Often, software claims present a fact pattern where the seller performs some steps of a claim, but the customer performs others, and such divided infringement can end a case. In those circumstances, for an infringement claim to be viable, there must be evidence that the seller had some degree of control over the customer, such that the jury can attribute the customer’s actions to the seller (ie, joint infringement). Similarly, system and method claims are more likely to require contributory and induced infringement theories, and litigants should be mindful of the mental state requirements – knowing or wilfully blind infringement – which can make such claims challenging to prove. Without pre-suit notice to the defendant of the asserted patents, the viability of such claims is questionable, and, at a minimum, this can substantially reduce the amount of damages.

Litigants should also keep in mind that the accused products are software, effectively written in a foreign language that US jurors (and most judges) will not understand. It is critical not to rely on source code alone to show infringement or to support defences; rather, an expert should show a point with more digestible documents or testimony, and then the expert can explain how that evidence aligns with the source code. This makes expert credibility particularly important because the jury will need to trust that the expert faithfully translated the ‘foreign language’.

SUBJECT-MATTER ELIGIBILITY

Perhaps counterintuitively, software patents have become one area of relative predictability under US law concerning patent-eligible subject matter. Starting with the 2016 *Enfish* decision, the Federal Circuit has issued several decisions establishing the eligibility of claims that address a problem that arises in the context of computer systems, and provide a specific technique that solves such a problem and improves computer system performance. That 'safe harbour' typically arises in the context of software-related claims, and it has made software-related claims an unexpected area of relative predictability when it comes to navigating complex US law relating to patent-eligible subject matter (sometimes called '101').

This will not save a claim directed to the idea of solving a problem that arises in computer systems – for example, a claim directed to the idea of screening email attachments for malware. But when the claim recites a specific technique, the claim typically will fall within the safe harbour as a technique that improves computer system performance, as opposed to conventional computer based automation of a common task, which frequently is found not to be eligible for patenting under US law. Defendants in US litigation often raise subject matter eligibility issues very early in a case – as part of a motion to dismiss or motion for judgment on the pleadings – so this issue warrants careful consideration before a patent owner brings a claim and soon after a defendant receives a complaint.

DAMAGES

Many companies distribute software via global electronic networks, and the lines easily blur between US infringement and extraterritorial activities. That is especially true after the US Supreme Court's 2018 *WesternGeco* decision, and the district court decision of Judge Stark – now at the Federal Circuit – in *Power Integrations*. On both sides of litigation, these are critical issues because they can more than double damages. The Federal Circuit may be poised to issue further guidance on this issue in 2024 in *Brumfield v IBG LLC*, Case No. 22-1630.

Two points warrant emphasis. First, for security reasons, many software companies store master versions of software products in the United States, including versions 'localised' into a foreign language for sale in a foreign market. If a patent contains CRM claims, such master versions in the United States directly infringe, especially when further copied onto jump servers in the United States before electronic delivery abroad, often via a content delivery network. Second, a foreign entity may be liable for indirect infringement (induced or contributory) even if its acts occur in a foreign country, as long as the software users' direct infringement occurs in the United States. Similarly, if infringement is joint with a foreign customer – the seller performs some steps of the claim and the customer performs others – a controlling US-based seller may be the direct infringer in the United States, despite the fact that the customer performs its steps in a foreign country.

Again, on both sides of litigation, it is critical to pay attention to these issues, which are unique to software, and can have a material impact on the value of a patent and case.

ADMINISTRATIVE PROCEEDINGS AND INVALIDITY

We note a few final issues. First, the US ITC is an increasingly powerful venue for patent litigation because it can issue a border exclusion order that keeps products off the US market. Under current law, the ITC does not have jurisdiction over purely electronic imports, such as

infringing software. Although the ITC currently does not have such jurisdiction, it still can have jurisdiction over imports of hardware with infringing software installed, and imports of hardware where installation of software after import constitutes indirect infringement (contributory or induced). Thus, parties should not rule out successful assertion of software patents in the ITC – indeed, the ITC has signalled interest in testing the boundaries of its jurisdiction when it comes to electronic imports as that form of distribution becomes more common in a globalised economy.

Second, when it comes to inter partes review (IPR) – invalidity proceedings before the US Patent Office – litigants should familiarise themselves with the law concerning software source code as a printed publication, which a petitioner can raise in IPR. In that case, a prior art system (embodied in source code) may be subject to estoppel that prohibits an accused infringer from raising the system in court if the IPR is not successful. Here too, a seemingly academic issue can have serious consequences in litigation: the patent challenger loses the ability to challenge the validity of claims based on potentially important prior art systems.

Finally, if litigants plan to raise ‘prior use’ of a software-based system as an invalidity defence in court, litigants should consider how much a prior use actually disclosed to the public in terms of the structure and operation of the underlying source code. The law on this issue is continuing to evolve, for example, in the Federal Circuit’s 2023 WinGen decision concerning plant genetics, which is interesting to consider in principle when applied to software. On both sides of litigation, this issue can have a significant impact on invalidity defences. On the one hand, WinGen suggests that public use of a software-based system can invalidate a patent claim even if members of the public cannot discern anything about the source code. On the other hand, earlier precedents suggest that a public use would not be invalidating unless an ordinarily skilled artisan could discern the elements of the invention, which in the context of software, should require an ability to understand the operation of the source code. Litigants likely will challenge this issue in the near future, and both owners and potential challengers of software patents should keep up with the law as it develops on this potentially dispositive issue

CONCLUSION

In short, US software patents are far from dead, but on both sides of US litigation, there are unique issues that arise in the context of software products and patent claims directed to software inventions. When selecting counsel and experts for these matters, parties should be careful to look for specific experience with these issues, which might seem somewhat academic, but can have serious impact on success in assertion or defence, and thus on the value of the patents covering software-based inventions. In our experience, even seasoned patent litigators may not be familiar with these issues that are quite specific to software-based products and patents.

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Specialist Chapter: First Months of UPC See Broad Sector Engagement and CMS Teething Problems

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IN SUMMARY

The year 2023 signified a new era for patent litigation in Europe with the introduction of the new unitary patent (UP) and the Unified Patent Court (UPC) on 1 June 2023. The UPC aims to make patent litigation in Europe more streamlined and cost effective, and provide commercial certainty for businesses across all sectors. This article will review the establishment and first few months of the UPC.

DISCUSSION POINTS

- The development and commencement of the new UP and UPC system
 - Opting classic European patents out of the UPC system
 - A review of the early engagement with the new system across sectors
 - Pros and cons of central relief
 - How the unique structure of the UPC may impact litigation strategies
 - A review of early UPC decisions
-

REFERENCED IN THIS ARTICLE

- Convention on the Grant of European Patents
- Regulation (EU) No. 1257/2012 and Regulation (EU) No. 1260/2012
- Unified Patent Court Agreement
- Rules of Procedure of the Unified Patent Court
- *10x Genomics and others v NanoString Technologies and others*
- Communication on the 7th UPC Administrative Committee meeting on 26 June 2023

The year 2023 signified a new era for patent protection and litigation in Europe with the introduction of the unitary patent (UP) and Unified Patent Court (UPC) on 1 June 2023.

The UPC is a new supranational court that permits the enforcement of, or challenge to, patents, across a large geographical market in one action.

Within the first few months of its operation, the UPC is already driving change across all sectors where businesses have operations in Europe, providing new strategic patent commercialisation and litigation choices to defend existing markets, access new markets and secure global settlements.

This article will review the creation and early days of the UPC.

THE NEED FOR A NEW EUROPEAN PATENT SYSTEM

The European Patent Convention (EPC)^[1] has underpinned the successful European patent system since its creation in 1973, so questions may be asked as to why the new UP and UPC have been deemed necessary, particularly as not all European countries will participate.

To answer this, it is necessary to understand how the EPC system works. Via a centralised prosecution procedure, the European Patent Office (EPO) grants 'classic' European patents (EPs), which may be designated in any one or more EPC member countries,^[2] resulting in a 'bundle of national patents' (rather than one single patent), that are (subject to translation issues) identical in content and scope, but separately in force. Once the EPO's nine-month opposition period has expired, they could then only be invalidated or enforced by a national court.

Patent holders wishing to enforce, or third parties seeking to challenge, classic EPs therefore had to bring proceedings in each country of interest. National decisions have often been inconsistent owing to differences in litigation procedures and evidence before the courts, and relief is confined to smaller markets. This divergence, and the desire to create a cost-effective and streamlined process, led to a plan to create a centralised European patent court.

This plan took a long time to get off the ground, but the underlying UP Regulations^[3] were signed in 2012, and the UPC Agreement^[4] (UPCA) in 2013. However, for these arrangements to come into effect, 13 states including Germany, France and the United Kingdom, as the three countries with the highest patent filing numbers at the time, had to ratify and deposit their instruments of ratification, with the system starting four months after the last required deposit.

Before this threshold could be met, constitutional challenges in Germany and the United Kingdom's withdrawal of its UPCA ratification following Brexit, appeared to stall the project. However, it gained momentum when the constitutional challenges were rejected in July 2021, and Italy was subsequently substituted in place of the United Kingdom as the next highest filer of patents at the relevant date. As both Italy and France had already ratified the UPCA, once the 13th participating member state – Austria – ratified in January 2023, only German ratification was outstanding. Germany ratified on 17 February 2023, allowing the UPCA and the UP Regulations to enter into force on 1 June 2023.

A NEW DAWN: THE UP AND UPC

The commencement of the UP and UPC system on 1 June 2023 heralded a new dawn for patent protection and litigation in Europe.

The UP differs from the classic EP 'bundle of national patents', as it provides patent protection in all participating member states, with a single registration, without the need for national validation. Between 1 June 2023 and 1 September 2023, there was a steady uptake of the UP, with, at the time of writing, 9,199 registered UPs,^[5] the majority of UP requests being in infrastructure and mechanics, closely followed by health, and materials and production.

The UPC aims to provide a harmonised set of patent laws. One UPC action (as opposed to multiple national actions) provides one decision that is enforceable across a large European market of the 17^[6] participating member states that had ratified the UPCA at 1 June 2023. Some countries, including Ireland, are yet to ratify the UPCA, but they are expected to do so in due course. The UPC has exclusive jurisdiction for disputes relating to infringement and validity of UPs, and for classic EPs and EP applications that have not been opted out and not enforced in national courts during a seven-year transition period.^[7]

The UPC has one set of rules, and strict litigation timelines, with a first-instance decision expected in 12 to 14 months from proceedings being initiated. The first UPC preliminary

injunction (PI) hearings took place approximately 3 to 3.5 months after proceedings were initiated,^[8] showing an intention to meet the promise of adhering to tight time frames.

Of course, one quicker, centralised action as opposed to multiple national litigation cases should provide earlier commercial certainty for businesses, be more cost-effective, and therefore more attractive to a wider range of litigants, such as small and medium-sized enterprises (SMEs). Indeed, early UPC filings show that some SMEs are already seeking to enforce their rights before the UPC, demonstrated by myStromer, which has issued infringement proceedings against Revolt Zycling AG^[9] regarding e-bikes.

While the UPC provides an additional forum, national litigation will still form an important part of European patent litigation strategies. This is because national litigation is required in non-participating countries. This includes EU countries that have chosen not to participate (eg, Spain, Poland and Croatia), and non-EU EPC countries such as the UK. Patentees may also choose to opt out of the UPC during the transitional period, and these patents are enforced or challenged in national courts. Further, even if a classic EP has not been opted out of the UPC, it is subject to a dual jurisdiction during the transitional period, which means that litigants may choose where to bring proceedings – national courts or the UPC.^[10]

TO STAY IN OR OPT OUT?

The UPC is an untested system, therefore decisions as to whether to opt valuable classic EPs out dominated the thoughts of many patent and business professionals prior to the opening of the court. At the time of writing, 495,801^[11] classic EPs had been opted out of the UPC. While many expected a large number of patents – at least in the life sciences and technology spaces – to be opted out of the system, this figure is almost 10 times the initial estimate of 50,000 and spans a range of sectors.

However, the high opt-out numbers does not mean that the age of the UPC is over before it has begun. This is because the patentee's initial decision is not necessarily set in stone. An opt-out can be withdrawn at a later stage unless a revocation action is commenced against it in a national court, in which case the patent would be locked into the national system. Similarly, if a patentee chooses not to opt out, they can file an opt-out at a later stage unless a UPC action has been commenced against it. However, withdrawing an opt-out is a one-time opportunity: once an opt-out is withdrawn, a patentee cannot opt out again.

There is no escaping the fact that the opt-out numbers are higher than expected, but many patentees may have chosen to wait and leave their options open until UPC case law is more established. The balance in favour of or against opting out may shift in line with evolving business objectives or the factual landscape, as demonstrated by the fact that 90 opt-outs^[12] had already been withdrawn in the first 100 days of the UPC.

EARLY FILINGS AND SOME TEETHING PROBLEMS

This, and the number of UPC actions filed in the first three months, indicates that many are willing to engage with the new system.

UPC proceedings are filed using the publicly accessible online Case Management System (CMS). Adapting to a fully electronic CMS has unsurprisingly posed technical challenges, but has also notably led to one of the early reasoned decisions of the court. On the first day of the UPC, as part of a long-running global dispute, Sanofi filed a revocation action regarding Amgen's cholesterol-lowering medication patent.^[13] On the same day, Amgen sued Sanofi for infringement of the same patent.^[14] Being the first day, the UPC's CMS was not functioning

properly and the actions could not be filed electronically. Therefore, both parties filed their actions in hard copy. Amgen issued a preliminary objection to the admissibility of Sanofi's revocation action, arguing that it filed its infringement action first. The Court dismissed this objection because, on the facts, Sanofi filed its action 30 minutes earlier. In a robust decision, the UPC held that it is a matter of determining on the facts which case was lodged first, because this criterion is clear, predictable and can be objectively assessed.

CMS issues have also led to a lack of transparency as to the precise number of cases filed. The most reliable information has not come from the CMS, but has instead been provided by the UPC Administrative Committee, which confirmed an initial flurry of activity, with 19 cases being filed on the first day.^[15]

Since then, at the time of writing, while the UPC confirmed^[16] that it has 52 cases, comprising 35 infringement actions, seven revocation actions and 10 applications for provisional measures (eg, PIs, orders for preserving evidence and orders for inspection), not all actions were visible on the CMS. It is hoped that the UPC will take steps to improve transparency of CMS filings over time.

SURPRISING SECTOR ENGAGEMENT

Prior to the UPC's opening, there was an overwhelming expectation that the early cases would fall outside IP rich sectors such as life sciences and technology. Many thought they would take a back seat until the court's approach to key issues – such as PIs – became clearer.

While, in the first month, UPC actions were filed in a variety of sectors, perhaps surprisingly life sciences companies led the way in filing some of the early cases. The Sanofi and Amgen actions^[17] are part of a long-running global dispute, and put down a marker that the UPC will play a part in large, highly valuable multinational disputes.

The life sciences sector has also seen infringement actions filed by 10x Genomics against NanoString and Vizgen, interestingly with one action being the first case lodged before the UPC concerning the assertion of a UP.

There has since been a number of mobile telecommunications and standard essential patents actions. Panasonic has filed 12 infringement actions against various subsidiaries of two Chinese mobile phone implementers Xiaomi and Oppo.^[18] This is interesting because it demonstrates that the UPC is being used by multinational companies in high-value, technically complex disputes, and may be seen as a jurisdiction in which some difficult issues, such as standard essential patent assertions.

However, it would be wrong to say that those IP-rich sectors have dominated UPC filings. Of interest is a dispute in the luxury goods sector, where Agfa has filed a patent infringement action against Gucci,^[19] indicating engagement in the new court across a variety of sectors.

THE LURE OF CENTRAL RELIEF

Many of the businesses engaged in early UPC actions are household names, and the technologies are valuable. Why may such entities seek to enforce their valuable classic EPs through this untested system? There will be a multifaceted answer to this, based on the business objectives that underpin the factual scenario. Perhaps the greatest benefit of the UPC may be that its decisions will have effect in all participating member states.

For patentees, valuable PIs, final injunctions and damages awards apply to infringing activity in all UPC territories where the patent is in force. There have been a number of early UPC PI hearings. The UPC granted its first PI in favour of 10x Genomics^[20] to restrain NanoString's activities in respect of its RNA imaging technology across all UPC territories. This also relates to the first assertion of a UP. At the time of writing, NanoString had indicated that it will appeal the decision. The 10x Genomics PI was issued by the Munich Local Division. A few days earlier, the Vienna Local Division denied CUP&CINO's^[21] PI application against Alpina in respect of milk frothing devices, on the basis that it considered there was no infringement of the asserted patent. At the time of writing, no detailed written reasoning for either case was available. This will be eagerly awaited and will undoubtedly provide some guidance as to the court's general approach to PIs.

The downside is, of course, that it risks valuable patents being revoked across all participating member states. However, this is attractive to third parties – as in the Sanofi revocation proceedings^[22] – seeking freedom to operate, because the UPC may revoke a non-opted out classic EP or a new UP across all participating member states. Pursuing revocation via the UPC may offer significant costs savings and avoid the complexities of navigating multiple national actions, with potentially different outcomes.

Further, UPC proceedings may be used as leverage to encourage settlement, particularly in disputes where there are multiple national litigations. One such example is the dispute between AutoStore and Ocado, in which national actions had taken place in the United Kingdom and Germany. Ocado issued UPC infringement proceedings^[23] against AutoStore, which were subsequently withdrawn following a global settlement.

A UNIQUE COURT STRUCTURE

Once the court opened, attention turned to the question of where a UPC case may be filed. While a centralised court, it has a unique structure because the Court of First Instance is divided into local, regional and central divisions.^[24] Cases may commence in any one of these divisions according to the subject matter,^[25] and depending on the facts, more than one division may be competent.

Infringement and PI actions will be brought before either the UPC local^[26] or regional^[27] division in the member state where the infringement has occurred or where the defendant has residence or principal place of business, or if neither of these apply, the central division.

Claims for revocation or declarations of non-infringement will usually be brought before the central division.^[28] The central division has its seat in Paris, with a section in Munich. Following the United Kingdom's withdrawal, the UPC Administrative Committee announced in June 2023^[29] that, from June 2024, the London section will be relocated to Milan. There has been much discussion about case allocation between the different central division sections, which may impact litigation strategies for patent holders in different industries. Which section of the central division will hear cases relating to a particular technology depends on how the subject matter is classified under the International Patent Classification (IPC). From June 2024:

- the Munich section will hear IPC category C (chemistry, metallurgy without supplementary protection certificates (SPCs)) and IPC category F (mechanical engineering, lighting, heating, weapons, blasting) cases;
- Milan will hear IPC A cases (human necessities – life sciences – without SPCs); and

- everything else – including IPC B cases (performing operations, transporting), D (textiles, paper), E (fixed constructions), G (physics) and H (electricity) claims, as well as SPC claims (regardless of whether the subject matter is IPC A or C), will be heard in Paris.

Until the Milan section opens, human necessities (IPC A) cases, will be dealt with by Paris, and chemistry and metallurgy (IPC C) cases will be heard in Munich.

GERMANY FORGES AHEAD

Depending on the facts, more than one division may be competent, which allows some choice as to in which division a party may bring an action. This will be important to parties, and will feed into litigation strategies.

At the time of writing, 52 UPC cases have been commenced in 11 different UPC divisions, with the vast majority (34) initiated in a German division. This is not entirely surprising. There are four local divisions of the court in Germany, and while the UPC Rules of Procedure^[30] combine elements of patent litigation procedure from different national systems, there are some features that descend from German procedure that litigants involved in some of the early filed cases may be aiming to exploit. Amgen's preliminary objection decision^[31] means that, at this point, while technically two separate proceedings, infringement (considered by the Munich local division) and validity (considered by the Munich central division) of the same patent will effectively be bifurcated. While it is expected to be unlikely in most cases, bifurcation is known to those familiar with German patent litigation, and may be valuable strategic tool.

INFLUENCE OF LOCAL EXPERIENCE

Over time, it is expected that a body of case law from both the Court of First Instance and the Court of Appeal will provide consistency, but before then, the common view has been that UPC judges will inevitably make decisions largely based on their experiences from their national systems ('couleur locale').

Indeed, early ex parte UPC decisions in respect of applications for provisional measures have been influenced by local approaches. These decisions related to applications to preserve evidence by seizing infringing products, similar to the French saisie-contrefaçon and Italian descrizione. They were made by the Milan local division in favour of Oerlikon in respect of certain textile machines, which had been on display at an international trade fair by two Indian companies, Himson and Bhgat. The court considered the applications within hours of them being made, and found that the imminent closing of the trade fair justified the extreme urgency in respect of the application.

The role of protective letters has also been a hot topic, with 236 having been filed in the first month of the UPC. A protective letter is an outline by potential defendants of why an application for provisional measures should be rejected. Protective letters can be a valuable defensive tool, but an early UPC decision has demonstrated that they will not always guarantee success. Despite a protective letter having been on file, the Düsseldorf local division granted an ex parte preliminary injunction in favour of myStromer AG against the display of a bicycle by Revolt Zyçling AG at a trade fair, holding that there was credible irreparable damage given the importance of this trade fair to the industry.

Despite this decision, the number of protective letters filed at the UPC is expected to be higher, although the UPC has since indicated that it will no longer share information pertaining to how many are on file.

At the time of writing, the written reasoning behind the first substantive UPC PI decisions had not been published. However, it is understood that the influence of national procedure was also seen in the Vienna Local Division (in respect of the CUP&CINO PI hearing) and the Munich Local Division (in respect of the 10x Genomics PI hearing). Once the decisions are published, it will be interesting to see the extent to which such couleur locale has permeated the court's approach to the issues before it.

COMMENT

The first few months of the UPC has confirmed some early expectations but has also thrown up some surprises. It is too early to draw any definitive conclusions, but it is clear that engagement is positive and the next 12 months will undoubtedly prove to be incredibly exciting for patent litigation in Europe.

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Endnotes



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Greece: Navigating the Patent Enforcement Landscape

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Summary

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IN SUMMARY

This chapter provides key information regarding patent litigation in Greece.

DISCUSSION POINTS

- Available means for defence against infringers
 - Information on proceedings, representation and legal practice
 - Doctrine of equivalents
 - Budget, recoverable costs and damage claims
 - Unitary patent and Unitary Patent Court
-

REFERENCED IN THIS ARTICLE

- Code of Civil Procedure
- Law 4512/2018
- Presidential Decree 31/2019
- Decision No. 3955/2015 of the Athens Multi-member Court of First Instance
- EU Directive 48/2004/EC
- Agreement on a Unified Patent Court

The most effective patent protection is prevention. Adopting a prevention strategy by establishing an efficient observation system is key. This can be achieved by filing a general request with the local customs authorities, which will notify the right holder or its representative on interception of suspected infringing goods.

The first and quickest way of acting against an infringer is to request a temporary restraining order. This will be granted if the petitioner proves the existence of a prima facie serious infringement as a matter of exceptional urgency.

This request is filed concurrently with a petition for injunction and, if granted, remains effective until the hearing of the injunction takes place. Within this framework, the patent owner may request cessation of the infringing acts and removal of the allegedly infringing products from the market. The patent owner may also request delivery of information (eg, sales figures and channels of distribution of the infringing products) and measures to preserve evidence.

The next step is the main infringement action, in which the patent owner may request compensation and moral damages.

The Code of Civil Procedure provides litigants in infringement cases the option of seeking an out-of-court settlement. Mediation and arbitration are also available means for resolving IP rights disputes.

Articles 867 et seq of the Code of Civil Procedure provide for the rules on arbitrations; however, neither mediation nor arbitration have been sufficiently tested in Greece.

Law 4512/2018 initiated compulsory use of mediation in legal disputes that arise from patent, trademark and industrial design infringements. It introduced a compulsory initial mediation session before the hearing of the case. This, along with proof of the lawyer's compliance to the obligation to inform the client in writing about the option of mediation, is a prerequisite for the admissibility of the lawsuit.

The compulsory initial mediation session in legal disputes arising from patent infringement is a significant change in recent years that was expected to affect patent litigation and contribute to the reduction of the workload of the Greek courts; however, it has not been sufficiently tested yet, especially within the patent litigation environment.

Preliminary injunctions are heard before the Single-Member Civil Court of First Instance and main infringement actions are heard before the Full-Member Civil Court of First Instance. Greece has two specialised EU trademark and patent courts based in Athens and Thessaloniki respectively.

The judges who serve in Greek specialised courts will have received special training in IP matters during their studies at the National School of Judges before their appointment to the bench; nonetheless, although they have excellent legal knowledge, they lack technical background. Consequently, in patent cases that involve complex technical issues, expert opinions are indispensable. Expert witnesses may testify before the court either orally or by affidavit. Expert opinions may often prove to be pivotal to the outcome of proceedings, particularly in complex cases. Judges tend to give the opinion of a distinguished expert more weight than that of a non-technical person.

Greece has a bifurcated system. The law provides for separate procedures before the competent civil courts for patent validity challenges and infringement actions. Consequently, full or partial nullity declarations can be made by means of an independent legal action or a counterclaim within the framework of the infringement proceedings. In practice, invalidity objections and nullity actions are the most common defences for infringers.

Competent representatives of the parties before the Greek civil courts are only lawyers (ie, attorneys at law) who are members of a Greek bar association, without restriction. The complexity of most patent disputes makes it imperative that litigants entrust their cases to lawyers who specialise in IP protection.

Presidential Decree 31/2019 established the Hellenic Industrial Property Academy, which aims to introduce a system of education at the national level that will provide suitable training in the industrial property field and will lead to the acquisition of the title of 'patent attorney' or 'certified patent consultant'. Certified individuals will have the right to act on behalf of their clients before the Greek Patent Office, but not before courts.

The academy has started functioning fully in 2023, and the first patent attorney exam is expected to take place in 2025.

Forum selection is important to ensure that court proceedings take place before a court with sufficient expertise in patent law. Patent owners may wish to initiate court proceedings before specialised courts and not before the local courts.

According to legal theory and case law, the competence of the specialised courts in Athens and Thessaloniki is reserved for main patent actions (ie, main infringement actions and nullity actions against a patent), but not for temporary restraining orders or injunctions.

The competent courts for preliminary proceedings are the local courts. The local courts' lack of expertise in patent law may negatively affect the protection of patent owners' rights; therefore, patent owners generally try to file preliminary proceedings before the specialised courts in Athens or Thessaloniki.

Greek law does not provide for pretrial discovery; however, it gives the patent owner the right to take measures to preserve evidence and request the defendant to provide information (eg, invoices or the number of products that have been distributed) within the framework of a trial.

For the most part, evidence is in writing. An introductory writ is filed with the court and served on the defendant. The civil action starts with the filing of the lawsuit with the competent first-instance court. The plaintiff must serve the lawsuit within 30 days (or 60 days if the defendant resides abroad) from filing. Parties must file their written arguments and evidence within 90 days (or 120 days if the defendant resides abroad) from the expiry of the deadline for officially serving the lawsuit, and a reply to each other's arguments and evidence must be filed within a further 15-day period. Witness testimonies are submitted in the form of sworn affidavits.

Upon the expiry of the term, the file is deemed closed and, within another 15 days, the judge in charge of the case is appointed. The hearing of the case takes place within the next 30 days, without examination of witnesses in court, unless the bench decides that this is absolutely necessary.

Expert witnesses may provide sworn affidavits. If the judge decides that an oral hearing is necessary, one expert witness may testify orally before the court. Given that the judges dealing with patent matters have only legal (not technical) backgrounds, the role of expert witnesses in the procedure is of paramount importance. Where complex issues are involved, such testimonies may prove to be decisive to the outcome of the case.

The Greek courts accept the doctrine of equivalents. More specifically, the courts accept that a patent may be infringed by means that are equivalent to the content of the claims.

The doctrine of equivalents applies when certain technical characteristics of the patented invention are identical to those of the infringing product or service, and certain characteristics of the latter fall within the meaning of 'variations' or 'imitations'; in other words, it applies when a third party, in its effort to illegally exploit an invention, changes certain secondary elements of the invention or adds certain minor or unnecessary elements thereto to disguise the infringement.

The court must determine whether there is an encroachment of the scope of protection of the invention. This scope is determined by extrapolating the range covered by the technical characteristics of the patent claims to items that, according to the average expert, are considered to achieve a technical solution that is equivalent to that protected by the patent.

A means of infringement, which as a rule comprises the copying of a technical characteristic, is considered as equivalent if it is obvious to the average expert that if that means is used, it will lead to a substantially similar result as the one achieved by the technical characteristics of the patent claims (Decision No. 3955/2015 of the Athens Multi-member Court of First Instance).

Certain rights that are considered patent rights in other jurisdictions are exempt from protection under Greek patent law (eg, software and business methods). In any case, the

factor that is most likely to give rise to difficulties in the enforcement of certain patent rights is the lack of technical training of Greek judges, as well as lack of extensive case law in complicated technical fields.

Precedential decisions are not binding on Greek courts; however, Greek judges take the established case law into consideration and tend to stay in line with it.

Although Greek courts are not bound by decisions from other jurisdictions, they tend to take them into consideration in similar cases – especially the case law of German, French and UK patent courts.

The current version of the Civil Procedure Rules has greatly limited the opportunities for defendants to obtain postponements, which used to be a tactic employed by parties to significantly delay proceedings; however, the appointment of technical experts may cause delays of 18 months or more.

For a petitioner to be granted a preliminary injunction, it must prove the existence of serious and urgent infringement. The petitioner must also prove the novelty and inventive step of the invention if the defendant raises objections in this respect.

In main infringement action proceedings, parties may expect the issuance of the court decision within six to eight months from the hearing.

The costs involved in taking a case through to a first-instance decision are not easy to estimate as they depend on the complexity of the case, the duration of the proceedings, potential involvement of technical experts and potential translation costs; however, litigation costs in Greece are considerably lower than those in other EU member states.

The costs of preliminary proceedings and main patent proceedings can be roughly estimated to range between €20,000 and €50,000, but higher fees should be expected in complicated cases where several technical experts are involved and close cooperation between client and counsel is necessary for an extended period.

According to the Civil Procedure Rules, the losing party must pay the winning party's legal fees, as determined by the court. Historically, this amount has often been calculated on a very conservative basis, not covering all attorney's fees.

However, since the incorporation of EU Directive 48/2004/EC into Greek law, the courts are obliged to determine the actual legal fees. If the plaintiff seeks compensation, the related court costs may be much higher, depending on the requested amount, and may reach approximately 1.1% thereof.

The typical remedies granted to a successful plaintiff are a temporary or permanent injunction, damages, and seizure or destruction of the infringing goods, or both. In many cases the courts may threaten the losing party with a monetary penalty for every breach of the judgment. They may also permit publication of a summary of the decision in the Greek daily press.

The patent owner may request compensation (ie, based on reasonable licensing fees) and moral damages, but not punitive damages. To obtain compensation or moral damages, the plaintiff must prove the negligence of the infringer.

In Greece, three factors determine the compensation claim: the actual loss, the defendant's unfair profits and reasonable licensing fees.

Proving the exact amount of the damage or enrichment is often considerably difficult. Where the patent owner cannot collect enough evidence, it may request the infringer to provide information such as invoices or the quantity of distributed products.

In addition to the compensation claim, a patent owner may request moral damages; however, the amount of moral damages is difficult to estimate.

The court will grant a permanent injunction if the petitioner shows that its patent is new and inventive and that the defendant is infringing it. Unfortunately, no data is available regarding the outcome of compensation actions in Greece.

All final decisions of the first-instance courts are open to appeal within 30 days of notification to the losing party for Greek nationals or within 60 days of notification for foreign nationals. If no official notification takes place, the decision may be appealed within two years of its publication.

The losing party may contest all aspects of the judgment that relate to legal issues or incorrect findings regarding the facts of the case.

The right to appeal is provided only in main infringement action proceedings; preliminary injunction decisions cannot be appealed.

The time frame for appeal proceedings is on average 18 months but may be longer, depending on the circumstances.

The losing party may appeal a second-instance decision before the Supreme Court within 30 days of notification to the losing party for Greek nationals or within 60 days of notification for foreign nationals. If no official notification takes place, the decision may be appealed within two years of its publication.

Nullification of validated European patents is rare in comparison with national patents because European patents are granted after substantial examination by the European Patent Office (EPO) regarding novelty and inventive step.

The unitary patent and Unitary Patent Court have become a reality as of 1 June 2023, bringing a significant change to the patent environment as we know it.

Patentees and potential litigants must bear in mind that Greece is among those countries which, at the time of writing, have signed but not yet ratified the Agreement on a Unified Patent Court (UPCA). Consequently, the Unified Patent Court (UPC) will have no jurisdiction over Greece until the country fully ratifies the UPCA. In the meantime, unitary patents granted by the EPO must be validated in Greece to have effect in the country.

It is also important for patentees and potential litigants to know that, even if Greece ratifies the Agreement, under article 83(1) UPCA, the exclusive competence of the UPC is subject to exceptions for a transitional period of seven years, which may be prolonged by up to a further seven years. During this period, actions for infringement or revocation even of non-opted out patents may still be brought before the Greek national courts.



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Summary

IN SUMMARY

DISCUSSION POINTS

REFERENCED IN THIS ARTICLE

FORUM SHOPPING IN HUNGARIAN PATENT LITIGATION

TRIAL FORMAT AND TIMING

INVALIDATION OF A PATENT

CONCLUSION

IN SUMMARY

Patent litigation is a vital aspect of Hungary's legal landscape, safeguarding intellectual property rights and promoting innovation. Defendants often use invalidity actions to delay cases, but Hungary's legislature aims to prevent such delays and protect innovators' rights. Hungary hasn't ratified the Agreement on a Unified Patent Court, so it lacks jurisdiction, but it's still a favorable venue for patent disputes. Skilled examiners at HIPO and specialized tribunals can handle revocation and invalidity claims efficiently. Recent legislative updates and case law changes suggest faster patent infringement proceedings, promising long-term benefits for patentees.

DISCUSSION POINTS

- Forum shopping in Hungarian patent litigation
 - Trial format and timing
 - Invalidation of a patent
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REFERENCED IN THIS ARTICLE

- Act XXXIII of 1995 on the protection of inventions by patents
- Act CXXX of 2016 on the Code of Civil Procedure
- Agreement on a Unified Patent Court

Patent litigation in Hungary makes up a significant part of the legal landscape, serving as the cornerstone for the preservation of intellectual property rights and the facilitation of innovative advancements. Invalidity actions against an enforced patent are a common tool for defendants to delay proceedings; however, the Hungarian legislature intends to prevent delays and provide an adequate tool for innovators to preserve their rights.

FORUM SHOPPING IN HUNGARIAN PATENT LITIGATION

Forum shopping refers to a legal strategy wherein a party presenting legal issues seeks to choose a court forum that is likely to best serve its interests. This practice is particularly important in international disputes, where jurisdictions and regulations can differ between countries. This strategy is also applied in patent litigation cases, often referred to as 'forum buying'. During forum shopping, parties take into consideration the expertise of the judicial body, the stability of legislation, the efficiency of the litigation process (speed) and potential legal remedies available.

Until recently, the Patent Act and case law did not allow forum shopping between the national revocation action of a validated European patent before the Hungarian Intellectual Property Office (HIPO) and the opposition of its European counterpart before the European Patent Office (EPO). Section 84/M(2) of the Patent Act – old legislation – advised HIPO to suspend its proceedings until the final decision of the EPO opposition. This meant, in practice, that when an opposition was filed, which was the case most of the time, HIPO quasi-automatically, based on a request, suspended the revocation. This action of HIPO was also confirmed by the courts (Metropolitan Court of Appeal 8.Pkf.26.264/2018/4).

Recent amendments to article 84/M(2) of the Patent Act allow the revocation action before HIPO to be suspended on a duly justified basis until the final conclusion of the EPO opposition. HIPO now has the discretion to suspend the proceeding, and this will only happen – according to HIPO – and give the EPO proceeding priority, if there are really duly justified cases. HIPO clarified that, in instances where an expedited revocation action measure was requested by either party (on the basis of pending litigation case), the Office must expedite its decision process; given that the EPO opposition procedure is anticipated to extend over an indefinite period, suspending the revocation action would only extend the existing legal ambiguity. It was clear to HIPO that the changes in the Patent Act gave it the freedom to decide on the suspension and the interest of the parties, including the effective enforcement of patent rights. The legislature intended to provide quick and high-level enforcement for patentees.

In the recent 3.Pk.22.731/2022/8-I Metropolitan Court and the 1.Pkf.25.375/2023/5 Court of Appeals decisions, the courts ruled that there is forum shopping and competition between the EPO and HIPO in the field of revocation actions and oppositions. There is no need to wait for the EPO's decision; the procedure can only be suspended in duly justified cases and, in an accelerated procedure, this can be interpreted even more narrowly, like HIPO did.

The Court of Appeals stated that the legislative intention behind recent amendments was to allow the suspension of revocation proceedings within a narrower scope than before. Centralised opposition proceedings and national invalidation proceedings do not preliminarily question each other, even though they concern the same patent; more precisely, national validated patents will cover the same scope as the central counterparts. The reason for this is that the two forums both have jurisdiction over validity issues in their own areas. Therefore, the two proceedings do not complement each other, but there is a choice – an opportunity for forum shopping. Accordingly, HIPO has wide discretion to take into account various facts of a case that may prove duly justified cases, for example: the current state of the competing proceedings (even if not final), the expedited nature of the proceeding and the joint request of the parties or the unilateral request of one of the parties (in the latter case, by which party, on the basis of what legitimate interest, the suspension of the proceedings is sought).

HIPO in one case rejected the suspension request where the EPO Opposition Division (EPO OD) at first instance confirmed the validity of the patent in its original claim, while in another case suspension was granted based on the EPO OD first-instance partial revocation decision. It seems that if an EPO opposition proceeding hasn't commenced, or the patent's validity is confirmed at first instance, HIPO will not suspend the revocation action.

Based on the above, there is strategic consideration to be made by claimants and defendants. On the one hand, patentees are not tied to long revocation actions and may obtain a final decision on patent infringement within 1.5 to 2.5 years (including bifurcated revocation actions and infringement proceedings to the second instance). On the other hand, if the defendant can raise solid invalidity grounds, it may obtain a quicker resolution on the validity of the asserted patent against it. Looking at this from both angles, the new possibility for forum shopping and the fact that expedited revocation actions are possible, the parties may obtain a first-instance decision from HIPO on validity earlier than the EPO opposition proceeding may commence (after a nine-month opposition period) or advance into the oral hearing phase (about 12 months after commencement).

In the majority of patent disputes, defendants are well prepared to start national revocation actions; consequently, opting for swift revocation proceedings within HIPO appears advantageous for potential defendants as well. If a defendant fails to file a revocation action before HIPO, there remains the option to initiate a counterclaim for invalidity in the infringement proceeding, which by law is an expedited proceeding (see more details below).

TRIAL FORMAT AND TIMING

Hungarian patent litigation has two stages: the first-instance adjudication and subsequent appellate recourse to the Court of Appeal. The invalidation phase, conducted within the first-instance court, engenders an incisive analysis of both substantive tenets and procedural difficulties. This encompasses the precise review of evidentiary grounds and legal contentions, underscored by written submissions and oral hearings. Upon the issuance of the first-instance judgment, the losing party is accorded the prerogative to invoke the appellate jurisdiction of the Court of Appeal, sending the case into a higher echelon of juridical scrutiny.

Act CXXX of 2016 on the Code of Civil Procedure is the cornerstone of patent litigation. It regulates civil court procedures, and the Patent Act includes some special rules. Section 170 lists parts that must be included in the statement of claims. According to subsection (1), section 179, if the statement of claims is acceptable, the court must notify the plaintiff and call upon the defendant to present a written defence statement within 45 days. Section 199 regulates the written defence statement. Section 201 allows the plaintiff to present a counter-memorial. After this, the defendant can provide a rejoinder. These latter two are not always asked to be presented by the court. If the facts or the legal questions are easy, or there is no counterclaim, these are rarely necessary. The court then summons the parties to a preparatory oral hearing (section 190). During this hearing, the aim is to clarify the claims and the evidence. The judge can adjourn the hearing, or can close the preparatory oral hearing and move onto hearing on the merits (section 196). The complete procedure takes about 10–12 months. After the first judgement is rendered, the parties can appeal to the Metropolitan Court of Appeals within 15 days. The oral hearings (if the parties initiate) are set within three to four months. During the second instance, only a written defence statement can be provided; the other statements can be performed at the trial. If there is a difference between the decisions of the first and second instance courts, a revision can be asked from the Supreme Court or in special cases, for example when first and second-instance decisions are aligned but are diverging from or have significant impact on precedent.

The Patent Act states that the defendant in a patent infringement action will be entitled to lodge a counterclaim for invalidity (subsection 1a, section 104). The court will hear a patent infringement action in a priority proceeding if the defendant makes a counterclaim for invalidity (subsection 1g). This means that the expert must provide the opinion within 30 days (subsection 1h). HIPO is entitled to provide this opinion, which means that the appointed patent examiners will have to provide a similar assessment on the validity as for a revocation action. While this short time frame may seem tempting, in practice it is a very short time to properly assess the validity.

For a national revocation action started before HIPO, before the infringement claim is filed at the court, the infringement proceeding must be suspended (subsection 1d). If the infringement proceeding already commenced, the court also may suspend the proceeding until the final decision in the revocation action, based on the general rules of the Code of Civil Procedure and prevailing case law, is rendered. Revocation actions may be examined

in an expedited manner if the infringement proceeding already commenced; thus, HIPO should render its decision within one year. The parties may file a petition for alteration to the Metropolitan Court if they are dissatisfied the decision. The Metropolitan Court as the first-instance court will in this case only render a decision on the validity as the infringement action was already suspended and the cases are considered separate actions. In general, the Metropolitan Court renders its decisions within four to six months, which can be appealed within 15 days to the Metropolitan Court of Appeal. The Metropolitan Court of Appeal may only hear the parties on request, but it delivers its decisions in writing within four to six months. Again, this decision may only be questioned based on the infringement of law before the Supreme Court if the decisions are diverging or there is significant impact on precedent.

INVALIDATION OF A PATENT

According to paragraph (c), subsection (2), section 44, the HIPO handles “invalidation of a patent, except if a claim for invalidation is made before the court hearing the patent infringement action, by way of a counterclaim in accordance with Subsection (1a) of Section 104”.

The procedural rules are regulated by the Patent Act. Subsection (2), section 47 regulates that HIPO will investigate the facts in revocation proceedings. Subsection (6), section 48 does not allow applications for continuation.

Section 80-81/A regulates revocation proceedings. Any person may file an application for revocation of a patent; thus, no special legitimacy must be proved. If the patent was granted not to the right person, only the person with a legal claim can apply. Documents and data must be attached. If the application for the declaration of invalidity fails to comply with the requirements prescribed in the Patent Act, the party requesting invalidation will be advised to remedy the deficiencies; if they have not paid the fee for the application, they will be advised to do so within the time limit prescribed in this Act. In the event of non-compliance, the application for the declaration of invalidity will be considered withdrawn. Where a counterclaim for a declaration of invalidity of a patent is submitted under subsection (1a), section 104, and an application for invalidation of the patent to which the counterclaim pertains is subsequently submitted before the HIPO under the same or different cause of action, the HIPO will suspend the procedure until the final conclusion of the court proceedings concerning the counterclaim. HIPO will dismiss the application for a declaration of invalidity if a counterclaim for a declaration of invalidity of a patent is submitted under subsection (1a), section 104 has already been resolved based on the same factual grounds, concerning the same patent, by a final court decision.

HIPO will request the patentee to provide an observation on the application, regarding which the applicant may also file a rejoinder, and sometimes the patentee may file a reply. HIPO then summons the parties for an oral hearing, where the parties may summarise their legal arguments, after which a decision is rendered and announced. If the patentee fails to introduce the facts and argument within the deadline, it cannot be added later. The decision is usually made in writing. The losing party will be compelled to bear the costs of the invalidation proceeding. The invalidation or restriction of the patent will be registered in the patent register (section 54), and will be published thereon in the official journal of the HIPO. The decision is usually written down and delivered within 30 days. The HIPO's decision can be reviewed by filing a petition for alteration within 30 days to the Metropolitan Court (subsection (2), section 53/A). After the petition for alteration has been filed with HIPO

and before HIPO refers it to the court, HIPO may also amend or withdraw its own decision (paragraph (c), subsection (3), section 53/A).

CONCLUSION

Hungary did not ratify the Agreement on a Unified Patent Court; therefore, the Unified Patent Court does not have jurisdiction. However, Hungary is a good choice for patent litigation, as Hungarian revocation and counterclaims for invalidity proceedings may be handled by experienced examiners at HIPO and specialised tribunals. After legislative changes and the latest case law, we expect swift patent infringement proceedings, from which patentees may benefit in the long term.



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Türkiye: How to navigate the patent litigation landscape

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Summary

IN SUMMARY

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IN SUMMARY

This article explores IP litigation in Turkey and answers some key questions for the jurisdiction.

DISCUSSION POINTS

- Emerging trends and significant policy updates in recent years
 - Any new industry-based or company trends starting to emerge?
 - What is the latest movement in damages awards and how damages are calculated?
 - How to make best use of forum shopping
 - What are the five key 'need to knows' for the jurisdiction?
 - Injunctions at a glance
-

REFERENCED IN THIS ARTICLE

- European Patent Convention
 - Industrial Property Law
 - Amendment of the Civil Litigation Law
 - IP Law No. 6769
-

In a landmark decision on 21 October 2021, the General Assembly of the Court of Cassation conducted a comprehensive evaluation of the issue of second medical use patents granted by the European Patent Office (EPO) being challenged frequently by generic drug manufacturers.

Prior to the introduction of article 54(5) in the European Patent Convention (EPC) 2000, which permitted purpose-limited product claims to encompass a known product used for a novel and inventive therapeutic purpose, patent safeguarding for an established drug employed in a novel and inventive therapeutic application was achievable solely through purpose-limited process claims in the Swiss-type format.

Türkiye became a member of the EPC in 2000, and its national patent law largely aligns with EPC provisions. Nevertheless, the national law does not explicitly address the patentability of second or subsequent medical use claims.

In the subject case, the first instance IP court acknowledged Türkiye's EPC membership but did not consider the EPO's Enlarged Board of Appeal's G5/83 case law as binding for Türkiye. Therefore, the first instance IP Court ruled that a patent revealing the second medical use of a known substance should be revoked. The court argued that this patent was granted before the EPC explicitly addressed the patentability of second/subsequent medical use claims.

As a result of an appeal, the Court of Cassation reversed the decision of the first instance court, in favour of the patent holder. As the first instance court resisted this decision, the case was referred to the General Assembly of the Court of Cassation.

The General Assembly rejected the lower court's claim that EPO case law was not binding for them. It was stressed that, as Türkiye had accepted both the EPC 1973 and EPC 2000 provisions, evaluating the validity of European Patents regarding first and second medical uses should consider EPC provisions and case law. The General Assembly concluded that a patent cannot be invalidated solely based on it being a second medical use patent granted during the EPC 1973 period.

A decision concerning mandatory arbitration for employee inventions for the determination of a reasonable fee was issued by the Council of State on 26 November 2020. The request for annulment and suspension of the execution of the related provisions was also discussed.

A lawsuit was filed before the IP Courts, aiming to determine the amount of compensation for an invention made by the employee, as the company had filed a patent application for the invention but did not remunerate the employee. The local court dismissed the case, citing that regulations prescribed arbitration for the determination of compensation.

The employee contested this decision on the basis that the mandatory arbitration provisions were unconstitutional, arguing that these provisions, which lacked a legal basis in the Industrial Property Law, deprived the courts of their jurisdiction, and that the matter should be resolved through judicial proceedings. Subsequently, the employee initiated an annulment lawsuit before the Council of State to challenge the mandatory arbitration provisions and request the suspension of their execution.

The Council of State found that the Regulation On Employee Inventions, Inventions Realised in Higher Education Institutions and Inventions Arising From Publicly Supported Projects, with the second sentence of article 11/2, the phrase 'through arbitration' in article 24/1 and article 24/4, went beyond what is allowed by the law. The Council of State emphasised that the general jurisdiction of the courts can only be abolished by law, and that any other means such as regulations by administrative bodies are not acceptable according to articles 9, 36 and 141 of the Constitution.

EMERGING TRENDS

The major IP law in Türkiye is Intellectual Property Law No. 6769, which regulates the IP system including patents. As a result of reflection of the Bolar exemption in the Law No. 6769, a significant number of court filings in Türkiye consist of lawsuits seeking determination of non-infringement of pharmaceutical patents by licence applications for generic products. Generic pharmaceutical companies aim to be able to launch their generic products as soon as the patent expires, by obtaining a non-infringement declaration during the licensing period before the Ministry of Health.

SIGNIFICANT POLICY UPDATES IN PAST YEARS

Law No. 7251 dated 28 July 2020 on the Amendment of the Civil Litigation Law, implemented a clause that permits an extension in the deadline to contest an expert's findings. This addition is a direct response to the practical difficulties previously experienced owing to the constrained two-week window originally allotted. The revision in the law now provides a potential doubling of this period, thereby enabling a month-long duration for parties to draft and submit their detailed assessments or objections.

This legislative refinement was motivated by the recognition that the complexities involved in dissecting and challenging expert evaluations often require more than the initial two-week period, especially when delving into specialised or highly technical content. The law now

explicitly states that parties can petition for more time if the complexity of the material makes timely response impractical or impossible.

The modification in the law is especially pertinent to patent disputes, which, by their nature, demand technical scrutiny and can benefit from the additional time for a thorough response to expert findings. The expectation of the practitioners is that similar amendments are made for other procedural steps in patent cases that require complex technical examinations at every level.

ANY NEW INDUSTRY-BASED OR COMPANY TRENDS STARTING TO EMERGE?

As mentioned above, owing to the incorporation of the Bolar exemption into Law No. 6769, a considerable portion of legal cases in Türkiye revolves around lawsuits that seek to establish the absence of patent infringement in generic pharmaceutical products through licensing applications. Generic pharmaceutical companies pursue the goal of being able to introduce their generic products immediately upon the expiration of the patent by securing a declaration of non-infringement during the licensing phase with the Ministry of Health.

WHAT IS THE LATEST MOVEMENT IN DAMAGES AWARDS AND HOW DAMAGES ARE CALCULATED?

Moral, material and reputational damages are available to a successful plaintiff. Moral damages are claimed as a set amount by the plaintiff initially in civil proceedings. On the condition that the amount initially claimed by the plaintiff is not exceeded, the judge determines the amount of moral damages by discretion.

Material damages are calculated by court-appointed experts in practice. Material damages, actual damages and profit loss can be claimed. As per the IP Law No. 6769, material damages can be calculated based on the following methods that the plaintiff is free to choose from:

- the reasonable licence fee that the infringing party would have paid if had the right been used lawfully through a licence agreement;
- the possible income of the patent owner without competition of the infringer; and
- net income made by the patent infringer.

As calculation of damages by court experts prolong court proceedings significantly, there is an trend that patent owners choose to claim moral damages only, which does not require expert examination.

HOW TO MAKE BEST USE OF FORUM SHOPPING

In Türkiye, specialised IP courts exist in four major cities, including Istanbul, Ankara, Izmir and Antalya. In jurisdictions where no specialised IP courts exist, general courts of first instance handle IP disputes.

As per the IP Law No. 6769, IP courts in Ankara have the sole jurisdiction over lawsuits against the decisions of the Turkish Patent and Trademark Office. No forum shopping is available in that respect.

For civil lawsuits to be filed by the IP right holder against third parties, that would include infringement actions, courts of the plaintiff's residence, courts of the location that the illegal act took place and the courts of the location that the effects of the illegal act can be seen

have jurisdiction. From those three forums, if available, it would be appropriate to choose the forum where a specialised IP court exists.

For civil lawsuits to be filed by third parties against the IP right holder, which includes invalidation actions, courts of the defendant’s residence have sole jurisdiction. No forum shopping is available in that respect.

WHAT ARE THE FIVE KEY ‘NEED TO KNOWS’ FOR THE JURISDICTION?

Türkiye is a party to the Patent Cooperation Treaty agreement. Türkiye is also a party to the EPC Agreement but not a member of the European Union. Therefore, Türkiye is not part of the Unified Patent Court (UPC) and unified patent (UP) system. The UPC/UP system is expected to have only indirect effects in Turkish patent practice.

There are specialised IP courts in Türkiye handling IP disputes. However, there are no courts dedicated to patent cases. Judges and other judicial staff of the IP courts are not required to have any technical background, and in practice none of the judges have such specification. For technical aspects in all patent cases, the system relies on expert examination handled by court-appointed neutral experts.

Patent infringement is not a criminal offence under Turkish law. Civil proceedings are available for patent infringement cases and main actions take around four to five years to finalise. Therefore, preliminary injunctions play a key role in patent infringement cases.

As a practical precondition for preliminary injunctions and as an important tool for documentation of the existing status of evidence, evidence-securing proceedings are largely used in Turkish patent practice. Evidence-securing proceedings are ex parte court actions at the end of which, an expert report is issued documenting the status of evidence through an expert examination either on site, online or on paper within a court file.

Under the Regulation on Implementation of the European Patent Convention Concerning Grant of European Patents in Türkiye, a European patent application designating Türkiye shall enjoy protection and shall be enforceable in Türkiye, starting from filing of translation of the claims with the Turkish Patent Office or from the date the other party is made aware of the invention. This is an important good to know for European patent applicants who would like to enforce their applications in Türkiye and possibly to claim damages.

INJUNCTIONS AT A GLANCE

<p>Preliminary injunctions – are they available, how can they be obtained?</p>	<p>Preliminary injunctions are available and can be granted by civil courts to prevent imminent infringement. The patent owner must prove serious risk of loss of rights or jeopardy of realisation of claims at the end of the lawsuit without the existence of a preliminary injunction. The infringement and validity of the patent must be very clear without any doubt. Generally, in patent cases preliminary injunctions are rarely issued and the time frame is several months.</p>
<p>Permanent injunctions – are they available, how can they be obtained?</p>	<p>Permanent injunctions are available and can be obtained through a main action</p>

	before civil courts as a result of a finalised judgement confirming infringement.
SEP injunctions – are they available, how can they be obtained?	A compulsory licence can be obtained through court action for an SEP if the patentee carries out activities distorting, hindering or limiting competition while a patent is being used. There is no case law in Türkiye on SEP injunctions. In 2019, the Turkish Competition Authority issued an administrative decision on SEPs in Vestel v Philips (19 - 46/790 - 344) and applied the FRAND criteria.
Is payment of a security/deposit necessary to secure an injunction?	A preliminary injunction can be issued without payment of any security/deposit. For enforcement of such injunctions however, courts generally order payment of a security/deposit.
What border measures are available to back up injunctions?	Customs seizures are theoretically available for suspected infringements. In practice, customs authorities would enforce court decisions in patent infringement cases.

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