Managing IP

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Matchmaking

How firms pick perfect partners

IP arbitration
How and when to do it

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Max Walters
Deputy editor

Legal matchmaking

I'm sure many readers will be familiar with the struggles of picking the right partner in their personal life.

There are many factors to weigh up: initial attraction is high up the list for some, but so too are shared interests and similar life goals.

Unsurprisingly, it's not that different in the world of business, including when it comes to law firm mergers.

In the cover story of this PDF, Sukanya Sarkar, our senior reporter based in Asia, brings you a behind-the-scenes look into what goes on when firms consider mergers.

She has spoken at length to senior sources at three firms that have all been through the merger process. They reveal why they coupled with their selected partners and how they got the deals over the line.

Of course, where there are unions there are sadly splits.

A parting of ways between Dentons and Chinese firm Dacheng Law Offices earlier this year made headlines in the legal press.

Both firms joined forces under a 'verein' structure in 2015 to become the largest law firm globally by headcount, with 6,500 lawyers in around 50 offices. That structure allowed the firms to use the same branding but separate their finances.

In the same article, Sukanya analyses the reasons behind the split and whether it will spark more break-ups.

Elsewhere, this PDF contains an analysis of the IP implications of the UK joining the Comprehensive and Progressive Agreement for Trans-Pacific Partnership, as well as a handy guide on when arbitration may be suitable for IP disputes and how to go about it.

We also have our usual mix of local insights and other sponsored content.

In other news, we would like to announce that this issue marks the final quarterly PDF publication that will be produced by Managing IP. Nevertheless, all content will continue to be published on our website, managingip.com, as it has been for many years.

Rest assured we will continue to provide daily in-depth news, analysis, and other expert content – not just via our website but in our regular email newsletters and on other channels, including social media.

We hope you enjoy reading everything on offer.

Managing IP

Delinian Limited
4 Bouverie Street
London, EC4Y 8AX
T: +44 20 7779 8682
F: +44 20 7779 8500
mip@managingip.com

SUBSCRIPTIONS
Head of subscriptions
Jack Avent
+44 20 7779 8379
jack.avent@delinian.com

CUSTOMER SERVICES
+44 (0) 20 7779 8610

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Commercial editor
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Maiwald GmbH

Munich

Elisenhof, Elisenstraße 3
80335 Munich
Germany

T +49 (0)89 747 266 0
F +49 (0)89 747 424
info@maiwald.eu

Düsseldorf

Grünstraße 25
40212 Düsseldorf
Germany

T +49 (0)211 301 257 0
F +49 (0)211 301 257 11
mail@maiwald.eu

www.maiwald.eu

Matchmaking: how firms pick merger partners

Sukanya Sarkar, our senior reporter in Asia, brings you insight from firms that have completed mergers on how they found their perfect partners and asks if a recent high-profile break-up in China will trigger more splits

Picking the right merger partner can make or break a business, so firms must choose those that share similar values and complement their existing offering, sources at three firms that have been through the process tell Managing IP.

However, they warn that differences in visions and the absence of due diligence can often lead to potential partnerships falling apart.

Law firm mergers have gathered pace, slightly, in 2023.

In the first six months of the year, 28 mergers were concluded globally. In contrast, only 25 deals were completed during the first halves of both 2021 and 2022.

However, despite the uptick, some well-known partnerships and potential deals have crumbled.

In August global firm Dentons and China-based Dacheng Law Offices confirmed that they will operate as separate entities in future.

Both firms joined forces under a 'verein' structure in 2015 to become the largest law firm globally by headcount, with 6,500 lawyers in around 50 offices. The verein structure allowed both firms to use the same branding but separate their finances.

In March, Hogan Lovells and Shearman & Sterling abandoned plans for a possible combination. The pair

"In the first six months of the year, 28 mergers were concluded globally. In contrast, only 25 deals were completed during the first halves of both 2021 and 2022."

had revealed their intention to join forces in December 2022.

In May, however, Shearman & Sterling announced merger plans with another international law firm – Allen & Overy. The deal has yet to be concluded.

While mergers can be tricky and risky, there are several ways to increase the chances of success.

Culture conversations

The first lesson is probably obvious – don't take up any offer that may come your way, irrespective of how attractive it may seem.

Jesper Knudsen, CEO at IP consultancy Brandit in Zurich, says he rejected around 20 merger offers before deciding to partner with Swedish brand protection company Ports Group in April this year.

Knudsen says he turned down the other proposals because they weren't interesting or exciting enough, especially given that Brandit already had a successful practice.

But when he met Magdalena Bonde, CEO of Ports Group, the duo quickly found they shared several common interests.

"A two-hour coffee ended up being a five-hour coffee," Knudsen says. "We talked about everything other than business – ambitions, personal goals, how to create the best culture, how to challenge things, how to change, and where we wanted to go in life.

"From our conversation, I could feel that we both had very similar values."

It was this connection that made him consider another firm's offer for the first time, he says.

According to Knudsen, the right partnerships are always about ensuring a good cultural fit.

"We are not merging to close down or for any financial optimisation. We are merging to build.

"Therefore, we didn't want to enter into a deal without having all the founders completely embedded in the vision and mission."

Lisa Moyles, formerly head of US-based boutique firm Moyles IP, which combined with global firm Womble Bond Dickinson in April, echoes Knudsen's views on cultural compatibility.

She says when she met the firm's leadership group she was "thrilled to find the same focus on making a good cultural fit" that she had tried to build at her own firm.

"We were impressed by how Womble Bond Dickinson had grown over the years while remaining disciplined about aligning its services with client needs in a timely and efficient manner and maintaining its collaborative culture."

The idea for a merger became a natural discussion, she adds.

"The negotiations were short and sweet, taking a few months to iron out the details and structure."

New opportunities

Besides ensuring cultural compatibility, it's crucial to find a partner that can help a firm grow.

Moyles says she joined forces with Womble Bond Dickinson because she realised that a full-service international platform would provide considerable value for her clients, as well as offer opportunities for developing the next phase of her and her team's careers.

Both firms had a close-knit relationship even before the merger and had worked as co-counsel in several IP cases.

Moyles notes that the decision to merge was an easy and natural extension of that relationship.

"We saw an opportunity to strengthen and deepen our client relationships by ensuring that they would have access to the full range of experienced lawyers and professionals necessary to meet all their legal needs.

"Combining with Womble Bond Dickinson opened up access to new resources, opportunities, and markets for our clients."

Filling the gaps

Sources say the right partner is also the one that can help firms fill gaps in their practice areas and technical capabilities.

Knudsen at Brandit notes that Ports Group wanted a stronger trademark expertise and presence in the international market, which Brandit offered.

Likewise, Ports Group offered a great technical platform and considerable experience in M&As, which Brandit was lacking.

"Maybe we could have built those capabilities ourselves – but Ports Group was a company that had all these competencies already.

"When I was sitting and doing the math, I could see that we were a match made in heaven on paper," Knudsen says.

It's also important to assess whether a prospective partner can help a firm expand its regional outreach and help clients explore new opportunities.

Zhan Hao, former managing partner at AnJie Law Firm in Beijing, which merged with Asia-focused practice Broad & Bright in December 2022, says several factors were weighed up before that decision.

Hao says even though AnJie had more accolades, recognitions and a larger practice, Broad & Bright boasted a more mature market presence.

He adds that Broad & Bright's office in Guangzhou – one of the key cities in China's Greater Bay region, an area that the Chinese government is focusing on – was a key draw.

Partnering with a firm that already had an office in an up-and-coming region made sense, he adds.

Hao says Broad & Bright's extensive experience in foreign direct investments and knowledge about overseas countries presented significant opportunities for AnJie's clients.

Taking your time

However, Hao warns that even though a partnership may look good on paper, it's important to take care to ensure that it'll work out in the long term.

"We've seen a lot of mergers between different Chinese firms in the past years, but only a few have been successful. I wanted to prepare well in advance to avoid any issues later."

He says the firms took their time to discuss their visions for the future, how to use both law firm names, how to lay out their new website, and how to set up the new management team.

"We also made a detailed plan to avoid conflicts of interest," Hao says.

Both firms conducted detailed due diligence including on the financial health of both entities, whether any Chinese authority had imposed any administrative penalty on either outfit, and employee history.

The journey was not a smooth run for either firm, Hao notes, adding that open and honest conversations can iron out any issues.

"We faced many challenges because we had unique cultures and management structures.

"These were sometimes a little frustrating, but both sides learned how to compromise with each other, and those initial conversations and negotiations helped us form a successful partnership."

Irrespective of how much work goes into planning and executing a deal, the decoupling of Dentons and Dacheng Law Offices, reportedly down to the Chinese government's recent mandates on cybersecurity and data protection, shows that it can be difficult to predict whether a merger will ultimately work.

Having said that, careful due diligence and identifying respective strengths and gaps is still a good idea.

If firms follow those steps, they could be a match made in heaven.

Parting ways

But a heavenly match is not always possible.

When Dentons and Dacheng Law Offices parted ways, it marked the end of the world's largest law firm merger by headcount.

Dentons said an evolving regulatory environment for law firms in China, including new mandates and requirements around data privacy, cybersecurity, capital control, and governance, was behind the decision to end the combination.

Since the news came out, there has been plenty of speculation about the future of foreign law firms in China.

According to sources at IP-focused practices, whether a firm will be affected will depend on the nature of the

"There may have been more to the Dentons-Dacheng split than meets the eye. But that doesn't mean that the future of foreign law firms in China looks good."

work it handles and the arrangement with its Chinese partner.

In most cases, IP-focused practices may not have enough reason to worry, but the future doesn't look promising even so.

While the Dentons and Dacheng break-up may serve as a sign of tougher times, onlookers say there may be more behind the split than what the official announcement revealed.

A source at a US-based firm claims that Dacheng hadn't turned out to be a very profitable partnership for Dentons.

"I feel these new laws and regulations were just an excuse to break up and not admit that the merger just didn't work out financially," he says.

Saving face?

A partner at an international law firm in Shanghai says he finds it hard to believe that cybersecurity and data privacy, which were touted as reasons for the demerger, could substantially motivate such a split.

"There are so many physical and legal tools to separate and protect data.

"However, I must admit, data and cybersecurity sound like a trendy and credible motivation in these times of daily and loud confrontation between China and the Western world, particularly the US."

The partner says it's more likely that the drop in foreign investments in China that has, in turn, reduced cross-border legal business caused the split.

He adds that Dentons may have also found it tough to be so tightly linked to a Chinese law firm. Before the split, Dentons used the Chinese characters of Dacheng in its branding.

"Can you imagine going around now in the US to pitch clients with that name card?" the partner asks. "It is crazy, forget about it."

It makes sense that foreign firms with close ties in China would want to assess how their relationships in the mainland are affecting their reputation and business elsewhere.

But anyway, Dentons' decision to merge with Dacheng was somewhat unusual from the get-go, note sources.

While most foreign firms in China prefer to work through a local firm rather than formally integrating, Dentons and Dacheng worked under a so-called 'Swiss verein' arrangement, which allowed both entities to share branding but separate their finances.

The Dentons situation had even more particularities.

Joe Simone, partner at IP firm SIPS in Hong Kong, notes that an overseas Dentons lawyer was reportedly prevented from leaving China recently. And despite the latest development, the international firm and Dacheng were working on commencing a new phase of "integration".

"It's quite possible that the Chinese partners in Dacheng decided that the tie-up with Dentons was not worth the costs and hassles," he notes.

Tough times

There may have been more to the Dentons-Dacheng split than meets the eye. But that doesn't mean that the future of foreign law firms in China looks good.

Even before Dentons' announcement, China's counter-espionage laws had pushed other foreign entities out of the mainland.

Earlier this year, Chinese authorities raided offices of US firms Bain & Company and Mintz Group, which

were gathering data about Chinese companies for foreign investors. Employees of foreign firms have also been prohibited from travelling overseas in the recent months, according to reports.

What's more, law firms that had tie-ups with the 'big four' accounting firms have been shut down in recent years because the Chinese government concluded that the foreign firms effectively controlled the operations of the local entities.

It seems, therefore, that whether a foreign firm's activities would draw the attention of the Chinese government would depend on the type of arrangement it has with its China arm.

Simone from SIPS says it's hard to generalise how China's data protection laws would affect international practices because there are several different modes of cooperation between foreign and Chinese firms.

"But any arrangements that give the foreign partner excessive control over management decisions, big and small, run a higher risk of being forcibly unwound," he adds.

Again, what counts as excessive control over management decisions could depend on a subjective interpretation by Chinese authorities, particularly since even those foreign practices that only have cooperation arrangements with a partner firm in China often have some supervision mechanisms in place.

Albert Tsui, partner at AnJie Broad Law Firm in Beijing, says all law firms that have any relationship with a Chinese practice would have to comply with the latest cybersecurity and data protection laws, including foreign firms that are simply instructing local mainland firms from overseas.

He highlights that Dentons-Dacheng's Swiss verein structure meant that it wasn't all that different from a foreign firm instructing a mainland China firm, even though the partnership was promoted as a formal integration.

However, he adds that if a government official wants to pick one or two cases of non-compliance to set an example that it's important to follow the law, they would obviously select an international firm with a formal presence in China.

He Jing, founder of Gen Law Firm in Beijing, says both local and foreign firms need to reassess their partnerships in light of the recent developments.

He notes that general counsel prefer to have a trusted group of lawyers in different locations working under the same branding who can provide quality services in a timely manner and at a reasonable cost.

"The biggest challenge for any firm doing cross-border work will now be adapting to the changed business environment, finding the right arrangement with their international partners, and balancing trust and expertise," says Jing.

"It will be a soul-searching moment for most managing partners."

Uncertain future

Despite the reasons given for the demerger, law firm sources don't consider the compliance requirements under the cybersecurity and data protection laws as excessively unfair.

Tsui points out that China's recently revised data protection law requires the sender and the recipient of any cross-border data to sign a standard contract, and secure approval from the cyberspace administration if such exchange exceeds a certain threshold. "These are similar to compliance issues you face in Europe," he says.

Tsui notes that the controversy surrounding the Dentons-Dacheng split seems to be more about the confidence in China's laws at the international level.

For now, he says companies transferring data to another country may find some compliance requirements difficult. However, lawyer-to-lawyer transactions should be relatively less troubling.

"For example, if a Chinese company wants to file their IP in Europe, when the client passes on its personal information to me, there's an implied consent for me to carry out their instruction and export their data."

Another Beijing-based international law firm partner points out that foreign IP firms with offices in China usually cater to more inbound work than outbound work. For that reason, too, they may not run into significant data transfer and cybersecurity issues.

At any rate, he says that information exchange for IP filing and litigation is unlikely to be considered to violate the data protection law unless the technology involved relates to national security.

"What happened with Dentons and Dacheng was very unusual," the lawyer says.

Foreign firms that choose to continue operating in China will, however, need to relook at how they handle data internally and possibly also whether their arrangements with their local arms will likely put them on the radar of Chinese authorities.

It may not be surprising, therefore, if more reshuffles follow.

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The why and how of IP arbitration

Lawyers at Allen & Overy explain why arbitration has become a popular method for resolving IP disputes, and outline when to take that option

When negotiating intellectual property contracts, parties may spend little time considering dispute resolution mechanisms. Many assume that courts are the go-to forum. However, fighting a battle in court is not the only option. Arbitration has become an increasingly popular means to resolve IP disputes in recent years.

Beyond IP licensing agreements for hardware manufacturing and software products, which have historically been more receptive to arbitration dispute resolution clauses, there is growing discussion, including from judges, about the benefits of arbitration as a forum for resolving fair, reasonable and non-discriminatory (FRAND) disputes regarding standard-essential patents (SEPs).

That the newly established Unified Patent Court recognised the need for out-of-court resolution – it has established a dedicated Patent Mediation and Arbitration Centre seated in Lisbon, Portugal, and Ljubljana, Slovenia – further confirms that complex disputes involving intellectual property are on the rise.

Choosing an appropriate forum to resolve IP disputes is critical for minimising the risk of unfavourable or unpredictable decisions, ensuring that the procedures cater to the needs of all parties (eg, confidentiality and decision-maker expertise), and bringing potential cost savings.

"Unlike court cases, where judgments are published and hearings are listed in cause lists, arbitral awards are generally confidential."

We draw from Allen & Overy's broad experience in negotiating cross-border IP contracts, litigating IP disputes in national courts, and acting in international IP arbitrations to summarise when arbitration is well-suited for IP disputes and strategies for managing IP arbitrations.

When to arbitrate?

Where confidentiality is key

Unlike court cases, where judgments are published and hearings are listed in cause lists, arbitral awards are generally confidential.

The existence of an arbitral proceeding is usually not published. The level of confidentiality depends on the applicable rules and laws at the seat of the arbitration. In emotionally charged cases, such as trade secret disputes, arbitration's confidential nature may help lower the temperature and create a more open environment for resolving the dispute.

Where multiple jurisdictions are involved

When a dispute is global, arbitration can provide a single forum for resolving it. This can reduce the complexity, uncertainty and costs associated with multiple parallel litigations in different national courts. Litigating before numerous national courts creates complexities, such as competing and differing laws, rules and standards of proof. Moreover, practical concerns, such as engaging different teams and burdening clients with numerous matters, favour a consolidated arbitration proceeding.

This is particularly relevant for FRAND disputes. Since 2017, when the England and Wales High Court determined and set a global FRAND royalty rate in a dispute between a large implementer and a non-practising entity (NPE) SEP-owner in *Huawei v Unwired Planet*, other national courts have indicated they are willing to do the same. As a result, parties to FRAND disputes have undertaken jurisdictional battles, leading to competing courts issuing costly and prohibitive anti-suit and anti-anti-suit injunctions against parties.

Giving exclusive jurisdiction to an arbitral tribunal can avoid such jurisdictional issues and enable the parties to reach a global settlement through a single proceeding, rather than requiring the same parties to participate in multiple FRAND court proceedings, run in parallel, in different jurisdictions.

The same advantages apply to infringement disputes. If an infringing product appears in multiple markets, taking enforcement action in each jurisdiction can be costly and time-consuming. Awards made by arbitral tribunals are binding on the parties to the dispute and are recognised by the courts of New York Convention member states, which include most of the major economies that are relevant to the technology sector, except for Taiwan. By providing a single decision that is enforceable in all major markets, arbitration offers an effective and cost-efficient way to stop infringement activity. However, as ever, it relies on the parties agreeing to arbitration; an agreement that can be difficult to obtain in infringement actions, unless a pre-existing contractual relationship underpins the dispute.

Where court neutrality is a concern

IP owners often license sensitive technologies and trade secrets to foreign partners to leverage the lower-cost manufacturing available in other countries or to facilitate their entry into a highly regulated or little-known markets. In such circumstances, there may be concerns about courts in host countries holding protectionist inclinations against foreign parties and difficulties with enforcing the judgments of home jurisdiction courts in host jurisdictions due to misconduct.

Arbitration may be a more neutral option than litigation in court because arbitrators are selected by the parties or an independent third party, such as the appointments committee of an arbitral institution. A sole arbitrator, or the presiding arbitrator in a three-member tribunal, is often required to be of a different nationality to a party. Parties can also choose to seat the arbitration in an arbitration-friendly third country unrelated to the parties, so the arbitration will be governed by that country's laws and supervised by its courts. These features of arbitration remove any perceived biases based on national origin and promote a more diverse outlook that is more suitable for cross-border disputes.

Where special expertise is needed

In the same vein, some jurisdictions do not have specialist IP courts or a well-developed body of IP law. Rather than leaving the decision-making to the hands

of judges who are inexperienced in IP matters, or indeed a jury, arbitration allows parties to appoint arbitrators with experience in IP, a scientific background, subject matter or sector expertise, or relevant technical and legal qualifications, among other requirements. Parties can also specify desired qualities of an arbitrator in concrete and objective terms in arbitration clauses to ensure that the right person decides their case.

Several leading arbitral institutions, including the World Intellectual Property Organization (WIPO) and the Hong Kong and Singapore International Arbitration Centres, maintain panels of arbitrators specialising in IP disputes, which include retired senior IP judges and respected IP practitioners. Having an arbitrator with IP expertise can increase the efficiency of the arbitration process and reduce the need for extensive expert evidence or technical explanations.

It is important to note that arbitration may not always be appropriate. The choice of arbitration over litigation will depend on the IP rights, jurisdictions (including local law advice), and the party dynamics and atmospherics involved.

How to do it?

For those who do include an arbitration clause in their IP contract, here are five tips for in-house counsel when managing arbitration of IP disputes.

1. Assemble counsel teams and select arbitrators with technical expertise and a thorough understanding of the arbitral process

IP disputes often involve highly technical issues that are unique to that sector. Engaging counsel and selecting arbitrators who have experience in that industry and the ability to understand complex IP concepts quickly, is critical. It is advisable to engage a multidisciplinary counsel team competent in technical, legal and arbitration procedural aspects to enhance the party's credibility before the tribunal and avoid unnecessary inefficiency.

2. Establish robust procedural rules for the arbitration

Most mainstream commercial arbitration rules (with some exceptions, such as the WIPO Arbitration Rules) are not designed with IP disputes in mind. Therefore, they may not contain provisions regulating procedural aspects which are important for IP disputes, such as the disclosure of trade secrets and confidential information, the use of experimental evidence, and the availability of site visits. But this can be an opportunity for parties to design their own rules, either in the contract's arbitration clause or in a Procedural Order No. 1, which sets out an arbitral tribunal's first procedural directions after its constitution. A robust set of procedural rules can promote the fair and efficient conduct during the arbitration and bridge expectations of parties from different legal traditions towards procedures, such as discovery (or document disclosure) and the repetition of experiments.

3. Make full use of the available legal toolkit, including emergency arbitrator proceedings and court-ordered interim measures

A common misconception about arbitration is parties are required to seek all remedies for the dispute from the arbitral tribunal, compromising a party's ability to seek urgent interim relief from a court. This is not so, as many modern arbitration laws and rules allow courts to issue interim relief, including interim injunctions and orders requiring preservation of evidence or the production of documents, to aid arbitration.

Some arbitration rules also provide emergency arbitrator procedures that allow a party to seek urgent interim relief before commencing arbitration or the full tribunal's constitution. An emergency arbitrator will usually make a decision within around two weeks of an application.

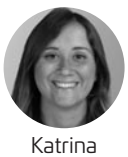
4. Don't lose sight of settlement strategies

The confidentiality of arbitral proceedings, and the fact that arbitral awards only bind the parties to the dispute (not third parties), allow parties to pursue settlement discussions more easily alongside ongoing arbitration. Success in strategic procedural applications (eg, winning an order to disclose commercially sensitive source codes from an opposing party) can help a party secure a strong position when negotiating a settlement.

5. Frame legal claims carefully to mitigate the risk of jurisdictional challenges

In certain jurisdictions, where the arbitrability of IP rights is not well settled, it is important to frame legal arguments carefully to make sure that the arbitral award issued by a tribunal is enforceable where the assets are found. Arguments such as the invalidity of an IP right and antitrust allegations are particularly at risk of enforcement challenges. Presenting the IP dispute in contractual terms can mitigate this risk in some jurisdictions.


Bijal Vakil


Katrina Limond


James Fox


Timothy Tai

Bijal Vakil is a partner at Allen & Overy in California. Katrina Limond and James Fox are senior associates at at Allen & Overy in London while Timothy Tai is an associate based in Hong Kong SAR.

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How to minimise preliminary injunction risk in the UPC

Jan Zecher and John Pegram of Fish & Richardson describe the risk of provisional measures in the UPC and how they can be reduced using protective letters

Do you fear the possibility of a preliminary injunction or other provisional measures involving patent infringement allegations in the EU? You probably should at least consider the possibility. Provisional measures are more common in EU patent litigation than in the UK or the US. The risk may have become greater with the advent of the Unified Patent Court (UPC), which can have jurisdiction for both conventional and unitary European patents in 17 EU states.

The possibility of a surprise preliminary injunction (PI) or other provisional measure in the UPC can be reduced by filing a confidential 'protective letter'. Using such letters, potential defendants can put their arguments on record in advance (which one of our colleagues calls a "prebuttal"). When a temporary restraining order (TRO) or PI request is filed, the court clerk or registrar will check for protective letters, and they will be provided to the judge(s) with any TRO or PI request.

UPC provisional measures

Article 62 of the UPC Agreement provides possibilities for several types of provisional and protective measures in the early stage of UPC proceedings. Principal among them is the power of the court to "grant injunctions against an alleged infringer or against an intermediary whose services are used by the alleged infringer, intended to prevent any imminent infringement" and "to

prohibit, on a provisional basis … the continuation of the alleged infringement or to make such continuation subject to the lodging of guarantees intended to ensure the compensation of the right holder". The court appears to have a wide degree of discretion, as compared—for example—with the law regulating preliminary injunctions in the US and the UK. The standard is a weighing of the interests of the parties and, in particular, the potential harm resulting from granting or refusing the injunction.

The court may also order the seizure or delivery up of the products suspected of infringing a patent to prevent their entry into, or movement within, the channels of commerce. If the applicant demonstrates circumstances likely to endanger the recovery of damages, the court may order the precautionary seizure of the movable and immovable property of the alleged infringer, including the blocking of the bank accounts and other assets of the alleged infringer.

UPC Rules of Practice 205-213 contain detailed provisions concerning when and how provisional measures will be granted. Perhaps of most concern are the provisions of Rule 212, permitting the court to "order provisional measures without the defendant having been heard, in particular where any delay is likely to cause irreparable harm to the applicant or where there is a demonstrable risk of evidence being destroyed". Although there are provisions for a hearing after such an ex parte order has been granted, that is not a very satisfactory remedy. Fortunately, however, there is a way of practically guaranteeing an oral hearing before imposition of protective measures: filing a protective letter.

Protective letter procedure

The protective letter in the UPC is similar to a protective brief in German courts. However, the procedure is a bit different. UPC Rule 207 permits a person who considers it likely that an application for provisional measures against them may be lodged before the court in the near future to file a protective letter in the language of the patent. The letter may contain an indication of the facts relied on, including a challenge to the facts expected to be relied on by the presumed applicant; any assertion that the patent is invalid and the grounds for such assertion; the written evidence relied on; and arguments of law.

The UPC Registry will record the protective letter and maintain it as confidential. When an application for provisional measures has already been, or is later, lodged, the registry will inform the panel or the single judge dealing with the application about the filing of the letter. The applicant will also be informed of the existence of a protective letter and given a brief opportunity to withdraw the application. If the application is not withdrawn, the letter will be forwarded to the applicant, who will have an opportunity to respond. An oral hearing is then very likely, given that it is clear from the letter on record that the defendant has already been warned.

"The possibility of a surprise preliminary injunction or other provisional measure in the UPC can be reduced by filing a confidential 'protective letter'."

Practical aspects

It is common that a potential patent infringement defendant in the EU will know of the potential litigation. For example, there may be an existing opposition in the EPO, or litigation in another jurisdiction involving the same or a related patent. Also, because a losing party will pay court fees and those of the successful party, it is likely that the patent owner will contact the accused party before suing. As a result, the accused party is likely to have organised at least some of its defences, for example, in an opposition or US inter partes review petition or attorney opinion. Any of these can be used to prepare a UPC protective letter at a relatively low cost.

Although many European patents have been opted out of the UPC's jurisdiction, that should not be a reason for believing UPC litigation is unlikely. The opt-out can be withdrawn at any time, reviving the UPC's jurisdiction just before the owner asserts that patent in the UPC.

The protective letter must be filed through the court's case management system, which currently permits a filing on behalf of only one party. The UPC filing fee is a bargain (currently €200, $219). Although a protective letter is only effective for six months, it can be renewed for a fee (currently €100).

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Jan Zecher

John Pegram

Jan Zecher is principal at Fish & Richardson and John Pegram is of counsel at Fish & Richardson in New York.

GREECE

PATRINOS & KILIMIRIS
SINCE 1919

7 Hatziyianni Mexi
GR-11528 Athens
Greece

Tel: +30210 7222906
+30210 7222050
+30210 7252866
Fax: +30210 7222889
Email: info@patrinoskilimiris.com
Website: www.patrinoskilimiris.com

IP contacts

Constantinos Kilimiris, Maria Kilimiris, Manolis Metaxakis, Electra Kilimiris, Evangelia Sioumala and Youli Angelou

Firm profile

Established in 1919 by Dr. E. Patrinos, Patrinos & Kilimiris is the oldest Patent and Trade Mark Agency in Greece. Since then, the firm has expanded to become one of the leading law firms in Greece, with more than 20 collaborators, including 5 attorneys. The firm actively practices in all sectors of commercial law, with a primary focus on Intellectual Property protection under European and Greek Law.

Areas of specialization

The firm provides a full range of legal and technical services provided by experienced patent and trademark attorneys including Patent, Trade Mark and Design counseling, filing and prosecution, Copyright protection, Domain Name registration and disputes, customs actions, franchising, distribution and license agreements as well as technical translations.

Furthermore, the firm undertakes substantial IP litigation up to the Supreme Court, having well established relations with eminent judicial, technical, law scholars and other appropriate experts. Patrinos & Kilimiris has a strong record of successful litigation in IP infringement proceedings acting for large international and domestic companies in all areas of IP and have established an unparallel expertise in patent litigation relating to the pharmaceutical industry.

International memberships

AIPPI, ECTA, EPI, EPLAW, FICPI, INTA, PTMG, MARQUES

IP implications of the UK's accession to Pacific trade pact

Armin Lambertz and Yohan Liyanage of Linklaters unpick the IP implications of the UK's decision to join the Comprehensive and Progressive Agreement for Trans-Pacific Partnership

On July 16, 2023, the UK formally signed a treaty to accede to the Comprehensive and Progressive Agreement for Trans-Pacific Partnership, a free trade agreement better known by its acronym: CPTPP.

This makes the UK the first European country and the first non-founding member to join the trade pact that was established in 2018 by 11 countries from around the Pacific Rim (Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, and Vietnam).

CPTPP will take effect in the UK once the UK and a sufficient number of contracting states have completed their ratification processes, which is expected to happen in the second half of 2024.

The estimated combined gross domestic product (GDP) of CPTPP countries exceeds £10 trillion ($12.7 trillion), accounting for about 15% of global GDP.

However, despite these impressive figures, the economic impact of CPTPP membership is expected to be relatively small, with an estimated increase to UK GDP of only 0.08%.

The main reason for this is that the UK already had in place bilateral free trade agreements (FTAs) with many CPTPP countries that were "rolled over" after the UK's withdrawal from the EU. In addition, it recently signed separate FTAs with Australia and New Zealand. This means that the UK already had extensive market access to most CPTPP countries.

Like many other recent FTAs, CPTPP has extensive chapters on the protection and enforcement of intellectual property rights, with which all contracting states must comply.

However, as the UK already has a very well-developed IP system, accession to CPTPP will not require extensive changes to the framework of IP protection in the UK. Yet there are some provisions of CPTPP that are not consistent with the current IP regime in the UK.

It is expected that the UK government will implement some amendments to IP legislation to comply with CPTPP. Some of the key changes are outlined below.

Relationship between trademarks and geographical indications

Geographical indications (GIs) are signs that identify a product as originating from a specific geographical origin. Examples of UK GIs include Stilton Blue Cheese, Welsh Lamb and Scotch Whisky.

The protection of GIs in the UK and their interaction with registered trademarks have been largely shaped by EU law and policy. The current UK regime is referred to as a system of "co-existence", in which trademarks and GIs are two separate rights that exist in parallel.

Where the co-existence leads to a potential conflict (e.g. because a GI is similar to a trademark), GIs are often treated more favourably. For instance, an application for a GI in the UK can proceed to grant even if the GI conflicts with an earlier registered or unregistered trademark. The GI application would be refused only on the basis of an earlier trademark in the limited circumstances where a) in light of a trademark's reputation, renown, and the length of time it has been used, the GI would be liable to mislead consumers or b) the GI jeopardises the existence of an entirely or partly identical trademark.

In contrast, CPTPP provides that contracting states must treat GIs and trademarks on an equal footing, which is preferable for trademark owners. This approach is referred to as "first in time, first in right" and considers GIs and trademarks as part of the same system. Crucially, Articles 18.32(1) and (2) of CPTPP require contracting states to provide procedures to oppose and challenge GIs and GI applications where the GI is likely to cause confusion with an earlier trademark registration or application or unregistered trademark. The UK government has already confirmed that changes will be made to implement this system.

However, implementing a "first in time, first in right" system is not straightforward. The UK previously entered into a number of other FTAs (e.g. with Georgia and Ukraine) that actually require it to maintain a system of co-existence, such that the UK's obligations under CPTPP and some earlier FTAs are potentially inconsistent. It remains to be seen how the UK will seek to reconcile these discrepancies.

Damages for trademark counterfeiting

Acceding to CPTPP may also require legislative changes with respect to the type of damages available for trademark counterfeiting. CPTPP contracting states must ensure that, for trademark counterfeiting, courts are entitled to award either pre-established damages (a fixed minimum amount of damages for infringement) or additional damages (damages that are not purely compensatory and which may have an exemplary or punitive element). UK legislation currently provides for additional damages for copyright infringement, but neither type of damages is currently available for trademark counterfeiting.

No reciprocity exception

CPTPP contains a very broad "national treatment" obligation, which requires each contracting state to afford no less favourable treatment to nationals of other CPTPP contracting states than to their own nationals with regard to the protection of IP rights. National treatment obligations are commonplace in many FTAs, as well as under the World Trade Organization's Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, but they are normally subject to a "reciprocity exception". This exception allows a contracting state not to afford a particular right to nationals of a second contracting state if that second contracting state does not afford an equivalent right to nationals of the first state.

CPTPP, however, does not have a reciprocity exception, meaning the UK must afford the same rights to all nationals of CPTPP countries that it affords to UK nationals. This may require the UK to make amendments to some legislation regarding copyright and related rights legislation. For example, the UK currently has a system whereby performers and producers of phonograms (sound recordings) are entitled to receive equitable remuneration for the use of their performances and phonograms in broadcasts and other communications to the public. This is consistent with Article 15 of the WIPO Performance and Phonograms Treaty and is expressly permitted under CPTPP.

However, not all CPTPP countries afford the right to such equitable remuneration to their own nationals (or UK nationals for that matter), and the lack of a reciprocity exception means that the UK will nonetheless need to afford nationals of other CPTPP countries the equitable remuneration right.

While this may appear to be a relatively specific issue, it would constitute a significant departure from established IP policy in the UK.

Requirement for patent linkage

CPTPP also contains provisions regarding "patent linkage", which refers to a system which provides for a certain degree of co-ordination between the expiry of patent protection for a pharmaceutical product and the market approval process for generic versions. CPTPP is not overly prescriptive on how contracting states should implement such a system, but it does require a system under which either: a) notice is given to a patentee in respect of applications for marketing authorisations for generics; or b) the patentee's consent is required for the issuance of marketing authorisations for generic products. The UK's current system does not appear to be compliant with these requirements.

It is highly unlikely that the UK will introduce a system requiring a patentee's consent to generic marketing authorisations. However, it is possible that a notification system might be introduced, which would create a

significant shift in the dynamics of pharmaceutical patent litigation and would be welcomed by patent owners.

Patent grace period

When the UK announced that it was considering accession to CPTPP, one of the major inconsistencies between existing UK IP law and the requirements of CPTPP was in relation to the grace period for disclosures by inventors when assessing patent applications.

CPTPP requires contracting states to provide a 12-month grace period for public disclosures by a patent applicant when assessing novelty and inventive step. However, the European Patent Convention (EPC) has an "absolute" test for novelty and inventive step and does not permit a grace period. This raised the question of whether accession to CPTPP was compatible with the UK continuing to be an EPC member.

The problem was resolved earlier this year by the UK entering into side letter agreements with the other CPTPP countries, allowing for a derogation from the grace period requirements of CPTPP.

In return, the UK has agreed that it will endeavour to promote further international harmonisation regarding a grace period that is consistent with CPTPP, including by promoting amendments to the EPC, and provide annual written reports to other CPTPP countries on progress. It remains to be seen what the UK government will do in practice to seek to introduce a grace period into the EPC.

While the UK already complies with the vast majority of IP provisions in CPTPP, there are a handful of areas where we can expect changes to IP legislation in the near future before CPTPP is ratified in the UK.

Some of these, such as the change in the regime for the protection of GIs and the introduction of a patent linkage procedure for the authorisation of generic pharmaceutical products, will be welcomed by trademark and patent owners alike.

Yohan Liyanage

Armin Lambertz

Yohan Liyanage is a partner and Armin Lambertz is a senior associate at Linklaters in London.

Opinion: Why SEP owners have lost the FRAND debate

Patrick Van de Wille, former chief communications officer at InterDigital, argues that SEP owners have turned to needless complexity to try to maintain an untenable status quo

Although there remains some discussion, the recent proposal by the European Commission to implement a new framework for FRAND determination in standards signals one clear truth to the IP community: that the pro-standard-essential patent (SEP) side has comprehensively lost the debate of ideas when it comes to defending the current mobile phone licensing regime. The best it seems willing to hope for is an exemption under the premise that mobile phone licensing is well-established, but that sector has also seen the lion's share of big-ticket disputes and it doesn't look like the other side of the debate agrees that things are as calm as they'd like to say.

As chief communications officer for one of the main licensors for close to 10 years (2012 to 2021), I was in an interesting position to watch and attempt to influence that discussion. I'm not an expert in patent law, but I am an expert – to the extent anyone can be – on language, on argument. And I can summarise for you why the SEP side is losing, and indeed may have lost, the debate: because it has turned to needlessly complex language and nuanced arguments to try to maintain a status quo that is untenable, while the other side hammers out a simple message: it's unfair.

Qualcomm domination

Let's start with the second part: an untenable status quo rooted in unfairness. With their arguments, what status

"The pro-SEP side of the debate has worked mightily to have the entire discussion lost in a myriad of details."

quo are the major licensors trying to defend? It is one where a single company, Qualcomm, manages to seize for itself more revenue than all other major licensors, combined, multiplied by two. The pro-SEP side frames the discussion as implementers v SEP holders and licensors, but the licensor side of the debate, economically, is disproportionately made up of the interests of one company: Qualcomm.

If you ask any 3GPP standards engineer, or any one of the hundreds of people who go to standards meetings, they will tell you that the major standards contributors – Nokia, Qualcomm, Ericsson and, recently through brute force, Huawei – all contribute roughly equally to the development of the standard. Those advancements are captured in portfolios that become the object of endless debate. What percentage of US patents? How large the Chinese portfolio, and of what value? How to categorise patent quality? How many jurisdictions covered in the portfolio, and to what extent do those jurisdictions provide leverage in the case of an injunction? And yet, for all these details – and don't get me wrong, they are important in the world of IP management, but they're still details – the crux of the matter is that they are a proxy, a means of measuring contribution to a global technical standard, which can then be rewarded through licensing.

Still, the Qualcomm Technology Licensing revenues were more than double the added licensing revenues of Nokia, Ericsson and all other major licensors, combined, in 2022. I was once told by a longtime former Qualcomm licensing executive, who still clearly felt much allegiance to the programme, that "Qualcomm charge so much because their portfolio is very valuable!" When I asked what made it so valuable, he replied: "Look how much licensing revenue it generates!" It was awkward: I was going to laugh at this obvious joke, but it was said with no hint of a chuckle.

The absurdity of this yin-yang snake-eating-its-tail logic is not lost on anyone, and because people are polite, especially in places like Brussels, no one will specifically call it out. What they will do is ask for greater "transparency" and yearn for a "balanced framework", as indeed the European Commission's proposal does. They will propose "expert-driven dispute resolution mechanisms". But what they're trying to say is that the system as it stands is unfair, that it's based on an unfair distribution of business leverage that is divorced from standards development, and which has seen Qualcomm fined, over the past decade or so, a billion dollars each by basically every single major trade commission worldwide with the exception of its home country's (the US), where they won on appeal.

Why do the industry's leaders try to uphold this system and, in doing so, find some of the blame for a bad system fall on them? Because, despite the unfairness of this system-that-isn't-a-system, it treats them pretty well. Over the last 15 years, as Ericsson's profitability stayed stubbornly low or swung to loss despite the uptake of 4G, then 5G, licensing contributed approximately half – and sometimes all – of its net income. As Nokia looked everywhere for a life raft to survive the tsunami of the iPhone and its Android cohorts, jettisoning businesses and employees and losing a cumulative $6 billion between 2011 and 2013, licensing likely kept the company afloat. Neither of these companies was going to do anything that might upset the system. And so, locked into that pattern of behaviour, they continue to defend a side of the debate that, economically, is almost entirely about Qualcomm. In IP Europe's latest comment on the commission plan, discussing aggregate royalties, the word 'Qualcomm' appears only once, as a member of the Avanci licensing pool, despite – once again – Qualcomm's royalties being more, in fiscal year 2022, than those of Ericsson, Nokia and all other major licensors combined, and multiplied by two.

Complexity is king

Which gets us to the first issue: needlessly complex language and arguments, designed to make positive action impossible and preserve the status quo. Indeed, the pro-SEP side of the debate has worked mightily to have the entire discussion lost in a myriad of details. Is it contract law v competition law? What about patents that read onto options in the standard? Is a FRAND offer necessarily global, or can it be regional? Is a top-down analysis valid? Or should it be comparable licences (an obvious effort to perpetuate a status quo), or age-normalised citations? Indeed, which licences are comparable? Is a Nokia patent worth as much as a Qualcomm one? A Cisco one? What about one bought by a licensing company and asserted? Theoretically, if that patent – or portfolio – were that good, the original owner, an

active licensor, would have kept it for itself, no? Ah, but now we're into the muddy waters of patent valuation, and what indeed is a standards-essential patent (beyond simply a patent, of whatever value, that was declared by its filing entity as possibly standards-essential, pending a ruling by a court … which can be appealed, and anyway, that's just one court, in one country, and there are many other such courts, and many other patents …).

The previous paragraph reads like an agenda from any IP conference over the past decade. If you're a patent attorney or licensing executive, and more specifically one working on behalf of licensing companies, all of the above questions are matters of specific and significant importance. But if you're not a patent attorney or licensing executive – say, you're a regulator, a member of an elected political body, a member of its staff, or in my very direct experience, a reporter – these arguments are the zenith of irrelevancy. Even Mr Justice Marcus Smith, in his May 10 ruling in *Optis v Apple* at the England and Wales High Court (a disappointing one for SEP owners, to be sure), characterised a topic that has spilled gallons of ink in the IP space – the discussion about holdout v holdup – as "wasting valuable time and money" and "entirely irrelevant".

Elsewhere, I read the position paper by IP Europe, the SEP licensors' lobbying group, responding to the European Commission proposal. If the SEP side lost the debate through needless complexity, the IP Europe paper doubles down on it, with added layers of appeals to regional chauvinism, purported harm to innovation, and unfairness. Instead of a single, clear argument in favour of fairness – which could have been made long ago if they weren't hobbled by Qualcomm being a contributing member and needing the status quo maintained – they've adopted a strategy inspired by the old Saturday Night Live "Taco Town" skit that more is better, including four mini-studies and a live blog that documents their efforts to gain support (which includes a panel at a conference sponsored by IP Europe with no less than 10 speakers on it). They hint at unknown complexities. The proposal is "detrimental to European interests," they say, and "disadvantages all firms holding European patents" (reminding the commission folks that Nokia and Ericsson are European, as though they'd forgotten). "It undermines both European national courts and the nascent Unified Patent Court," it says, "in favour of a new 'Competence' Centre at the EUIPO, which … has no current competence or experience in the complexities of standard-essential patenting or FRAND licensing valuation."

Experience in the complexities of FRAND valuation? And what is that experience worth, when many major IP conferences feature a panel titled along the lines of "What is FRAND?", with experts on both sides of the debate disagreeing wholeheartedly on the meaning. Would greater expertise in FRAND lead the European Commission to greater consensus on its meaning and economic value? On the contrary: the industry has proven that greater expertise in FRAND simply provides either side with the tools for greater disagreement.

Revenue realities

There's an argument to be made that Qualcomm deserves what it gets – in terms of revenue, I mean. Certainly I'm in admiration of the company's chip capabilities, which have given it so much leverage. Ask Apple what it's like going without them. Ask Intel what it's like competing with them, pouring money into mobile chip R&D year after year only to fall further and further behind before finally throwing in the towel (the company exited the mobile chip market in 2019). In a recent LinkedIn comment on an article by WiseHarbor's Keith Mallinson, Eric Stasik, the former head of Ericsson's IP division, argued that Qualcomm was the only company getting a FRAND rate because its tied chip and licensing businesses made it immune to holdout. It's an interesting idea, but practically speaking I don't think a licensing industry that charges mobile phone makers upwards of $40 billion a year would find favour in Brussels or elsewhere.

What's the way forward? It may indeed be too late for the Nokias, Ericssons and others of the world to distance themselves from Qualcomm, so locked are they into arguing that all change is bad instead of lobbying for change to an unfair system that would preserve them. Based on the same Eric Stasik numbers, it looks like everyone except Nokia may just have to accept dramatically reduced revenues, which would be unfortunate because – when it comes to implementers wanting to change how licensing is done, with perhaps Apple in the lead – I don't think Nokia, Ericsson and other licensors are the targets of the reform they're advocating for. Indeed, Apple has just recently signed new agreements with Ericsson and, in the past few weeks, Nokia. I'm reminded of 2016, when Apple signed a licence with a major licensor, absent litigation, and sued Qualcomm a month later.

If it isn't too late, the major licensors sans Qualcomm need to get together and bring something to Europe (or elsewhere) that would be prescriptive instead of destructive. They don't think the European Commission's proposed regulations are fair and smart? Propose some that are. But as long as they opt for arguments that attempt to drown the issue in an ocean of complexity, continue to pretend that their side represents varied interests when, economically, there is only one interest at play, and continue to try to defend a status quo that is, on its face, indefensible, the pro-SEP side will continue to lose.

Patrick Van de Wille

Patrick Van de Wille is a principal at Magritte Partners in the US.

How does pharmacological action affect the defence of a pharmaceutical compound patent in China?

Honghui Hu of Wanhuida Intellectual Property explains that a CNIPA ruling on a patent covering an antidepressant could help to determine the patentability of pharmaceutical compounds

In April 2023, the China National Intellectual Property Administration (CNIPA) released the Top Ten Patent Reexamination and Invalidation Cases of 2022. Three of them relate to the pharmaceutical field.

One involves the inventiveness assessment of small interfering RNA inventions, another discusses the authenticity determination of experimental data recorded in a traditional Chinese medicine patent, and the third elaborates on the correlation between a pharmacological mechanism and a drug indication, between in vitro and in vivo experiments and the technical effect as required under the patent law.

The third case will be discussed in detail in this article.

Background

The case relates to the Chinese invention patent ZL02819025.4, entitled 'Phenyl-piperazine derivatives as serotonin reuptake inhibitors', which is owned by Lundbeck. The patent is a compound patent covering an antidepressant marketed as Brintellix®.

The patent has survived four successive invalidation proceedings. The case discussed herein is the fourth

invalidation decision, No. 54793, made by the CNIPA, which affirmed the validity of the patent at issue.

The patent claims a compound with a general formula, covering vortioxetine, the active ingredient of Brintellix®.

In the invalidation proceeding, the petitioner raised several grounds for invalidation, including sufficient disclosure and inventiveness, both challenging the technical effect achieved by the patent. In fact, the patent description has recorded an IC50 (the half maximal inhibitory concentration) value of the claimed compound for inhibiting serotonin reuptake in an in vitro experimental model. However, the petitioner asserted that the technical effect achieved by a pharmaceutical compound patent shall be ascertained based on the data showing the efficacy for an indication, rather than the in vitro data.

The main reasoning behind the assertion is that depression involves very complex mechanisms and the serotonin reuptake recorded by the patent at issue is just one of them. Therefore, the inhibition of serotonin reuptake is not sufficient to show the potential of the claimed compound as an antidepressant. On top of that, the petitioner also asserted that the inhibition effect claimed by the patent is an in vitro test result, which cannot be equated to effectiveness in treating depression.

The CNIPA's decision

The panel dismissed the petitioner's assertions and clarified in the decision the interplay of pharmacological mechanisms, indications for treatment and the technical effect required by the law.

The panel elucidated that there is no legal provision mandating that the technical effect achieved by a pharmaceutical patent be established based on verification of the efficacy of the claimed compound in treating an indication. In other words, under the framework of patent law, it is not necessary for a patent to prove the medical use of a compound patent all the way up to the level of indication.

As the legislative purpose of the patent law is to encourage inventions and advance technologies, the parameters on which the law relies in deciding whether to grant a patent are markedly different from those in drug market approval.

Where a person skilled in the art could anticipate the medical use of a compound from the patent description and the prior art, the medical use would be recognised under the patent law. The patentee would be under no obligation to verify the efficacy of the compound in the patent by way of administering the compound to a human subject for treating an indication.

Moreover, if there is a general consensus over the correlation between the pharmacological mechanism and an indication in the art, and if the person skilled in the art could reasonably expect that the pharmaceutical compound has the potential for treating an indication based on the verified pharmacological mechanism, the patent claiming the compound shall be deemed as meeting the requirement for disclosure of the medical use and/or technical effect of a pharmaceutical compound.

The panel also affirmed the significance of in vitro data for proving the technical effect of a patented invention. The panel opined that different experiments or tests are needed at different stages of a drug R&D process. In vitro tests are used at an early stage to screen and narrow down compounds, which could also lay the groundwork for subsequent studies.

In vitro tests or animal experiments cannot be replaced

Honghui Hu
Partner
Wanhuida Intellectual Property
huhonghui@wanhuida.com

Honghui is a partner and a senior patent counsel of Wanhuida Intellectual Property. She is qualified as a patent attorney and as a lawyer in China.

Honghui has abundant experience in prosecuting and litigating patent- and technology-related matters, with her technical expertise primarily focusing on chemistry, biotech, pharmaceutical and food technology. She excels in advising clients on intricate matters such as patent validity analysis, freedom-to-operate and infringement risk assessment. Honghui is a sought-after counsel for her niche expertise in handling complex patent matters concerning validity and infringement litigation. She frequently advises multinational corporations in the pharmaceutical, biotech and chemistry industries.

Honghui is one of the lead counsels who helped to defend the validity of Bayer's compound patent of the blockbuster anticoagulant drug rivaroxaban, a case selected as one of CNIPA's Top Ten Patent Reexamination and Invalidation Cases in 2020.

by clinical trials, for cost and ethics reasons. The fact that some compounds with in vitro activity may not be considered as promising in the context of in vivo tests does not negate the significance of in vitro testing.

In this case, since the prior art has clearly established the correlation between serotonin reuptake inhibitory activity and alleviating depression, it would be understandable to a person skilled in the art that the patent used the in vitro tests to verify the compound's activity, so as to show its potential for treating depression.

The panel therefore recognised the technical effect of the invention, based on the activity of inhibiting serotonin reuptake verified in the patent at issue. Given the technical effect verified, the patent fulfilled the requirement of sufficient disclosure.

Accordingly, in assessing the inventiveness of the claimed compound, the panel ascertained that the technical problem actually solved is to provide a serotonin reuptake inhibitor, rather than to treat depression.

The panel thus concluded that the prior art evidence concerning the treatment of depression presented by the petitioner did not have merits, as it was silent on the serotonin reuptake inhibition, even though the prior art discloses a compound with a very similar structure to the claimed compound.

Wanhuida comments

Ascertaining the technical effect achieved by an invention patent is crucial to defend its validity. That is particularly true when the sufficient disclosure and inventiveness of a pharmaceutical patent is challenged.

The technical effect or experimental data of a pharmaceutical patent is an easy target of the petitioner in the invalidation proceeding. In that sense, the petitioner could launch attacks on various fronts, including:

- The pharmacological mechanisms;
- The correlation with an indication; and
- More specifically, the pharmacological action on a target.

In certain cases, with regard to inventiveness assessment, the petitioner overlooking the role of the action mechanism, such as the action on a target, would erroneously simplify the technical effect achieved by a patent as the treatment of the indication. This would inappropriately generalise the technical problem actually solved by the patent and lead to the conclusion that the patent is obvious and unpatentable.

This case, which elucidates the correlation between a pharmacological mechanism and an indication, could serve as a point of reference in assessing the patentability of a pharmaceutical compound.

China's SPC finds hydrates fall within the protection scope of compound patents

Wu Xiaoping of Wanhuida Intellectual Property analyses a decision that carries great weight in differentiating between monopolistic behaviour and the exercise of valid intellectual property rights

Under China's patent regime, patents for chemical compounds are most desirable for pharmaceutical companies, as they offer broad coverage and strong protection over the patented technology. A hydrate refers to a chemical compound with crystalline water in its structure. In practice, opinions vary as to whether the hydrates of a patented chemical compound fall within the latter's protection scope.

The initial ruling in Yangtze River v HIPI

On May 25 2023, the Intellectual Property Court of the Supreme People's Court (SPC) elucidated this matter in its decision *re Yangtze River Pharmaceutical (Group) Co., Ltd. et al. v HIPI Corporation Ltd. et al.*

This case originates from the dispute over abuse of dominant market position which was brought by Yangtze River Pharmaceutical (Group) Co., Ltd. and its subsidiary (collectively referred to as Yangtze River) against HIPI Corporation Ltd. (HIPI) et al. before the Nanjing Intermediate Court in 2019. Yangtze River requested, among others:

- The cessation of monopolistic practices;
- The indemnification of RMB 90 million (approximately $12.5 million) for the losses arising from the monopolistic conducts; and
- The reimbursement of reasonable costs of RMB 500,000.

Wu Xiaoping
Senior patent counsel
Wanhuida Intellectual Property
wuxiaoping@wanhuida.com

Dr. Wu Xiaoping is a senior patent counsel at Wanhuida Intellectual Property. She has handled a substantial number of patent prosecution, invalidation, administrative, and infringement litigation cases. Xiaoping has profound understanding of the substance of China's Patent Law and deep technical expertise in chemical engineering, inorganic/organic chemical engineering, and organic chemistry.

She successfully defended the validity of the patent concerning the formulation of amlodipine and irbesartan compound preparation in *Simcere v Patent Reexamination Board* (the predecessor of the Patent Reexamination and Invalidation Department of the China National Intellectual Property Administration) in the administrative retrial litigation before the Supreme People's Court (SPC), a case selected to be included in the SPC's Annual Report on Intellectual Property Cases of the Year.

In the past few years, Xiaoping has been honing her skill set in litigating pharmaceutical invention patent disputes and has developed an insight into judicial practice in the pharmaceutical field.

On March 18 2020, the Nanjing Intermediate Court ruled in favour of the plaintiffs and awarded damages of over RMB 68 million. HIPI and its subsidiary appealed before the SPC.

At the core of the suit is a compound invention patent, 'ZL02128998.0' ('Patent 998'), covering specific kinds of desloratadine polyacid-base metal or alkaline-earth metal complex salt, such as desloratadine citrate disodium, which is an antihistamine registered eponymously with the National Medical Products Administration as a new drug. The invention patent is owned by HIPI's subsidiary.

In 2006, Yangtze River signed a technology transfer contract with HIPI in exchange for the latter's production approval and production technology of desloratadine citrate disodium tablets, which Yangtze River marketed as BEIXUE.

According to the contractual terms, HIPI was obligated to provide Yangtze River with the active pharmaceutical ingredient (API). Nevertheless, the technology transfer contract neither covered HIPI's production technology of the API nor the hard capsules of desloratadine citrate disodium, which were later marketed as RUIPUKANG by HIPI's subsidiary. The collaboration started to fall apart as bitter legal wrangling broke out due to the steep rise of the API price and the rivalry between the BEIXUE tablets and RUIPUKANG capsules.

Of the allegations made by Yangtze River, one pivotal issue concerned whether the API at issue fell within the protection scope of 'Patent 998'. If the API at issue were found to be covered by 'Patent 998', the monopolistic allegation was unlikely to stand because unless licensed by the patentee, other entities are not allowed to implement the patent and the alleged monopolistic practice would be nothing but legitimate execution of a valid invention patent.

Yangtze River contended that the patented compound is desloratadine citrate disodium salt (Chemical Abstracts Service No. 1602766-05-1), while the API at issue is desloratadine citrate disodium salt dihydrate (Chemical Abstracts Service No. 1450805-34-1). Thus, qualitatively speaking, they are different compounds.

SPC decision

The SPC found that the disputes revolved around the definition of the relevant market, whether HIPI has a, and abuses its, dominant market position, and the legal liability thereof, which are highly relevant to whether the API of desloratadine citrate disodium tablets falls within the protection scope of 'Patent 998'. The court held the following:

- 'Patent 998' is a compound invention patent, the protection scope of which covers the complex salt of desloratadine citrate disodium.
- It is widely known to a person skilled in the art that desloratadine citrate disodium dihydrate is one of the crystal forms of desloratadine citrate disodium complex salt. It, of course, falls within the protection scope of 'Patent 998'.
- The instructions of BEIXUE tablets read: "The main ingredient of this product is desloratadine citrate disodium. Its chemical name is 8-chloro-6,11-dihydro-11 – (4-piperidinylidene)-5H-benzo[5,6]cyclohepta[1,2-b]pyridine citrate disodium salt dihydrate... Molecular formula: C25H25ClN2O7Na2·2H2O." The statement should not be construed as a redefinition of desloratadine citrate disodium. The instructions of BEIXUE recognise desloratadine citrate disodium as its main component, and express the chemical name as complex salt dihydrate, which neatly illustrates that desloratadine

citrate disodium existing in BEIXUE is in the crystal form of hydrate. Therefore, the instructions cannot be used as evidence to prove that desloratadine citrate disodium dihydrate does not fall within the protection scope of 'Patent 998'.

- The difference of desloratadine citrate disodium from its dihydrate in terms of physical and chemical properties does not negate the fact that desloratadine citrate disodium dihydrate falls within the protection scope of 'Patent 998'. It is perfectly normal for the physical and chemical properties of anhydrous and hydrate of the same compound to be different, which has no bearing on whether desloratadine citrate disodium dihydrate falls within the protection scope of 'Patent 998'.

The SPC thus concluded that the API at issue (desloratadine citrate disodium dihydrate) falls within the protection scope of 'Patent 998' and HIPI's exercise of its valid patent did not constitute exclusion or restriction of competition in the sense of the Anti-Monopoly Law.

The parameters to be considered

The SPC's decision illustrates that the following parameters come into play in assessing whether the hydrates of a patented compound fall within the latter's protection scope.

Common knowledge in the art

'Patent 998' claims the complex salts, which shall cover all forms of the compounds, such as anhydrous, solvate, hydrate, amorphous, and polycrystalline.

Description of patent specification

'Patent 998' solves two problems vis-à-vis the prior art:

- The poor solubility of desloratadine; and
- The compatible stability of desloratadine with lactose.

The first problem could be solved by salting. As to the second problem, the brown products formed by lactose and desloratadine could cause degradation and lead to the stability problems of desloratadine.

Based on the description of the specification, the only reason the aforesaid problem could be effectively solved is that the formed complex salt significantly reduces the reaction activity of desloratadine with lactose. That is, 'Patent 998' manages to solve both problems of the prior art by forming complex salt. The therapeutic active ingredient desloratadine also originates from the release of the dissolved complex salt. And hydrates are not different from the complex salt in these respects.

Corroboration from other literature

In March 2015, Yangtze River's subsidiary patented an invention patent, 'ZL201310052197.9', titled 'Pseudopolycrystalline of desloratadine citrate disodium and the preparation method thereof'. The background technology of the patent states: "Under the influence of various environmental factors, during the process of crystallisation... substances could form different crystalline structures... There are also drugs that regularly introduce, during crystallisation, a second foreign molecule, especially a solvent molecule, into the crystalline structure of the compound, a phenomenon sometimes referred to as pseudopolycrystalline... When the second foreign molecule is a solvent molecule, the pseudopolycrystalline may also be called a solvate." The statement corroborates the fact that solvates, including hydrates, are merely a form of a substance that is covered by compound claims.

Final thoughts

The case is of empirical significance because the SPC uses it to expatiate on the distinction between a monopoly and the exercise of valid intellectual property rights. In the event that the two are closely intertwined, the judiciary shall weigh in on the legal consequences stemming from the legitimate exercise of valid intellectual property rights, in assessing whether the alleged monopolistic behaviour gives rise to exclusion or restriction of competition.

Where the alleged effect of excluding or limiting competition is the inevitable result of the legitimate execution of intellectual property rights and such execution does not extend beyond the purview of the intellectual property rights, the Anti-Monopoly Law shall not apply.

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AFRICA

Ghana establishes a new IP office to embrace the knowledge-based economy

Spoor & Fisher

Megan Dinnie

The Ghanaian authorities have published an important bill, the Ghana Industrial Property Office Bill, 2023 (the Bill).

Overview of the Bill

The purpose of the Bill is to establish a new IP office, the Ghana Industrial Property Office (GHIPO).

The GHIPO will administer the use and protection of patents, trademarks, industrial designs, geographical indications and plant varieties in Ghana. Copyright is, however, excluded from the GHIPO's ambit and is administered by a separate entity, the Copyright Office.

Why create a new IP office?

As the memorandum to the Bill points out, we live in interesting times. Ghana now operates in a "knowledge-based economy", one in which "innovation will be a key driving force in creating wealth and economic growth for Ghanaians."

In this brave new world, "the intellectual property system plays a role in facilitating the effective exploitation of innovative knowledge." This system enhances "Ghana's climate of innovation to the benefit of the Ghanaian economy and society." There is a "constant challenge to modernise intellectual property offices as the needs of their clients are evolving rapidly."

The Bill in more detail

The Bill deals with issues that are administrative in nature. Here is a very brief summary of the provisions:

- IP office – the Bill establishes the GHIPO as a body corporate.
- Board – the Bill creates a governing body, the Board, with representatives from various ministries. The Board can establish committees and it must meet at least every three months.
- A director-general – the GHIPO will be led by a director-general with at least 15 years' experience in IP. Other staff can be appointed as required.
- Finances – the GHIPO's finances will be managed as per the Public Financial Management Act, 2016. The GHIPO must keep proper books and records.
- Regulations – there is provision for regulations governing IP rights.
- Rights, assets and liabilities – the rights, assets and liabilities of the present Registrar General's Department relating to industrial property will be transferred to the GHIPO.
- Employees – employees of the present Industrial Property Section of the Registrar-General's Department will be transferred to the GHIPO.

A positive development

The changes brought about by the Bill flow from a very clear recognition that the world in which IP operates is changing rapidly. That recognition is welcome.

GERMANY

A path towards a crisis-proof EU pharmaceutical legislation? The European Commission proposal

Maiwald

Gisela Grabow

On April 27 2023, the European Commission presented a proposal for the reform of the general pharmaceutical legislation in the EU. The proposal is based on the Pharmaceutical Strategy for Europe and is divided into a Directive on the creation of an EU code for medicinal products for human use and a proposal for a Regulation establishing EU procedures for the authorisation and supervision of medicinal products for human use and establishing rules for the European Medicines Agency.

The Pharmaceutical Strategy's objectives

The Pharmaceutical Strategy for Europe, which includes legislative and non-legislative measures, serves four main objectives, as defined by the European Commission:

- To ensure access to affordable medicines for patients and to address unmet medical needs (particularly in the areas of antimicrobial resistance and rare diseases);
- To promote the competitiveness, innovation and sustainability of the EU pharmaceutical industry, as well as the development of high-quality, safe, effective and more environmentally friendly medicines;
- To improve crisis preparedness and response mechanisms; and
- To ensure a strong EU voice in the world by promoting high levels of quality, efficacy and safety standards.

The proposal

Commencing with an Impact Assessment and public consultation in March 2021, the European Commission had considered three options, and had commissioned a study for the evaluation and impact assessment of the EU's general pharmaceutical legislation (Directive 2001/83/EC and Regulation (EC) No. 726/2004).

The proposal for the Directive includes substantial and numerous amendments to Directive 2001/83/EC, intending to repeal and replace it. From the three options proposed in the initiative, the European Commission opted for option C, including:

- Variable protection periods (standard and conditional periods);
- A balance between innovation and advanced access to medicines; and
- Early notification of supply

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shortages and the introduction of the environmental risk assessment.

The main issues

Issues of particular relevance for stakeholders are provisions pertaining to market access (data protection, market exclusivity, Bolar exemption, vouchers) on the one hand, and the marketing of medicines on the other. The current regulation of data protection for a period of eight years from the approval of the medicinal product and the subsequent market exclusivity, with the possibility of extending the protection by a year if the medicinal product is approved for a new indication in which the medicinal product is of significant benefit (the 8+2+1 rule), would become obsolete.

In the context of intellectual property (IP) rights and pharmaceuticals, it is worth taking a closer look at the interaction of IP rights and data protection.

The Impact Assessment on the recently published proposals for the Directive and Regulation revising the pharmaceutical legislation refers to the Intellectual Property Action Plan and the modernization of the Supplementary Protection Certificate (SPC) system, and states that other policies are more appropriate than the amendments to the pharmaceutical legislation to promote innovation: "In this context, other policies and initiatives working in synergy with this revision, like the R&I [research and innovation] policy, industrial strategy, the EU system of intellectual property rights (patents and supplementary protection periods), the creation of the European Health Data Space, are key factors to promote innovation and EU competitiveness" (Commission Staff Working Document, Impact Assessment Report, SWD(2023) 192 final).

The suggested provisions on data protection would be demanding for originators, particularly with regard to possible extensions of the envisaged six-year standard period.

The argument put forward in the Impact Assessment is that the introduction of the conditions for the extension of the protection periods will lead to additional incentives for market entrance in all member states. Whether these changes will benefit competition in the EU and at the same time promote innovation remains to be seen.

A key challenge in creating a new system

The proposals reflect the challenge in creating a future-proof and crisis-resistant EU pharmaceutical system in the face of different stakeholder interests. The European Commission's consultation period ends on June 27 2023.

GREECE

Quantification of damages not an admissibility requirement for a preliminary injunction in Greece

Patrinos & Kilimiris

Constantinos Kilimiris

The Athens First Instance Single Member Court was recently called to examine the issue of whether quantification of damages is a prerequisite in order to uphold urgency for the grant of a preliminary injunction in the context of a pharmaceutical patent's infringement.

Background to the case

The case involved a preliminary injunction application in the name of an originator pharmaceutical company against a company attempting to market at-risk generic products falling within the scope of a pharmaceutical patent. The generic company, inter alia, objected to the preliminary injunction sought, arguing that the claimant had failed to provide an estimate of the damages to be suffered in the event of actual launch of the generic products at issue on to the market.

Such an objection was based on a couple of judgments of the same court, according to which the quantification of damages was compulsory in order for the court to assess whether the harm to be suffered would justify the grant of a preliminary injunction.

The court's ruling

The court rejected the objection, ruling that the claimant does not have the burden to specifically quantify damages in order to satisfy the condition of urgency, provided that there are other circumstances showing urgency in the case under consideration.

This judgment is in line with a well-established case law and practice of the Greek courts, which have routinely granted preliminary injunctions under similar circumstances, as well as with the case law of the Court of Justice of the EU, under which a launch at risk under similar circumstances may constitute an objective indication of irreparable harm for the patent holder.

The court accepted this line of reasoning, ruling that the marketing of a generic product that is covered by a patent in force involves the risk of an important monetary damage for the patent holder but also of damage to the reputation of the patent holder and the pharmaceutical product at issue.

The fact that the generic company had already launched the product in suit before the grant of a temporary restraining order did not change the finding of the court in relation to urgency, since it was ruled that any such sales have taken place without a legal right.

Impact of the decision

This judgment seems to put things back on track, if they had ever gone astray, and lift any doubt that might have been raised by a couple of judgments to the contrary, and definitely contributes to the effective judicial protection of patent rights.

INDIA

Contours of well-known marks protection in India

RNA Technology and IP Attorneys

Ranjan Narula and Daleep Kumar

Attaining a well-known status for a trademark provides a multitude of benefits. This includes, but is not limited to: safeguarding the brand's integrity, bolstering its legal position, and contributing to its overall exclusivity in the minds of consumers and traders. Thus, most businesses strive to attain this coveted status for their brand.

The recognition and protection of well-known marks in India is governed by Section 11(6) to (9) of the Trade Marks Act, 1999 ('the Act'). These provisions provide broad criteria to be considered when determining a mark as a well-known mark and are modeled on the provisions in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement. Rule 124 of the Trade Marks Rules, 2017 ('the Rules') lays down the procedure to file and process an application for recording a mark as a well-known mark before the Registrar of Trade Marks. Since Rule 124 was added in 2017, several brand owners have filed the applications to declare their mark as well-known.

List of marks declared as well-known

Before the establishment of the rules and procedure for recording well-known marks in India (March 2017), the Trade Marks Registry (TMR) issued a roster of 84 marks that were declared as well-known. This was based on the findings of the High Courts of India or the Appellate Board in proceedings pertaining to enforcement of those marks. The list, accessible on the TMR's website, presently encompasses a total of 137 marks that have been officially declared as well-known as of October 10, 2022.

Navigating key legal issues in court

1) With the procedure for declaring marks to be recorded as well-known, a number of issues have come up before the courts, both substantive and procedural. A few of them are summarised below:
2) In *Tata Sia Airlines Limited v. Union of India (2021)*, the High Court of Delhi considered the procedure to be adopted for marks declared as well-known by the court: do they need to be freshly examined by the registrar? The court held, even where a trademark is declared to be well-known by the court, Rule 124 will apply with respect to the procedure for publication and inclusion. The procedure will include making a request through Form TM-M with the prescribed fee, followed by requisite action under Rule 124(5). After verification of the certified copy of the judgement of the court and other administrative tasks, the mark will be published and accepted as well-known;
3) In *Kamdhenu Ltd. v. The Registrar of Trade Marks (2021)*, the issue before the court was whether an affidavit in support of the documents submitted for consideration of a mark to be declared well-known is a necessary requirement. The Delhi High Court allowed the appeal providing the appellant an opportunity to file a supporting affidavit and any further documents in support of its application for grant of well-known status for its mark 'KAMDHENU'. The Court held that:
   - Under the Act and Rules, it is not a mandatory requirement to file an affidavit by way of evidence to determine the well-known status of a trademark, provided sufficient documentary evidence is supplied;
   - As per Section 129 of the Act read with Section 3 of the Evidence Act, 'evidence' includes both "oral evidence" and "documentary evidence";
   - At best, the registrar can always grant the applicant an opportunity to file such an affidavit if the documentary evidence and the statement of case are insufficient; and
   - Failure to file the affidavit will not result in the application being dismissed.
4) In *Kent Cables Private Limited & Ors. v. Union of India (2023)*, Kent Cables invoked the jurisdiction of the Delhi High Court to contest the inclusion of the "KENT" mark, widely associated with reverse osmosis (RO) systems, in the list of well-known trademarks published in a recent Trademark Journal under Rule 124(5) of the Rules. Kent Cables contended that both parties are embroiled in a contentious battle over the rights to the coveted "KENT" mark. It further challenged the validity of two decisions that Kent RO may have relied upon, asserting that these decisions do not confer the status of a well-known mark upon their mark.
   Considering the submissions of Kent Cables, the court directed the Registrar of Trademarks to produce the complete evidence or documentation reviewed by them prior to accepting Kent RO's application for grant of well-known status, leading to its publication under Rule 124(5).

> *"The well-known marks declaration can prove to be an important tool in brands' armoury"*

Recent developments at the TMR

The TMR has lately become active in processing the applications filed by several brand owners for declaration of their marks as well-known marks. The backlog had accumulated during the COVID-19

pandemic, but is now being cleared rapidly. In the last three months, several applications have been accepted and published in the Trademark Journal falling in the following two categories:

a) Publication of marks under Rule 124(4) of the Rules, where the Registrar would examine the evidence and assess whether the mark qualifies to be included in the list of well-known marks. Further, upon acceptance and publication of such marks, objections are invited from the public, before their determination as well-known marks; and
b) Notification of the marks under Rule 124(5) of the Rules, in which the High Courts of India declared the marks as well-known, and the committee has determined them to be published in the Trademark Journal for inclusion in the list of well-known marks. No objections are invited against such marks from the public.

A compilation of such recently published marks can be accessed here.

Final thoughts

As brands jostle to increase their market share, the well-known marks declaration can prove to be an important tool in their armoury. The well-known status not only serves as a constructive notice on third parties adopting a similar mark but also prevents its use by dissimilar goods, claiming such use will dilute the brand reputation.

JAPAN

Generic should sue the Minister of Health, Labour and Welfare instead of filing a DJ action, says IP High Court

Abe & Partners

Takanori Abe

The Japanese patent linkage system has problems such as difficulties associated with patent decisions, lack of involvement of patent experts, and lack of transparency and predictability. A generic company raised the issue so that relief may be obtained through the court.

Summary of the case

Eisai R & D Management Co., Ltd. (Eisai RD) owns a patent entitled 'Use of Eribulin in the Treatment of Breast Cancer'.

Eisai Co., Ltd. (Eisai) began manufacturing and selling "Halaven Injection 1mg (Eribulin Mesilate formulation), an antineoplastic medicinal product", with effectiveness and efficacy regarding "inoperable or recurrent breast cancer".

Nipro Corporation (Nipro) filed a declaratory judgment (DJ) action against Eisai RD and Eisai seeking a declaration of non-infringement and non-existence of the obligation to pay damages.

Nipro alleged that Eisai RD is substantially enforcing an injunction against Nipro by taking advantage of the patent linkage. Under the current system, Nipro could only file a request for an invalidation trial at the JPO, which is a time-consuming and roundabout process; therefore, the most direct and effective means is to seek a declaration of non-infringement, etc.

Judgment of August 30 2022, Tokyo District Court

The Tokyo District Court (Presiding judge Shibata) dismissed the claim, holding as follows.

The Joint Notification by Two Division Directors dated June 5 2009 titled "Approval examination of generic drug for medical treatment under the Pharmaceutical Affairs Act and handling of drug patents related to National Health Insurance (NHI) price listing" states that it is the policy of the Minister of Health, Labour and Welfare not to grant marketing authorisation (MA) of generic products when a patent exists for the active ingredient of the originator product or for some effectiveness and efficacy of the originator product.

The notification also states that, with regard to the listing of generics in the NHI price listing, if a company wishes to list an item having a possibility of patent disputes, the policy is that coordination with the originator company, the patent holder, shall be arranged in advance and only those items considered to be in stable supply in the future will be listed.

According to the above, Nipro alleged that in this case, the Minister of Health, Labour and Welfare will not authorise the marketing of Nipro's medicinal product, which is a generic of Eisai RD/Eisai's product. Based on these circumstances and the evidence, there is not a high probability that the Minister of Health, Labour and Welfare will authorise the marketing of Nipro's medicinal product in the near future, and that Nipro's medicinal product will be listed in the NHI price listing.

Judgment of May 10 2023, IP High Court

Nipro appealed to the IP High Court and alleged as follows.

Because the Ministry of Health, Labour and Welfare (MHLW) is unable to determine whether generic products infringe the patents owned by the originator company, MA will not be granted under the patent linkage system if a substance patent or a use patent formally exists, which causes a serious legal problem. The situation where such patent linkage becomes a problem itself is a situation of legal dispute.

Eisai RD and Eisai alleged as follows.

If, as Nipro alleges, the "practice based on the Joint Notification by Two Division Directors is the cause of the lack of the right to demand an injunction or damages", and that this is a problem, then Nipro should file an administrative lawsuit against the MHLW. Even if Nipro were to obtain the DJ, the judgment is not legally binding on the MHLW, and

it is not clear whether the MHLW would grant MA in accordance with the said judgment.

The IP High Court (Presiding judge Otaka) dismissed the appeal, holding as follows.

Even if it is a problem for Nipro that the Minister of Health, Labour and Welfare does not grant authorisation for the marketing of Nipro's medicinal product because of the existence of the patents according to the practice based on the Joint Notification by Two Division Directors, that is a dispute under public law between Nipro and the Minister of Health, Labour and Welfare, not a legal dispute between individuals; i.e., Nipro and Eisai RD/Eisai. Such a dispute under public law should be remedied by legal means such as filing an action for the declaration of illegality of inaction against the application for authorisation or filing an appeal to the Minister of Health, Labour and Welfare.

Practical tips

Nipro's strategy to obtain MA from the MHLW by obtaining a DJ of non-infringement and non-existence of the obligation to pay damages did not work. Nipro's allegation that generic products would never be authorised based on the patent linkage was taken against it, and was used as a reason to dismiss Nipro's claim.

In response to Nipro's allegation, the IP High Court clearly stated that "it should be remedied by legal means such as filing an action for the declaration of illegality of inaction against the application for authorisation or filing an appeal to the Minister of Health, Labour and Welfare."

It is pointed out that "Nipro, who had harshly criticized the MHLW in its lawsuit, is sure to be supported by many generic companies who have so far been weeping over the Joint Notification by Two Division Directors when it comes to commencing an administrative lawsuit against the MHLW." The future outcome should be closely watched.

MEXICO

Product-by-process claims: a Mexican approach

OLIVARES

Erika Rocío Santillán

There are certain inventions in which it is impossible to define a claimed product other than in terms of a manufacturing process. The claims protecting these inventions are known as product-by-process claims.

In other words, these products are defined by a manufacturing process which includes a technical step that confers technical characteristics to the product, which in the same way provides novelty and inventive step to the matter sought to be protected.

Product-by-process claims have the following structure: "Product X characterised by A, B, C..., which is prepared/obtained/obtainable by process Y."

Mexican practice

In Mexico, product-by-process claims are allowed in practice. The country's previous Industrial Property Law, which applies to all patent applications filed in Mexico before November 5 2020, states in its Article 45, Section I that the following can be protected: "The claims of a specific product and those related to *processes especially conceived for its manufacture or use* [emphasis added]."

Likewise, the current Federal Industrial Property Protection Law, which entered into force on November 5 2020, mentions in its Article 55 that "if the subject matter of the patent is a process, the patent confers the right to prevent other persons from using that process and from using, selling, offering for sale or importing the *product obtained directly from that process*, without their consent [emphasis added]."

Product-by-process claims usually confuse inventors and applicants. Thus, when a product is defined by its manufacturing method, it is relevant to review whether the product obtained is identical to other products that are already known, which will help us not to lose sight of the novelty of the product itself.

Onus on the applicant

It is a reality in several jurisdictions that when a product-by-process-type invention is sought to be protected, it is the applicant's responsibility to provide evidence that the parameters of the process give rise to the claimed product. This is achieved by demonstrating the clear differences in the technical characteristics (properties) of the products.

Finally, it should be noted that a product is not patentable if it is not new, even if the products are manufactured by different processes.

Even for a new product, if the process can be used to manufacture a different product, the manufacturing process and the product produced by the process would be reviewed as two different inventions and would be subject to restrictions.

PHILIPPINES

Philippines: unlicensed radio broadcast is copyright infringement

Hechanova & Co

Editha R Hechanova

Is the unlicensed playing of radio broadcasts as background music in restaurants copyright infringement? Yes, according to the Supreme Court (SC) in the case of Filipino Society of Composers, Authors and Publishers Inc. (FILSCAP) vs. Anrey, Inc., published in June. The SC ordered Anrey to pay FILSCAP 10,000,00 Philippine pesos (PHP) as temperate damages for the unlicensed

public performance of the copyrighted songs from FILSCAP's repertoire and PHP 50,000,00 as attorney's fees.

FILSCAP is a collective management organisation accredited by the Intellectual Property Office of the Philippines (IPOPHL) and is a member of the Paris-based International Confederation of Societies of Authors and Composers. FILSCAP assists its members in the enforcement of their economic and moral rights, and owns the right to license public performances of the copyrighted works of its members.

Sometime between July and September 2008, FILSCAP found the chain of Sizzling Plate restaurants owned by Anrey playing copyrighted songs of its members without licence. FILSCAP sent several letters to Anrey demanding payment of annual licence fees for said public performance, which Anrey ignored, resulting in FILSCAP suing Anrey for copyright infringement.

In its defence, Anrey claimed that its restaurants play whatever is being broadcast on the radio station they are tuned into, and even if the broadcast played copyrighted music, the radio stations have already paid the corresponding royalties. Thus, FILSCAP would be recovering twice: from the station that broadcast the copyrighted music, and from its restaurants. Anrey further claimed that the public performance, if it were such, were only for its employees, and thus is not copyright infringement.

The Regional Trial Court dismissed FILSCAP's complaint on the ground that the IP Code exempts public performances by a club or institution for charitable or educational purposes, provided they are not profit making and do not charge admission fees. FILSCAP appealed to the Court of Appeals (CA), which likewise denied the appeal based on the application of the exemption known in the US as 'the homestyle and business exemption', designed for small businesses to use television or radio sets within its premises.

The Supreme Court, however, reversed the CA decision, stating that under Section 177.6 of the IP Code, public performance is an exclusive economic right of the author, and unless the act falls within the ambit of fair use, is copyright infringement. While Anrey does not directly charge a fee for playing radio broadcasts over its speakers, it can enhance profit by providing entertainment to the public, particularly its customers, who pay for the dining experience in Anrey's restaurants.

The SC also ruled that Anrey's act, applying the four-factor application and analysis, is not fair use, declaring:

i) The purpose and character of the use of the copyrighted songs are commercial;
ii) The nature of the copyrighted songs is creative rather than factual, and thus fair use is weighed against the user, Anrey;
iii) An exact reproduction of the copyrighted songs is made when they are played via radio-overloudspeakers, not just small portions thereof; and
iv) The use of the copyrighted songs in this case could "result in a substantially adverse impact on the potential market" for said songs.

The SC, however, commented further that the broad definition of a public performance in the IP Code is a cause for concern: "By the mere definition of what a public performance is, listeners of a radio station, to some extent, risk copyright infringement." The SC recommended lawmakers amend the IP Code, and adopt the WTO three-step test to determine whether the limitation or exception on the rights of an owner exceed said threshold. This would mean they:

1) Must be confined to certain special cases;
2) Cannot conflict with a normal exploitation of the work; and
3) Cannot unreasonably prejudice the legitimate interests of the rights holder.

These tests can also be applied cumulatively.

SOUTH KOREA

Design protection strengthened in Korea and becomes more applicant friendly

Hanol IP & Law

Min Son

The South Korean Design Protection Act has recently been revised to provide an expanded window for filing related designs, and to relax procedural requirements for novelty grace period claims and priority claims. The revisions will take effect on December 21 2023.

Period for filing related designs to be extended

The Korean Design Protection Act provides a related design system that allows one to continuously file designs similar to their prior-filed or prior-registered design (referred to as 'the principal design') as related designs. In this way, an applicant can register multiple variations of a design or a series of designs as related designs without their being rejected on the basis of violation of novelty or the first-to-file rule pertaining to the applicant's earlier designs.

This system is very useful, given that for a product with an innovative design which becomes popular, it is common practice in the industry to develop and merchandise follow-up products with some modifications to the initial design.

A registered related design expires on the expiry date of the principal design – namely, 20 years from the filing date of the principal design – but can continue to exist separately even if the principal design right is abandoned/withdrawn or invalidated by a third party's invalidation action. Furthermore, since a related design has its own scope of design right exceeding the scope of right of the principal design, it can provide a more effective safeguard from turnaround or copycat designs.

Currently, a related design must be filed within one year from the filing date of the application for the principal design. This one-year period has been thought too short to enjoy the benefit of the design right protecting against copycat products on the basis of the principal design and the related design rights.

Under the revised act, the one-year period for filing a related design will be extended to three years. This revision will apply to related designs filed on or after December 21 2023, and principal designs with a filing date of December 22 2022 or later can enjoy the benefit from the revised provision.

With the extension of the period for filing a related design application to three years, it will be easier to secure design rights for follow-up products in multiple variations from an initial 'hit' design. Accordingly, it is expected that the right holders of innovative designs will be able to more actively deal with copycat designs.

Grace period for novelty can be claimed at any time

In Korea, the grace period for novelty of a design application is 12 months from the initial public disclosure of the design. Compared with patent cases, the grace period for design novelty can be claimed quite flexibly, even under the current act; namely, it can be claimed during the entire prosecution period for design applications. In addition, claiming the grace period for novelty is also available after registration of a design when responding to an invalidation action or an opposition.

Under the revised act, the provisions of the time restrictions on claiming the grace period have been completely deleted, so the grace period for novelty can be claimed at any time. Accordingly, claiming the grace period for novelty will be available when design right holders are involved in various kinds of disputes, such as infringement actions at the court, or confirmation-of-scope trials which seek a declaratory judgment regarding the scope of a registered design at the Intellectual Property Trial and Appeal Board of the KIPO. This revision will apply to design applications filed on or after December 21 2023.

Still, it should be noted that if the design at issue was published or laid open through an official gazette for designs in any other jurisdiction(s) before the filing date of that design in Korea, it is not possible to claim the grace period for novelty.

Priority claim requirements to be eased

A design application claiming priority must be filed within six months from the earliest design application in any country. The priority claim should be made 'at the time of filing', while indicating the country and the filing date of the priority application. A priority document or the WIPO Digital Access Service (DAS) code certifying the detailed information of the priority application should be submitted at the time of filing or within three months from the filing date of the design application in Korea.

Under the current act, the priority claim requirements for a design application as above shall be strictly observed, and no additional period for priority claim or submission of priority documents is allowed. Furthermore, unlike in patents, where priority claims can be added within a prescribed period, adding priority claims is not available in design applications, even if some parts of priority claims in a multiple design application were omitted at the time of filing in Korea.

Under the revised act, if there is a justifiable reason for not observing the original deadline, an additional two months for claiming priority or submission of priority documents will be allowed. It is also possible to amend or add a priority claim within three months from the filing date of the application in Korea. Accordingly, foreign applicants for design applications claiming priority will be able to more conveniently enjoy the benefit of priority. The revised provisions will apply to design applications filed on or after December 21 2023.

A positive step forward

With the above improvements to procedural practices in the revised act, it is expected that the protection of design applicants' rights will be strengthened.

TAIWAN

Taiwanese court throws hat into ring over when a design is considered purely functional

Saint Island International Patent & Law Offices

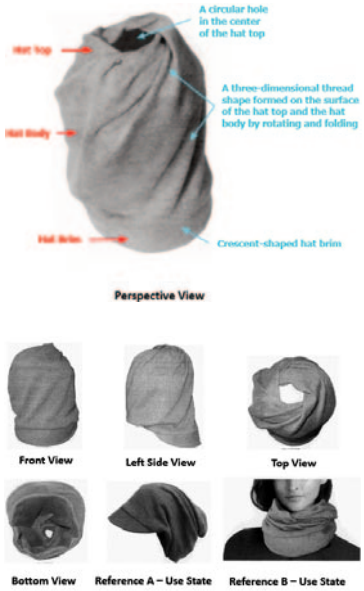
Ming-yeh Lin

'New design', as referred to in the Taiwan Patent Act, means any novel design created with respect to the shape, pattern or colour of a portion of an, or an entire, article, or any combination thereof, thereby creating an appealing aesthetic effect. However, if the configuration of an article is purely dictated by its function, the article shall be excluded from design patent protection. For instance, the threads of a screw and a nut, the key slots of a lock, and the grooves of a key are statutorily unpatentable.

Taiwan's Intellectual Property and Commercial Court has recently rendered its opinion in a design patent infringement lawsuit regarding whether the features of a design patent are purely functional.

Background to the case

The design patent in question is a scarf-hat. This soft scarf-hat, in its entirety, is substantially in the form of a hollow arcuate rectangular body. It has, from top to bottom, three parts: the hat top, the hat body, and the hat brim. There is a circular hole in the centre of the hat top, the perimeter of which extends downward to connect with the hat body, and a three-dimensional thread shape is formed on the



surface of the hat top and the hat body by rotating and folding. The bottom of the hat body extends forward on one side to form a crescent-shaped hat brim, and a fold strip is provided at the seam between the hat body and the hat brim.

The Intellectual Property and Commercial Court's ruling

The court held that if a design is entirely dictated by functional considerations and there is no creative leeway to design its appearance, the design shall be considered purely functional. Moreover, if the design of an article is solely determined by the basic shape of a part that must inevitably fit with another commonly known article, and if the overall design is simply the result of attaching or assembling another commonly known article, with no creative ideas incorporated, the design shall be regarded as purely functional and cannot be granted a design patent.

Although the design patent in question functions both as a hat and a scarf, its overall appearance, as illustrated in the drawings submitted when filing the design application, does not have any features that are created to conform to the shape of another commonly known hat or scarf. In other words, the overall design is not an inevitable result of attaching or assembling another commonly known article.

Moreover, although the evidential materials submitted by the defendant were sufficient to support that the design patent in question has the function of a scarf and a hat, the designs illustrated in the evidential materials submitted by the defendant respectively exhibited distinct aesthetical feature and shape, proving that the design patent in question is not created purely due to functional considerations that result in a necessary basic shape.

Final thoughts

As evident from the above ruling, if the design of an article is not solely determined by the basic shape of a part that must inevitably fit with another commonly known article, and if there is a space to create a design which varies from the basic shape of an article, it would be reasonable for the design patent owner to aver that the design is not purely functional.

If this argumentation is supplemented with examples of other designs in different shapes or configurations but that have the same, or a similar, function, the design patent owner would be in a better position to argue that the design patent is not purely functional.

TURKEY

Highly logical: Turkish IP Office's Vulcan salute ruling sets final frontier for copyright ownership argument

Gün + Partners

Güldeniz Doğan Alkan and Ayşenur Çıtak Bozdağ

According to Article 6/6 of the Turkish Industrial Property Code, "An application for registration of a trademark shall be refused upon the opposition of the right holder if it consists of a person's name, trade name, photography, copyright or any other intellectual property right of another." Based on this provision, it is possible to oppose an application relying upon the opponent's other intellectual property rights ownership.

On December 20 2022, the Re-Examination and Evaluation Board (the Higher Board) of the Turkish Patent and Trademark Office (the IP Office) rendered a decision including detailed explanations regarding the copyright ownership argument and set an excellent example of the IP Office's criteria for accepting such an argument. Before discussing the decision, it should be noted that the Higher Board consists of three senior examiners and generally conducts a comprehensive and consistent examination. So, the Higher Board's decisions are valuable as precedents in opposition proceedings.

The application and CBS opposition

An application was filed for the following for the services in class 35 by a real person.

As illustrated, the application consists of a hand gesture known as the 'Vulcan salute', which was used in the *Star Trek* series by the character Mr. Spock and become famous throughout the world.

An opposition was filed against the application by CBS Studios Inc. (CBS), the owner of certain rights regarding the television series *Star Trek* and all the related rights. CBS' rights include numerous copyrights, trademarks, and merchandising and other subsidiary rights relating to the series and 13 motion pictures, including logos, ships, characters' names, fictional species, phrases, uniforms, props, and other elements appearing therein (Star Trek Properties). The opposition was based on CBS's genuine right ownership over Star Trek Properties, CBS's copyright over Star Trek Properties, the well-known status of Star Trek Properties, and the applicant's bad faith.

The Turkish IP Office's decision

The Trademark Department of the IP Office rejected the opposition

entirely. Upon CBS's appeal, the matter was reviewed by the Higher Board. In its decision, the Higher Board mentioned the facts below, which were included in CBS's petitions and evidence:

- *Star Trek* was first broadcast in 1966;
- There are numerous books, comic books, magazines, and collectibles dedicated to *Star Trek*;
- Mr. Spock is the iconic character of *Star Trek*, who makes the authentic hand gesture known as the Vulcan salute;
- The Vulcan salute gesture has been made in reference to *Star Trek* by Barack Obama, NASA, Hollywood stars, and Turkish celebrities;
- The *Star Trek* series have been broadcast in Turkey since the 1970s, on several channels;
- The series were presented as comics in the most highly circulated newspapers;
- The series are still followed by Turkish audiences; and
- CBS is the holder of the intellectual property rights emerging from the trademarks related to *Star Trek*.

Within this context, the Higher Board stated that the application includes the iconic figurative device of the Vulcan salute, associated with the famous *Star Trek* series, and directly evokes or references the relevant series, and accepted CBS's appeal based on Article 6/6 of the Turkish Industrial Property Code (CBS's copyrights over *Star Trek* properties). The decision was finalised upon no further appeal by the applicant.

The importance of the ruling

Based on the decision, a copyright ownership argument is supported by providing the history, showing extensive use nationally and internationally, and underlining the popularity of the artistic work.

Precedents regarding implementation of this article by the office are limited since it is considered as a supporting argument and generally alleged with bad faith and genuine right ownership. Therefore, the Higher Board's decision sets an important example, since it accepted the opposition based solely on copyright ownership. Also, it provides the criteria that the office considers while assessing a copyright ownership argument.

UK

Patent power play: the growing importance in Ireland of 'clearing the path'

Bird & Bird

Michael Finn and Denis Halton

Rising trend for Irish injunctions

In a series of recent decisions, a clear trend has emerged in the Irish courts that preliminary injunction (PI) applications now strongly favour patentees, and generic entrants have many hurdles to overcome to resist a PI. This is in stark contrast to the situation that existed in Ireland less than five years ago, when the case law favoured generic entrants.

The injunction test in Ireland comprises a number of elements to be weighed up. However, this article reviews the development of the principle of 'clearing the path' and what this means for PI applications.

The leading Irish authority on preliminary injunctions

In 2019, the Irish Supreme Court clarified the injunction test in Ireland, following on from a series of decisions in which PIs had been refused on the basis that damages would be an adequate remedy for the patentee. The leading Irish authority on PIs is now the Supreme Court decision in *Merck Sharp & Dohme v Clonmel Healthcare* (the *MSD Decision*). In deciding that case, the Supreme Court set out eight steps that a court should follow in determining whether to grant an injunction. Distilled down, the key questions a court will consider are:

- Is there a fair/serious issue to be tried?
- What does the balance of convenience favour?

In its judgment, the Supreme Court highlighted that the most important element in the balance of convenience assessment is, in most cases, the question of adequacy of damages. However, the Supreme Court also commented that weight should be given to the clearing the path argument but warned that it could not be accepted without qualification as dispositive of the issue. It was part of the balance of convenience limb of the injunction test, with the Supreme Court remarking that the fact that the supplementary protection certificate in question "is valid until otherwise declared invalid by a court [...] is also relevant to the balance of convenience".

Interestingly, in relation to the argument that a generic challenger should always clear the path, the Supreme Court observed that clearing the path poses problems for generics, since any such invalidity proceedings would clear the path not just for the applicant, but for any other generic, which would essentially be given a free ride on the application.

Recent Irish case law following the MSD Decision

More recent cases of the Irish courts applying the principles set out in the *MSD* case shed light on what expectations the courts now have as to the lengths that a generic entrant must go to in order to sufficiently clear the path to resist a PI. In March 2023, the Court of Appeal ruled in *Biogen MA Inc. & Biogen International GMBH v Laboratorios Lesvi SL & Neuraxpharm Ireland Ltd.* (*Biogen*) that, when assessing clearing the path arguments in the balance of convenience, "the threshold test is that the case for invalidity must be strong and/or that there have been successive determinations on the merits invalidating the right" and only then "it *might* weigh against the grant of an injunction" (court's emphasis).

In a more recent Court of Appeal decision, *Bristol-Myers Squibb Holdings Ireland Unlimited Company v Norton (Waterford) Limited T/A Teva Pharmaceuticals Ireland,* the principle of clearing the path was given further consideration. In this case, the generic producer had

issued a revocation action on the grounds of invalidity and lack of priority. The purpose of the revocation action was to clear the path. When notice was given during the proceedings of intention to launch, the patentee sought an interlocutory injunction restraining entry. The High Court granted a PI, which was appealed.

In its judgment, the Court of Appeal was firmly of the view that if a generic producer seeks to clear the path, it must do so until "all arguable objections from the patentee have been eliminated", including the conclusion of any appeal. Furthermore, in response to the argument that a generic entrant should get credit for the steps that it had taken to attempt to clear the path, the court dismissed this argument, commenting that no cogent argument was advanced as to what weight, if any, should be given to a generic manufacturer that has tried to clear the path but has ultimately not yet done so.

Outlook

It is clear that the principle of clearing the path is a significant and evolving concept in the realm of PI law in Ireland. While the principle has been applied in several Irish patent cases since the *MSD Decision*, it is the Court of Appeal's most recent decision, involving Bristol-Myers Squibb, that highlights the lengths that generic producers will be expected to go to clear the way in order to fend off a PI.

To comply with the most recent jurisprudence, generic producers must undertake the costly and time-consuming processes of clearing the path in the first instance and resisting any subsequent appeals, which, as the Court of Appeal remarked, are virtually guaranteed to be brought by the unsuccessful party.

This makes Ireland a very favourable venue to patentees with regard to PIs. Given the current trend, it is expected that PI law will eventually wind its way back to the Supreme Court, where the principle of clearing the path will need to be considered in further detail. In the meantime, it is difficult to imagine a scenario where the Irish courts will not grant a PI unless the generic entrant has knocked out the patent in every possible sense.

VIETNAM

Vietnam: film music copyright case raises questions

Tilleke & Gibbins

Linh Thi Mai Nguyen
and Son Thai Hoang

With Vietnam's entertainment industry booming, the demand for music to be used in films and video games has sharply increased. Sometimes a song featured in a movie's soundtrack can become as popular as the movie itself.

To use a song in a film, the producer of the film will typically need to enter into an agreement with the owner of a copyrighted work to have permission to use that work – with an agreed amount of royalty. Otherwise, their use could be considered a copyright infringement. However, what happens if the producer enters into an agreement with a song's purported copyright owner, only to later find that such person does not really own the song entirely? A recent high-profile case in Vietnam brought this issue to light.

The dispute and court rulings

The film "Face Off 4 – The Walking Guests," financed and produced by Ly Hai Promotion Co., Ltd ("Ly Hai") premiered in April 2019, and soon became a big success. In this film, Ly Hai used a song called "Ganh Me", based on a March 2019 contract to use the song signed with the musician Quach Beem, who was recognised as the song owner in a copyright certificate issued on 24 April 2019 by the Copyright Office of Vietnam (COV).

The dispute arose in November 2019 when an individual named Truong Minh Nhat discovered that the lyrics of "Ganh Me" were almost identical to a poem he had written and posted on his Facebook page in June 2014, well before the COV had issued the copyright certificate to Quach Beem. Mr. Nhat initiated a lawsuit against two defendants, Quach Beem and Ly Hai, for copyright infringement.

In his petition, Mr. Nhat requested that the court, among other things, recognise him as the author and owner of the lyrics of "Ganh Me" and order Quach Beem to correct false information in the copyright certificate and compensate for damages. Mr. Nhat also requested that the court order Ly Hai to:

- Stop using "Ganh Me" on all media and platforms until the effective date of the court verdict;
- Publish an apology in mass media for using his poem without permission and providing incorrect information about its author;
- Name him as the author and owner of the song lyrics in the film and all related articles and posts; and
- Compensate for damages.

In April 2022, the People's Court of Ho Chi Minh City (HCMC) issued its first-instance verdict, recognising that the plaintiff is the author and owner of the poem "Ganh Me". It further ruled that registering a copyright for the song "Ganh Me," containing his poem as lyrics, was an act of appropriating copyright to the plaintiff's poem. The court then accepted the plaintiff's claims against Quach Beem, including a part of the claim for damages.

Regarding Ly Hai, the court ruled that the company's use of the song in its film on the basis of a contract with the musician was in good faith. Therefore it rejected almost all of the plaintiff's claims, except the request that the plaintiff be credited as the writer of the song lyrics in the film and other related articles and posts.

The first-instance verdict was appealed by Quach Beem, but was affirmed in June 2023 by the HCMC High Court.

Different opinions on the rulings

Article 133.2 of Vietnam's Civil Code 2015 provides a mechanism for protecting a bona fide third party in civil transactions: "in cases where a civil transaction is void but the transacted property is registered at authorities and then transferred through another transaction to a bona fide third party, and this party relies on that registration to proceed with the transaction, such transaction shall be valid." In such case, while the owner of a property can request the party at fault to refund appropriate expenses and compensate for damages, it has no right to reclaim the property from the bona fide third party. However, there is neither further guidance on Article 133.2 nor a specific definition of "bona fide third party" under Vietnamese law.

In the first-instance verdict, the HCMC Court ruled that Ly Hai's use of the song was in good faith, but without specifying that it was a "bona fide third party" or providing clear legal grounds for its rulings. Thus, the verdict raised different opinions from lawyers and practitioners.

Many view that Ly Hai could not be viewed as a bona fide third party to enjoy protection under Article 133.2 because there was only a single transaction—the one between Quach Beem and Ly Hai. Without "another transaction," there could be no third party and, as a result, the plaintiff is entitled to request the court to declare the contract between Quach Beem and Ly Hai void due to Quach Beem's misrepresentation. In addition, under Vietnam's IP Law, any use of copyrighted works without the owner's permission, outside of specified permissible exceptions, would be considered infringement, so Ly Hai should bear liability for infringement charges as requested by the plaintiff.

In contrast, others argue that it is unnecessary to have more than one transaction to determine a bona fide third party. If the transacted property is registered with an authority, and a party relies on such registration to proceed with a civil transaction, this transaction is valid. As a result, such party would be viewed as a bona fide third party and can rely on Article 133.2 to protect its right and benefits. The first two parties would be the other party in the transaction and the true owner of the transacted property. It appears that the HCMC courts ruled on the dispute in line with this latter view.

Recommendations

The controversies above stem from having no clear definition of "bona fide third party" or guidelines on the conditions for protection of a bona fide third party in Vietnamese law. Thus, such matters need to be quickly guided or addressed by a Supreme Court resolution or precedent to ensure the consistent application by the lower courts in practice, so businesses feel safer in their operations in Vietnam.

Until those documents are issued, businesses are recommended to consult lawyers in Vietnam seeking advice for well-prepared contracts to minimise the relevant risk.

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